CORNERSTONE THERAPEUTICS INC
Form 10-K
March 03, 2011

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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, 2010

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. o

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

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

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

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant as of June 30, 2010 was approximately $45,567,920 based on a price per share of $5.89, the last reported sale price of the registrant s common stock on the NASDAQ Stock Market on that date.

As of February 28, 2011, the registrant had 25,700,463 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant s proxy statement for the registrant s 2011 annual meeting of stockholders currently expected to be held on May 18, 2011, 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, 2010, 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; our ability to replace the revenues from our marketed unapproved products, which we ceased manufacturing and distributing at the end of 2010, and from our propoxyphene products, which we voluntarily withdrew from the U.S. market in November 2010 at the request of the U.S. Food and Drug Administration, or FDA; 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 product acquisition, 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 develop and commercialize our product candidates before our competitors develop and commercialize competing products; our ability to satisfy FDA and other regulatory requirements; and our ability to obtain, maintain and enforce patent and other intellectual property protection for our products and product candidates. These and other risks are described in greater detail below in Item 1A. Risk Factors. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. In addition, any forward-looking statements in this annual report on Form 10-K represent our views only as of the date of this annual report on Form 10-K and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise. 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 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

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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.

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.

Overview

We are a specialty pharmaceutical company focused on acquiring, developing and commercializing products for the respiratory and related markets.

Our strategy is to:

- Leverage commercial capabilities by promoting respiratory and related products to high prescribing physicians through our respiratory sales force and to hospital-based healthcare professionals through our hospital sales force;

- Acquire rights to existing patent- or trade secret-protected, branded products, which can be promoted through the same channels to generate on-going high-value earnings streams;

- Advance our development projects and further build a robust pipeline; and

- Generate revenues by marketing approved generic products through our wholly owned subsidiary, Aristos Pharmaceuticals, Inc., or Aristos.

We believe that if we implement this strategy successfully, we can deliver consistent long-term earnings growth.

Our management team has broad experience in the acquisition, commercialization and development of pharmaceutical products. Additionally, our commercial understanding has allowed us to build effective sales forces that continue to grow our products and build relationships with key physicians within the respiratory and hospital markets.

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 respiratory space and can also be easily transferred to other related specialty market areas.

During 2010, we continued our intentional, strategic shift away from marketed unapproved products in order to focus on the branded approved products identified as Our Promoted Products below, and, as of December 31, 2010, we are no longer manufacturing or distributing any marketed unapproved products. Because we have historically derived significant revenues from sales of marketed unapproved products, we expect that our net product sales will begin to decline once all of our deferred revenue related to recent sales of these products has been recognized. We plan to

replace these revenues, as well as revenues from other products we withdrew from the market in 2010, with increased revenues from our branded approved products, particularly CUROSURF and ZYFLO CR, and with revenues from our cough/cold product candidate, CRTX 067, for which we are targeting FDA approval during 2011, and from any other approved products which we can acquire and commercialize.

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We have also developed a pipeline of products that includes line extensions for ZYFLO CR and controlled-release liquids, which are focused on the cough/cold segment of the acute respiratory marketplace. We plan to build on this base and focus on the following priorities in 2011:

- growing our existing product portfolio by acquiring companies and/or products that fit with our strategic focus and
- advancing our product pipeline with the expected FDA approval of CRTX 067 and the continued development of our other product candidates.

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

Our Promoted Products

CUROSURF

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

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

Market Opportunity. Approximately one out of every 10, or 50,000, premature infants require surfactant treatment in the United States each year. Surfactants are typically dispensed in over 2,000 hospital neonatal intensive care units annually. The surfactant market generated approximately $100 million in sales in 2010 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, or 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 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.

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.

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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.

ZYFLO CR

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

Net product sales of ZYFLO CR and ZYFLO combined were $30.6 million, $18.0 million and $888,000 in 2010, 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.

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

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

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

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

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

In addition, prior to FDA approval, a long-term, safety surveillance trial was conducted in 2,947 patients. In this safety trial, 4.6% of patients taking ZYFLO experienced ALT levels greater than three times the level normally seen in the bloodstream compared to 1.1% of patients receiving placebo, with 61.0% of the patients

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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.

Proprietary Rights. We licensed from Abbott exclusive worldwide rights to ZYFLO CR, ZYFLO and other formulations of zileuton for multiple diseases and conditions. The U.S. patent covering the composition of matter of zileuton that we licensed from Abbott expired in December 2010. The U.S. patent for ZYFLO CR will expire in June 2012 and relates only to the controlled-release technology used to control the bioavailability of zileuton over time. ZYFLO CR and ZYFLO are the only leukotriene synthesis inhibitor drugs approved for marketing by the FDA, and we believe that these products are not susceptible, in the near term, to generic competition. We do not expect the expiration of the composition of matter patent to materially affect our financial condition or results of operations.

FACTIVE

Overview. FACTIVE is a fluoroquinolone antibiotic with the API gemifloxacin mesylate. FACTIVE is currently available in 320 mg, once daily tablets packaged in five-day and seven-day dose packs. FACTIVE is approved for the treatment of acute bacterial exacerbation of chronic bronchitis, or ABECB, and community-acquired pneumonia, or CAP, of mild to moderate severity, caused by *Streptococcus pneumoniae* (including MDRSP), *Haemophilus influenzae, Moraxella catarrhalis, Mycoplasma pneumoniae, Chlamydia pneumoniae*, or *Klebsiella pneumoniae*. FACTIVE was launched in the United States in September 2004 and is the only fluoroquinolone approved in the United States for the five-day treatment of both ABECB and CAP. Our net sales of FACTIVE were $5.1 million in 2010 and $1.2 million during 2009 following our launch in September 2009. We acquired the FACTIVE product rights and related inventory from Oscient Pharmaceuticals Corporation, or Oscient, on September 9, 2009. We began earning revenues from FACTIVE in September 2009; however, we did not begin marketing and promoting FACTIVE until October 2009.

Market Opportunity. The U.S. oral solid antibiotic market is fairly fragmented, with approximately 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 2010, the U.S. oral solid antibiotic market generated approximately 222 million prescriptions, of which the U.S. oral solid fluoroquinolone market generated approximately 35 million prescriptions. Approximately 1.2 million prescriptions have been dispensed for FACTIVE since its launch. In 2009 and 2010, FACTIVE generated approximately 96,000 and 62,000 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 is the only fluoroquinolone that has an indication for five-day treatment for both CAP and ABECB.

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

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

SPECTRACEF

Overview. SPECTRACEF, an antibiotic administered orally in tablet form, is a third generation cephalosporin with the API cefditoren pivoxil. The SPECTRACEF product line currently includes SPECTRACEF 200 mg and SPECTRACEF 400 mg, cefditoren pivoxil 200mg and cefditoren pivoxil 400 mg. We sometimes refer to these products collectively as SPECTRACEF. SPECTRACEF 200 mg is currently available in a 10 day Dose Pack. SPECTRACEF 200 mg, two tablets twice daily, is indicated for the treatment of the same respiratory tract infections as SPECTRACEF 400 mg. Additionally, SPECTRACEF 200 mg, one tablet twice daily, is indicated for pharyngitis and tonsillitis and uncomplicated skin and skin-structure infections. In 2010, Cornerstone s Aristos division introduced cefditoren pivoxil 200 mg and 400 mg authorized generic products to prepare to compete more effectively with potential generic market entrants. While the short-term impact of introducing our authorized generics has been to replace higher margin sales of SPECTRACEF 200 mg and SPECTRACEF 400 mg with lower margin sales of our authorized generics, we believe being the first generic to market will provide long-term benefits for us. At this time, there are no competing generic cefditoren pivoxil products that have been approved by the FDA.

SPECTRACEF 400 mg and its generic equivalent, cefditoren pivoxil 400 mg are single 400 mg tablets, twice-daily dosages of SPECTRACEF, which are indicated for the treatment of mild to moderate infections in adults and adolescents 12 years of age or older that are caused by pathogens associated with particular respiratory tract infections, including CAP and ABECB. SPECTRACEF 400 mg is currently available in a 10-day Dose Pack and a 14-day Dose Pack. The generic equivalent is currently only available in a 10-day Dose Pack. We received approval for SPECTRACEF 400 mg in July 2008 and launched it in October 2008. We launched cefditoren pivoxil 400 mg in February 2010. We believe that patients find taking one 400 mg tablet twice daily to be more convenient than taking two 200 mg tablets twice daily. Our net sales of the SPECTRACEF product family were $5.3 million, $9.4 million and $7.0 million in 2010, 2009 and 2008, 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 8.0 million prescriptions written in the United States for second and third generation oral solid cephalosporins in 2010.

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,

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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.

Other Products

Through the end of 2010, we marketed but did not promote certain of our products, including ALLERX® (combinations of methscopolamine nitrate, pseudoephedrine hydrochloride, phenylephrine hydrochloride and chlorpheniramine maleate) tablets and HYOMAX® (hyoscyamine sulfate) tablets. We marketed these products without them having FDA-approved marketing applications. In August 2010, we announced our plan to cease manufacturing and distribution of all of our marketed unapproved products by the end of 2010, which include ALLERX Dose Pack products and the HYOMAX product family.

In December 2010, we sold our remaining inventory of our marketed unapproved products to distributors, wholesalers and retailers. Revenue related to these sales was deferred due to our inability to reasonably estimate returns as a result of large channel inventory levels and extended payment terms given related to certain sales. As a result, revenue from the sales of these products will be recorded at the later of when cash payment is received or the risk of product returns has been substantially eliminated, which we expect will be when the product is sold to the end-user based upon prescriptions filled. For this reason, net product sales for these products will continue to be recognized after 2010 even though we are no longer manufacturing and distributing these products.

Our net sales of our ALLERX Dose Pack and HYOMAX families of products were $37.4 million, $59.9 million and $49.4 million in 2010, 2009 and 2008, respectively. For a more complete discussion regarding FDA drug approval requirements, please see Item 1. Business Regulatory Matters in this annual report on Form 10-K and Item 1A. Risk Factors Some of our specialty pharmaceutical products have been marketed without approved NDAs or ANDAs in this annual report on Form 10-K.

Product Development Pipeline

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

Therapeutic Class	Developmental Stage	Regulatory Status
Allergy		
CRTX 058	Preclinical	Submission timeline under review by management
CRTX 070	Preclinical	Submission targeted in 2014
Anti-Asthma		
CRTX 073	Preclinical	Submission targeted in 2012
CRTX 809	Preclinical	Submission targeted in 2015

Cough/Cold		
Product Candidate Submitted		
CRTX 067	Under FDA Review	Regulatory application submitted in July 2009
Other Product Candidates		
CRTX 069	Preclinical	Submission timeline under review by management
CRTX 072	Preclinical	Submission targeted in 2013
CRTX 074	Preclinical	Submission timeline under review by management

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During 2010, 2009 and 2008, our research and development expenses were $4.5 million, $3.6 million and $3.7 million, respectively. Our development priorities may change from time to time, and the actual dates of regulatory submissions may differ from the target dates referenced above. For example, during 2010, management determined our anti-infective product candidates CRTX 062 and CRTX 068 were no longer viable product candidates.

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. During 2010, we held a pre-investigational new drug application meeting with the FDA. We plan to file an investigational new drug application, or IND, with the FDA and to commence the clinical program for CRTX 070 in 2011. If approved, we believe this anticholinergic therapy would be the first dosage form 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 271,000 prescriptions in 2010, which was significantly less than in 2009 due to limited availability of the API methscopolamine. In addition, second and third generation antihistamine and antihistamine combination products generated a total of approximately 44.3 million prescriptions in 2010.

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. 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.

Proprietary Rights. We have licensed from Neos Therapeutics, L.P., or Neos, the rights to market CRTX 058 and CRTX 070 utilizing Neos s Dynamic Variable Release® technology. This licensed technology allows us to formulate these products with one or more APIs that require immediate activation followed by extended release of the remaining APIs.

Anti-Asthma Product Candidates CRTX 073 and CRTX 809

Overview and Development Status. ZYFLO CR is an important asset to us; therefore, we have implemented a life cycle management strategy to improve the dosing regimen for this product. We believe that offering more convenient dosing for ZYFLO CR may improve patient compliance and overall quality of life as it relates to their asthma condition. We plan to file an IND with the FDA for CRTX 073 in 2011. We are finalizing our proposed development plan for CRTX 809 with a view to an FDA guidance meeting in 2011.

In addition, 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

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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.

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. We have worldwide patents pending which, if issued, could provide patent protection of an R(+) zileuton product through 2027.

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 2012 and beyond.

Market Opportunity. Cough can adversely affect quality of life, leading patients to seek medical attention. According to Wolters Kluwer Health, in 2010, there were approximately 36 million prescriptions generated for antitussive products. Over 8 million of these prescriptions were for products that only contained a narcotic antitussive and an antihistamine.

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

Proprietary Rights. We have licensed the rights to Neos 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 an issued U.S. patent application that will expire in 2025.

Sales and Marketing; Co-promotion Agreements

Sales and Marketing

We have built a commercial organization, consisting at February 28, 2011 of 100 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.

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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 and infections. Our marketing programs to support our products include patient co-payment assistance, health care provider education, pharmacoeconomic advantages, information to further support patient compliance and participation in national medical conventions. In addition, we use a respiratory advisory board with varying specialties to assist in developing our corporate strategy for both our products and product candidates.

Co-promotion Agreements

We may seek to enter into co-promotion arrangements to enhance our promotional efforts and sales of our products. We may enter into co-promotion agreements 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. 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, 2010 were greater than $20 million.

DEY has agreed not to manufacture, detail, sell, market or promote any product containing zileuton as one of the APIs for sale in the United States until the later of one year after expiration or termination of the co-promotion agreement or March 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.

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Trade and Distribution

Our customers consist of drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies in the United States. We primarily sell products directly to drug wholesalers, which in turn distribute the products to retail drug stores, hospitals, mass merchandisers and grocery store pharmacies. Our top three customers, which represented 94% of gross product sales in 2010, are all drug wholesalers and are listed below:

Customer	**2010**	**2009**
Cardinal Health	43%	34%
McKesson Corporation	29%	34%
AmerisourceBergen Corporation	22%	20%

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.

We rely on DDN/Obergfel, LLC, or DDN, a third-party logistics provider, for the distribution of our products to drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies. DDN ships our products from its warehouse in Memphis, Tennessee to our customers throughout the United States and its territories as orders are placed through our customer service center.

Manufacturing

We currently outsource the manufacturing of all of our commercially available products and the formulation development of our product candidates for use in clinical trials to third parties. We intend to continue to rely on third parties for our manufacturing requirements. We provide regular product forecasts to assist our third-party manufacturers with efficient production planning. 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
ZYFLO/ZYFLO CR	
API (zileuton)	Shasun Pharma Solutions Ltd. (or Shasun)
ZYFLO tablets	Patheon Pharmaceuticals Inc. (or Patheon)
ZYFLO CR tablet cores	Jagotec AG (or Jagotec)
ZYFLO CR tablet coating and packaging	Patheon
FACTIVE 5 and 7	
API (gemifloxacin mesylate)	LGLS
FACTIVE tablets	Patheon
FACTIVE packaging	Patheon
SPECTRACEF	
API (cefditoren pivoxil), tablets and packaging	Tedec-Meiji

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

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

Chiesi License and Distribution Agreement

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

Shasun Agreement for Manufacturing and Supply of Zileuton API

Shasun manufactures all of our commercial supplies of the zileuton API pursuant to an agreement dated February 8, 2005, as amended. The API purchased from Shasun currently has a shelf-life of 36 months. The agreement will expire on the earlier of the date on which we have purchased a specified amount of the API for zileuton or December 31, 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. We have not received written notice of cancellation.

Jagotec Manufacture and Supply Agreement for ZYFLO CR

Jagotec, a subsidiary of SkyePharma PLC, manufactures all of our bulk, uncoated tablets of ZYFLO CR pursuant to a manufacture and supply agreement dated August 20, 2007, as amended. We have agreed to purchase from Jagotec a

minimum of 20 million ZYFLO CR tablet cores in each of the four 12-month periods starting May 30, 2008. The agreement s initial term extends to May 22, 2012, and 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. We have not received written notice of cancellation.

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LGLS License and Option Agreement

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

Meiji SPECTRACEF License and Supply Agreement

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

Intellectual Property

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

Patents

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

The following table shows our U.S. patents relating to ZYFLO CR, FACTIVE and SPECTRACEF as of February 28, 2011:

Number	Issued Patents	Product(s)	Expiration
Licensed Patents			
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

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Number	Issued Patents	Product(s)	Expiration
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

All of the above patents were filed with and subsequently issued by the United States Patent and Trademark Office, or USPTO.

Other than FACTIVE, 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 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

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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 and ZYFLO trademarks, among others. CUROSURF is owned by Chiesi and is licensed to us for sales and marketing purposes in the United States. FACTIVE is owned by LGLS and is licensed to us for sales and marketing purposes in North America and many European countries. SPECTRACEF is owned by Meiji and licensed to us for sales and marketing purposes in the United States. Other trademarks or service marks appearing in this annual report are the property of their respective holders.

License and Collaboration Agreements

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

Chiesi CUROSURF License and Distribution Agreement

Overview. On May 6, 2009, we entered into a series of agreements with Chiesi pursuant to which we obtained an exclusive, 10-year license to the U.S. commercial rights to Chiesi s CUROSURF product and a two-year right of first offer on all drugs Chiesi intends to market in the United States.

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.

Abbott Zileuton License Agreements

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

Fees and Royalty Payments. In consideration for the December 2003 license, we paid Abbott an initial license fee and agreed to make aggregate milestone payments of up to $13.0 million to Abbott upon the achievement of various development and commercialization milestones, including the specified minimum net sales of licensed products. 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

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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.

LG Life Sciences FACTIVE License and Option Agreement

Overview. On September 9, 2009, we 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 through an asset purchase agreement with Oscient, for $8.1 million and quarterly royalty payments based on net sales through September 9, 2014, adjusted for royalties we pay to LGLS with respect to those net sales.

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

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

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

Meiji SPECTRACEF License and Supply Agreement

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

use Meiji s SPECTRACEF trademark in connection with the sale and promotion of SPECTRACEF for our currently approved therapeutic indications.

Fees, Milestones and Royalties. In consideration for the licenses Meiji granted to us, we agreed to pay Meiji a nonrefundable license fee of $6 million in six installments over a period of five years from the date of

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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 for both our branded and authorized generic products and, through October 2018, of SPECTRACEF 400 mg so long as Meiji is able to supply 100% of our requirements for SPECTRACEF 400 mg. Additionally, 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.

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 the portfolio of then pending patent applications relating to Neos s 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 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

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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 DTRS technology and Coating Place s patented 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 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 and further amended in May 2010, we engaged Neos to develop various extended-release liquid products using Neos s 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.

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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.

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®

ZYFLO CR or any anti-asthma product candidate IgE blockers, such as Genentech USA, Inc s and Novartis Pharmaceutical Corporation s Xolair®; bronchodilatory drugs, such as Teva Respiratory LLC s ProAir® HFA (albuterol sulfate) Inhalation Aerosol and Schering Corporation s, or Schering, Proventil® HFA (albuterol sulfate) Inhalation Aerosol; Leukotriene Receptor Agonists, such as Merck Sharp and Dohme Corporation s

Singulair® (montelukast sodium); inhaled corticosteroids, such as GlaxoSmithKline s, or GSK, Flovent® Diskus® (fluticasone propionate inhalation powder); and combination products, such as GSK s Advair Diskus® (fluticasone propionate and salmeterol inhalation powder) and AstraZeneca LP s Symbicort® (budesonide/formoterol fumarate dehydrate) Inhalation

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Solution. In addition, we may face competition from pharmaceutical companies seeking to develop new drugs for the asthma market.

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

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

Cough/cold product candidates various narcotic and non-narcotic antitussives, such as King Pharmaceuticals, Inc. s Tussigon® (hydrocodone and homatropine), Mallinckrodt, Inc. s TussiCaps® (hydrocodone polistirex and chlorpheniramine polistirex), UCB, Inc. s, or UCB, Tussionex® (hydrocodone polistirex and chlorpheniramine polistirex) 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) and Schering-Plough s HealthCare Products Inc. 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 applicable regulatory requirements may subject us and our products to administrative or judicial sanctions, such as a refusal by the FDA to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

FDA Regulation of Drug Products

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

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

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

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

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

submission to the FDA of an NDA;

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

FDA review and approval of the NDA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulations, as well as animal studies. The results of these pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the clinical trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or

questions before clinical trials can proceed. Submission of an IND may not result in FDA authorization to commence clinical trials. Once an IND is in effect, each clinical trial to be conducted under the IND must be submitted to the FDA, which may or may not allow the trial to proceed.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified physician-investigators and healthcare personnel. Clinical trials are conducted under protocols detailing, for example, the parameters to be used in monitoring patient safety and the safety and effectiveness criteria, or endpoints, to be evaluated. Clinical trials are typically conducted in three defined phases, but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent institutional review board, or IRB, or ethics committee before it can begin. Phase I usually involves the initial administration of the investigational drug to people to evaluate its safety, dosage, tolerance, pharmacodynamics, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population afflicted with the disease or condition for which the drug is being developed, to evaluate dosage tolerance and appropriate dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate the effectiveness of the drug for specific indications. Phase III trials usually further evaluate effectiveness and test further for safety by administering the drug in its final form in an expanded patient population. Any Phase I, Phase II or Phase III clinical trials we initiate may not be completed successfully within any specified period of time, if at all. Further, we, third parties assisting in our product development efforts or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or are obtaining no medical benefit from the product being studied.

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

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

Supplemental New Drug Applications. 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: 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

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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 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.

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Regulation of Controlled Substances

We, our contract manufacturers and packagers and certain of our product candidates, including those containing 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 product candidates, including registration, recordkeeping and reporting requirements; security controls; and, assuming regulatory approval is received, labeling and packaging requirements and certain restrictions on prescription refills.

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

The DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure by us or our contract manufacturers or packagers to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

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

Hazardous Materials

We rely on third parties to assist us in developing and manufacturing all of our products and do not directly handle, store or transport hazardous materials or waste products. We rely on third parties to comply with all applicable federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We do not expect the cost of complying with these laws and regulations to be material to us.

Pharmaceutical Pricing and Reimbursement

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

We participate in a number of governmental programs that require us to provide rebates or discounts or otherwise limit reimbursement for our products. Under the Medicare Part D prescription drug benefit, which took effect in

January 2006, Medicare beneficiaries can obtain prescription drug coverage from private plans that are permitted to limit the number of prescription drugs that are covered on their formularies in each therapeutic category and class. Some Medicare Part D plans cover some or all of our products, but the amount and level of coverage vary from plan to plan. Our products may be excluded from private plans formularies and may be subject to significant price competition that depresses the prices we are able to charge. We believe

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that it is likely that private insurers will pattern their coverage and reimbursement policies on Medicare coverage and reimbursement policies with respect to prescription drug benefits.

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

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

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

Third-party payors are increasingly challenging the prices charged for medicines and examining their cost-effectiveness, in addition to their safety and efficacy. In some cases, MCOs may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for SPECTRACEF. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Even with these studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may decide not to provide coverage and reimbursement for our products, in whole or in part. Even if third-party payors approve coverage and reimbursement for our products, the resulting payment rates may not be sufficient for us to sell our products at a profit.

Moreover, political, economic and regulatory influences are subjecting the health care industry in the United States to fundamental changes with respect to pricing and reimbursement. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, which contain cost-containment measures and health care reforms to be implemented over the next decade. We refer to the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 as Health Care Reform. The provisions of Health Care Reform that are likely to impact our pricing and reimbursement for our products include the requirement to provide a 50% discount off negotiated prices to applicable brand-name drugs for Medicare Part D beneficiaries during their coverage gap period; an increase in the Medicaid rebates that we must pay to state Medicaid programs under the MDRP; the inclusion of Medicaid MCO enrollees in the calculation of rebates owed under the MDRP; the revised definition of average manufacturer price for rebate reporting purposes; and an increase in the number of entities eligible for discounted pricing under the 340B Drug Pricing Program. Furthermore, Health Care Reform includes initiatives to study and implement payment reforms and cost-containment measures, the results of which could reduce reimbursement for our products and reduce our profits.

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

controls on government-funded reimbursement for drugs;

controls on payments to health care providers that affect demand for drug products;

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challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;

weakening of restrictions on imports of drugs; and

expansion of the use of managed care systems in which health care providers contract to provide comprehensive health care for a fixed cost per person.

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

We are unable to predict how all or portions of Health Care Reform will be implemented, what additional legislation, regulations or policies, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost-containment measures, including those listed above, or other health care system reforms that are adopted could impair our ability to set prices that cover our costs, constrain our ability to generate revenue from government-funded or private third-party 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, or private insurers. These laws are extremely complicated, apply broadly and may constrain our business and the financial arrangements through which we market, sell and distribute our products. Examples of these laws and regulations include:

Federal Anti-Kickback Law. The anti-kickback law contained in the federal Social Security Act is a criminal statute that makes it a felony for individuals or entities knowingly and willfully to offer or pay, or to solicit or receive, remuneration in order to induce the purchase, order, lease or recommending of items or services, or the referral of patients for services, that are reimbursed under a federal health care program, including Medicare and Medicaid. The term remuneration has been interpreted broadly and includes both direct and indirect compensation and other items and services of value. Both the party offering or paying remuneration and the recipient may be found to have violated the statute. Courts have interpreted the anti-kickback law to cover any arrangement where one purpose of the remuneration is to induce purchases or referrals, regardless of whether there are also legitimate purposes for the arrangement. There are narrow exemptions and regulatory safe harbors, but many legitimate transactions fall outside of the scope of any exemption or safe harbor, although that does not necessarily mean the arrangement will be subject to penalties under the anti-kickback statute. Penalties for federal anti-kickback violations are severe, including up to five years imprisonment, individual and corporate criminal fines, exclusion from participation in federal health care programs and civil monetary penalties in the form of treble damages plus $50,000 for each violation of the statute. Health Care Reform amended the intent requirement of the federal anti-kickback statute so that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it. Violations of the federal anti-kickback

statute may now also be treated as a false or fraudulent claim for purposes of the federal false claims act or a violation of the criminal health care fraud law.

Federal False Claims Law. The federal false claims act imposes liability on any person who knowingly submits, or causes another person or entity to submit, a false or fraudulent claim for payment of government funds or knowingly makes a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Penalties include three times the government s

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damages plus civil penalties of $5,500 to $11,000 per false claim. In addition, the federal false claims act permits a person with knowledge of fraud, referred to as a *qui tam* plaintiff or whistleblower, to file a lawsuit on behalf of the government against the person or entity that committed the fraud. If the government determines to intervene in the lawsuit and the government prevails, the *qui tam* plaintiff is rewarded with a percentage of the recovery.

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

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

State Laws. Various states have enacted laws and regulations comparable to the federal fraud and abuse laws and regulations. These state laws and regulations may apply to items or services reimbursed by any third-party payor, including private payors, 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.

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

Employees

As of February 28, 2011, we had 147 full-time employees, 115 of whom were engaged in marketing and sales; eight of whom were engaged in research, development and regulatory affairs; and 24 of whom were engaged in management, administration and finance. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages. We believe that relations with our employees are good.

Available Information

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

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ITEM 1A. *RISK FACTORS*

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

Risks Relating to Commercialization and Product Acquisitions

We use third parties to manufacture all of our products and product candidates. This may increase the risk that we will not have sufficient quantities of our products or product candidates at an acceptable cost, which could 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 purchase raw materials for, manufacture, package and supply all of our products. Some of the agreements we have entered into are exclusive agreements in which the manufacturer is a single-source supplier, preventing us from using alternative sources. Similarly, many of our agreements may require us to make volume commitments or agree to long-term pricing arrangements that may affect our margins or constrain our ability to position our products optimally in the market. If we choose to cancel or are unable to meet our volume commitments, we may be subject to penalties or increased costs to manufacture our products. For a description of the manufacturing and packaging agreements related to our more important products, please see Item 1. Business Manufacturing.

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

- We may not be able to meet commercial demands for our products;
- We may be required to cease distribution or issue recalls;
- We may not be able to initiate or continue clinical trials of product candidates that are under development; and
- We may be delayed in submitting applications for regulatory approvals for product candidates.

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

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

We also rely on third-party manufacturers that, in some instances, have encountered difficulties obtaining raw materials needed to manufacture our product candidates as a result of DEA regulations. Although these difficulties have not had a material adverse impact on us, such problems could have a material adverse impact on us in the future.

In addition, supply interruptions or delays could occur that require us or our manufacturers to obtain substitute materials or products, which would require additional regulatory approvals. Changes in our raw material suppliers could result in delays in production, higher raw material costs and loss of sales and customers because regulatory authorities must generally approve raw material sources for pharmaceutical products. Any significant supply interruption could have a material adverse effect on our business, financial condition and results of operation.

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In addition, we import the API, tablet cores and/or finished product for all of our products from third parties that manufacture such items outside the United States, and we expect to do so in the future. This may give rise to difficulties in obtaining API, tablet cores or finished product in a timely manner as a result of, among other things, regulatory agency import inspections, incomplete or inaccurate import documentation or defective packaging. For example, in January 2009, the FDA released draft guidance on Good Importer Practices, which, if adopted, will impose additional requirements on us with respect to oversight of our third-party manufacturers outside the United States. The FDA has stated that it will inspect 100% of API, tablet cores and finished product that is imported into the United States. If the FDA requires additional documentation from third-party manufacturers relating to the safety or intended use of the API or finished product, the importation of the API or finished product could be delayed. While in transit from outside the United States or while stored with our third-party logistics provider, DDN, our API, tablet cores or finished product could be lost or suffer damage, which would render such items unusable. We have attempted to take appropriate risk mitigation steps and to obtain transit or casualty insurance. However, depending upon when the loss or damage occurs, we may have limited recourse for recovery against our manufacturers or insurers. As a result, our financial performance could be impacted by any such loss or damage.

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.

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 not successful in identifying and acquiring rights to products, or if we are not successful in developing product candidates, we may not be able to increase our revenues in future periods, which could result in significant harm to our financial condition, results of operations and prospects.

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

The development and commercialization of drugs is highly competitive. We face competition with respect to our currently marketed products, our current product candidates and any products that we may seek to develop or commercialize in the future. Our competitors include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other private and public research organizations that seek patent protection and establish collaborative arrangements for development, manufacturing and commercialization. We face significant competition for our currently marketed products.

Some or all of our product candidates, if approved, may face competition from other branded and generic drugs approved for the same therapeutic indications, approved drugs used off label for such indications and novel drugs in

clinical development. For example, our CRTX 073 product candidate, which is a modified formulation of an existing product, may not demonstrate sufficient additional clinical benefits to health care providers to justify a higher price compared to generic equivalents within the same therapeutic class. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop.

Our patents will not protect our products if competitors devise ways of making products that compete with our products without legally infringing our patents. The FDCA and FDA regulations and policies provide

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certain exclusivity incentives to manufacturers to create modified, non-infringing versions of a drug in order to facilitate the approval of ANDAs for generic substitutes. These same types of exclusivity incentives encourage manufacturers to submit NDAs that rely, in part, on literature and clinical data not prepared for or by such manufacturers. Manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same API, dosage form, strength, route of administration and conditions of use or labeling as our product and that the generic product is absorbed in the body at the same rate and to the same extent as our product, a comparison known as bioequivalence. Such products would be significantly less costly than our products to bring to market and could lead to the existence of multiple lower-priced competitive products, which would substantially limit our ability to obtain a return on the investments we have made in those products.

Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates. The FDCA provides a five-year period of exclusivity for a drug approved under the first NDA covering an API, and the drug approval for any of our product candidates may be blocked by such a period of marketing exclusivity. Similarly, the FDCA provides a three-year period of exclusivity for a drug approved under the first NDA covering a new indication or formulation of a drug that includes a previously approved API. These provisions may delay approval of our product candidates.

Even if we are not excluded from obtaining marketing approval for our product candidates, it may adversely affect the revenue potential of those product candidates if our competitors succeed in commercializing similar products more rapidly or effectively than we are able to. For instance, in October 2010, one of our competitors, Par Pharmaceutical Companies, Inc., with its licensing partner, Tris Pharma, Inc., launched an FDA-approved generic hydrocodone polistirex and chlorpheniramine polistirex extended-release oral suspension product, which, like our CRTX 067 product candidate, is a generic version of UCB s, Tussionex. In addition, UCB launched its own generic version of Tussionex, through its generic subsidiary, Kremers Urban Pharmaceuticals Inc., which would make us the third entrant into the Tussionex generic market. While we continue to expect that CRTX 067 will receive marketing approval by the FDA in 2011, the presence of competing products in the market may adversely affect both the price we can charge for our product and the portion of the market for that product that may be available to us.

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

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

We will face competition based on the safety and effectiveness of our products, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our competitors may develop or commercialize more effective, safer or more affordable products, or products with more effective patent protection, than our products. Accordingly, our competitors may commercialize products more rapidly or effectively than we are able to, which would adversely affect our competitive position, the likelihood that our product candidates will achieve initial market acceptance and our ability to generate

meaningful revenues from our product candidates. Even if our product candidates achieve initial market acceptance, competitive products may render our

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products noncompetitive. If our product candidates are rendered noncompetitive, we may not be able to recover the expenses of developing and commercializing those product candidates.

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

Our plan to grow our existing product portfolio is based upon our ability to acquire or in-license products and to acquire companies that fit with our strategic focus. These acquisitions and licenses involve risks. If we fail to address adequately the financial, operational or legal risks of our acquisitions or licensing arrangements, or if we are unable to integrate our acquisitions successfully, our results of operations and financial condition could be materially and adversely affected. For example:

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

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

We may overuse our cash resources.

We may experience higher than anticipated acquisition costs and expenses.

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

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

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

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

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

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

Any acquisition could substantially increase our amortization expenses.

If we are unable to identify and acquire acquisitions successfully, our ability to realize the value of completed acquisitions and our ability to commercialize or develop new products and expand our product pipeline may be limited, which could adversely affect 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. 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

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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 or a manufacturer contracted to market an authorized generic to the brand may enter the market and, as a result, the price of the drug may decline significantly. In such event, we may in our discretion provide our customers a credit with respect to the customers remaining inventory for the difference between our new price and the price at which we originally sold the product to our customers. There are circumstances under which we may, as a matter of business strategy, not provide price adjustments to certain customers and, consequently, we may lose future sales to competitors.

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 plan to submit our initial REMS assessment update in the second quarter of 2011.

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

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

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

issues, which could make them reluctant to prescribe or accept ZYFLO CR, ZYFLO or any other zileuton product candidates that we successfully develop and commercialize, which could limit their commercial acceptance.

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

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

We face an inherent risk of product liability exposure related to the sale of our currently marketed products, previously marketed products that have been withdrawn or discontinued, any other products that we successfully develop and the testing of our product candidates in human clinical trials. If we cannot successfully defend against claims that our products or product candidates caused injuries, we 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
- inability to commercialize the products that we may develop.

As discussed in the risk factors above, there are concerns regarding the safety of the products containing the APIs gemifloxacin or zileuton. In November 2010, the FDA requested that all products containing the API propoxyphene be voluntarily withdrawn from the market due to safety concerns. While all of our products containing propoxyphene have been removed and we are not aware of any pending or threatened product liability claims against us related to the previously marketed propoxyphene products or currently marketed gemifloxacin or zileuton products, such claims may 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 product liability insurance was approximately $308,000 for the policy year beginning September 13, 2010. 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.

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

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

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 approximately 94% of our gross product sales during 2010.

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.

We also depend on the distribution abilities of our wholesale customers to ensure that products are effectively distributed throughout the supply chain. If there are any interruptions in our customers ability to distribute products through their distribution centers, our products may not be effectively distributed, which could cause confusion and frustration among pharmacists and lead to product substitution. For example, in the fourth quarter of 2007 and the first quarter of 2008, several Cardinal Health distribution centers were placed on probation by the DEA and were prohibited from distributing controlled substances. Although Cardinal Health had a plan in place to re-route all orders to the next closest distribution center for fulfillment, system inefficiency resulted in a failure to effectively distribute our products to all areas.

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

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

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, 2011 of 100 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.

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

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

We are obligated to make aggregate combined purchases of cefditoren pivoxil API, the SPECTRACEF products and sample packs of SPECTRACEF 400 mg exceeding specified dollar amounts annually over a five-year period under our supply agreement with Meiji. Under the agreement, the required annual aggregate combined purchases of cefditoren pivoxil API, the SPECTRACEF products and sample packs of SPECTRACEF 400 mg are $20.0 million for the sales year ended October 2010, $25.0 million for the sales year ending October 2011, $30.0 million for the sales year ending October 2012 and $35.0 million for the sales year ending October 2013. If we do not meet our minimum purchase requirement in a given year, we must pay Meiji an amount equal to 50% of the shortfall in that year.

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

condition, results of operations and cash flows.

Product acquisitions typically include the purchase of existing inventory. If the previous company has distributed product to the wholesalers and distributors that exceeds current demand, such inventory levels

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could affect our ability to sell product to the wholesalers. Until the inventory levels decline, revenues for the acquired product could be minimal. For example, when we acquired FACTIVE, the wholesaler and distributor levels of inventory exceeded demand, which prevented us from selling significant amounts of product for the first three months following the acquisition.

Our ability to maintain optimal inventory levels also depends on the performance of third-party contract manufacturers. In some instances, third-party manufacturers have encountered difficulties obtaining raw materials needed to manufacture our product candidates as a result of DEA regulations and because of the limited number of suppliers of certain APIs. Although these difficulties have not had a material adverse impact on us, such problems could have a material adverse impact on us in the future. If we are unable to manufacture and release inventory on a timely and consistent basis, if we fail to maintain an adequate level of product inventory, if inventory is destroyed or damaged or if our inventory reaches its expiration date, patients might not have access to our products, our reputation and our brands could be harmed and physicians may be less likely to prescribe our products in the future, each of which could have a material adverse effect on our financial condition, results of operations and cash flows.

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

Certain of our product candidates, including CRTX 067, 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 may manufacture, the amount of API it may use to manufacture those products and the amount of controlled substance drug products a packager may package. We rely on the third-party manufacturers and packagers of these product candidates, including Neos and Coating Place, to request and obtain from the DEA the annual quota allocation needed to meet our production requirements and we will continue to rely on our third-party manufacturers and packagers of these products to obtain necessary quotas following launch. If our manufacturers and packagers are unsuccessful in obtaining quotas, our controlled substance product candidates could be at risk of a delayed launch or we may be unable to meet commercial demand following launch.

If we or our contract manufacturers or packagers fail to comply with regulatory requirements for 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 (as discussed above) certain of our product candidates, including CRTX 067, 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 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.

Risks Relating to Product Development and Regulatory Matters

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

Even though the FDCA requires pre-marketing approval of all new drugs, as a matter of history and regulatory policy, the FDA has practiced enforcement discretion against some marketed, unapproved new drugs by employing a risk-based enforcement policy. Although the FDA considers all such drugs to require its

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approval, the FDA s enforcement policy prioritizes unapproved products that pose potential safety risks, lack evidence of effectiveness, prevent patients from seeking effective therapies or are marketed fraudulently. In addition, the FDA is more likely to bring an enforcement action with respect to an unapproved drug if it finds that the marketer and its manufacturers are also allegedly in non-compliance with current Good Manufacturing Practices, or cGMP requirements.

In accordance with our overall business strategy, we discontinued manufacturing and distribution of all of our marketed unapproved products, including our ALLERX Dose Pack products and our HYOMAX line of products, as of December 31, 2010. Our decision does not limit the FDA s enforcement authority and there is no certainty that the FDA will not seek to require the withdrawal of these products while revenue is still being recognized based off wholesaler and distributor pull-through.

For the years ended December 31, 2009 and 2010, our ALLERX Dose Pack products and our HYOMAX line of products generated $59.9 million and $37.4 million of net product sales, respectively. There is no guarantee that we will be able to replace these revenues with revenues from our strategic products. If we are not able to replace these product revenues, our discontinuance of these products could have a material adverse effect on our business, financial condition and results of operations and cash flows.

If we fail to comply with regulatory requirements for our products or if we experience unanticipated problems with them, the FDA may take regulatory actions detrimental to our business, resulting in temporary or permanent interruption of distribution, withdrawal of products from the market or other penalties.

We, our products, our contract manufacturers and other partners are subject to comprehensive regulation by the FDA. These requirements include submissions of safety and other post-marketing information; record-keeping and reporting; annual registration of manufacturing facilities and listing of products with the FDA; ongoing compliance with cGMP regulations; and requirements regarding advertising, promotion and the distribution of samples to physicians and related recordkeeping. For example, we received a warning letter from the FDA s Division of Drug Marketing, Advertising and Communications on June 22, 2010 relating to certain promotional and labeling material for our ZYFLO CR extended release tablets. The FDA asserted that our ZYFLO CR webpage was false and misleading because it presented efficacy claims for ZYFLO CR, but failed to contain certain risk information associated with the product, and that certain promotional material was false or misleading because it omitted important information about the risks associated with the use of ZYFLO CR, made unsubstantiated superiority claims and omitted material facts. Additionally, the FDA stated that the web page and promotional material were disseminated with an outdated version of the FDA-approved product labeling for ZYFLO CR. Although we did not admit and in fact denied some of FDA s allegations, as part of our response and in connection with the close out of this matter, we ceased dissemination of the relevant promotional materials, disabled and revised the web page, retrieved and destroyed the relevant promotional materials and updated our procedures regarding promotional material and labeling. We disseminated updated messaging to the recipients of the aforementioned promotional materials and updated our website to include corrective messaging consistent with the FDA s observations. The corrective messaging will remain on the website for 12 months from implementation, or February 2, 2012. If our promotional activities fail to comply with the FDA s regulations and guidelines, we could be subject to additional regulatory actions by the FDA, including product seizure, injunctions and other penalties, and, if so, our business and reputation could be harmed.

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

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distributing our first REMS assessment and expect to file our initial update to the FDA in the second quarter 2011. 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. Our current quality assurance program may not be reasonably designed to, or may not, discover all instances of non-compliance by our third-party manufacturers with these regulations. For instance, in 2004, the FDA inspected the predecessor company to one of our current development partners and, as a result of alleged failure of the manufacturer to comply with cGMPs, the FDA issued a warning letter to the manufacturer. Subsequent action by the FDA related to the 2004 warning letter resulted in a permanent injunction, or consent decree, in 2007 against the manufacturer. The manufacturer is working closely with their FDA district office to satisfy the conditions of the injunction; however, the manufacturer remains under the auspices of the consent decree at this point in time.

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

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

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

injunctions or the imposition of civil or criminal penalties.

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

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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 our product candidates successfully.

Our product candidates are primarily in the preclinical stage 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 efficacy trials. We may not be able to obtain permission from the FDA, IRBs or other authorities to commence or complete necessary clinical trials. If permitted, such clinical testing may not prove that our product candidates are safe and effective to the extent necessary to permit us to obtain marketing approvals or clearances from regulatory authorities. One or more of our product candidates may not exhibit the expected therapeutic results in humans, may cause harmful side effects or may have other characteristics that may delay or preclude submission and regulatory approval, or cause imposition of burdensome post-approval requirements or limit commercial use if approved.

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

For example, Draft Guidance for Industry, revision one, issued by the FDA in 2008 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 2011 and 2012. We cannot predict whether we will encounter problems with any of our completed or planned clinical trials that will delay or cause regulatory authorities, IRBs or us to suspend those clinical trials or the analysis of data from such trials.

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

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

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

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

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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;

- exposure of participants to unacceptable health risks;

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

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

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

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

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

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

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

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

If clinical trials are delayed, the commercial viability of 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, and changes in or the enactment of additional statutes or regulations or medical and technical developments during the review process, may delay the approval or cause the rejection of an application. The FDA has substantial discretion in the approval process

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and may require additional clinical or other data as a condition of reviewing or approving an application. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

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

We expect to submit an NDA to the FDA in 2014 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.

There have been, there are and we expect there will continue to be federal and state legislative and administrative proposals that could limit the amount that government health care programs will pay to reimburse the cost of pharmaceutical products. Furthermore, private payors often implement similar reimbursement policies as government payors. For a discussion of the more important pharmaceutical pricing and reimbursement issues applicable to us, please see the Pharmaceutical Pricing and Reimbursement section of Item 1. Business above and Risks Related to Financial Results below.

Legislative or administrative acts that reduce reimbursement for our products could adversely impact our business. 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.

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We cannot be certain that our currently marketed products will continue to be, or any of our product candidates still in development will be, included in the Medicare Part D prescription drug benefit. Even if our products are included, the private health plans that administer the Medicare drug benefit can limit the number of prescription drugs that are covered on their formularies in each therapeutic category and class. In addition, private managed care plans and other government agencies continue to seek price discounts. Because many of these same private health plans administer the Medicare drug benefit, they have the ability to influence prescription decisions for a larger segment of the population. In addition, certain states have proposed or adopted 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. Moreover, Health Care Reform includes funding for comparative effectiveness research and the establishment of committees, such as the Independent Payment Advisory Board, to analyze different payment systems (including bundled payments) and recommend payment reform and other cost-containment measures, which all could reduce reimbursement for our products.

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

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

Health care providers play a primary role in the recommendation and prescribing of our products. Our arrangements with health care providers, third-party 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 a discussion of the more important laws and regulations applicable to us, please see the Regulatory Matters, Pharmaceutical Pricing and Reimbursement and Fraud and Abuse Regulation sections of Item 1. Business above.

We participate in the MDRP established by the Omnibus Budget Reconciliation Act of 1990, as amended, effective in 1993. Under the MDRP, we pay a rebate for each unit of our product reimbursed by Medicaid. The amount of the rebate for each product is set by law. We are also required to pay certain statutorily defined rebates on Medicaid purchases for reimbursement on prescription drugs under state Medicaid plans. There have been enhanced political attention, governmental scrutiny and litigation at the federal and state levels regarding the prices paid or reimbursed for pharmaceutical products under Medicaid and other government programs. Although we estimate that less than 2% of our sales qualify for Medicaid rebates, any investigation of our rebate practices could be costly, could divert the attention of our management away from operations and could damage our reputation.

Health Care Reform includes a number of provisions aimed at strengthening the government s ability to pursue federal anti-kickback and federal false claims act cases against health care entities, such as increased funding for health care fraud enforcement activities, enhanced investigative powers and amendments to the federal false claims act to make it easier for the government and whistleblowers to pursue alleged violations.

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Recently, several pharmaceutical and other health care companies have been prosecuted under the federal fraud and abuse laws for allegedly providing consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company s products, allegedly misrepresenting the pricing data which the federal government uses to set reimbursement rates and calculate Medicaid rebates under the MDRP and allegedly causing false claims to be submitted because of the company s marketing of the product for unapproved, and thus non-reimbursable, uses. This new growth in litigation and enforcement action has increased the risk that a pharmaceutical company will have to defend a false claims action, which can be expensive, time consuming and distracting, and can potentially impact its financial performance.

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

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

Risks Relating to Intellectual Property and Licenses

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

Our success depends in part on our ability to obtain and maintain protection for the intellectual property covering or incorporated into our technology and products, whether such technology is owned by us or licensed to us by third parties. Patent protection in the pharmaceutical field is highly uncertain and involves complex legal and scientific questions. We and our licensors may not be able to obtain additional issued patents relating to our respective technology or products. Even if issued, patents issued to us or our licensors may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the longevity of the patent protection we may have for our products. Additionally, changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Our owned or licensed patents also may not afford protection against competitors with similar technology. Because patent applications in the United States and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, we cannot be certain that we or our licensors were the first to make the inventions claimed in our or our licensors issued patents or pending patent applications, or that we or our licensors were the first to file for protection of the inventions set forth in these patent applications. If a third party has also filed a U.S. patent application covering our product candidates or a similar invention, we may have to participate in an adversarial

proceeding, known as an interference, declared by the USPTO to determine priority of invention in the United States. These proceedings are costly and time-consuming, and it is possible that our efforts could be unsuccessful, resulting in a loss of our U.S. patent protection. In addition, U.S. patents generally expire, regardless of the date of issue, 20 years from the earliest claimed non-

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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 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 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 FACTIVE. 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 FACTIVE 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 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.

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

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

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 or seek to cancel our similar trademarks based on the competitor s prior use. If we initiate legal proceedings to seek to protect our trademarks, the costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful.

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

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

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

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how. We seek to protect our unpatented proprietary information in part by confidentiality agreements with our current and

potential collaborators, employees, consultants, strategic partners, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine

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the scope of our proprietary rights. In addition, our trade secrets may otherwise become known or may be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, our competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

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

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

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

As a result of patent infringement or other similar claims or to avoid potential claims, we or our potential future collaborators may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the USPTO, regarding intellectual property rights with respect to our products and technology. The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

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

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Risks Relating to Financial Results

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

The implementation of Health Care Reform is expected to result in a transformation of the delivery of and payment for health care services in the United States. The combination of these measures will expand health insurance coverage to an estimated 32 million Americans. In addition, there are significant health insurance reforms that will improve patients ability to obtain and maintain health insurance. Such measures include the elimination of lifetime caps, no rescission of policies and no denial of coverage due to preexisting conditions. The expansion of health care insurance and these additional market reforms should result in greater access to our products; however, the substantial increase in the number of Americans with health insurance will not occur until 2014.

Moreover, a number of provisions contained in Health Care Reform may adversely affect reimbursement for our products. Effective January 2, 2010, Health Care Reform retroactively increased the minimum basic Medicaid rebate for brand-name prescription drugs from 15.1% to 23.1% and for generic drugs from 11% to 13%, potentially increased the additional Medicaid rebate calculation for line extensions of oral solid dosage forms of innovator products, expanded the entities eligible for 340B pricing and revised the average manufacturer price definition to remove certain classes of trade. In addition, in March 2010, pharmaceutical manufacturers were required to pay states rebates on prescription drugs dispensed to Medicaid MCO enrollees.

Beginning on January 1, 2011, Health Care Reform requires drug manufacturers to provide a 50% discount on brand-name prescriptions filled in the Medicare Part D coverage gap, also known as the donut hole. The legislation mandates the gradual elimination of the coverage gap, beginning in 2011 and finishing in 2020. Moreover, Health Care Reform reduces Part D premium subsidies for higher-income beneficiaries, expands medication therapy management requirements and makes a number of other revisions to Part D program requirements. The elimination of the coverage gap may result in greater access to our products for Part D beneficiaries.

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

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

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

We have incurred and expect to continue to incur significant development expenses in connection with our ongoing activities, particularly if and when we conduct clinical trials for product candidates. In addition, we incur significant

commercialization expenses related to our currently marketed products for sales, marketing, manufacturing and distribution. We expect these commercialization expenses to increase in future

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periods if we are successful in obtaining FDA approval to market our product candidates or any newly acquired products. We have used, and expect to continue to use, revenue from sales of our marketed products to fund a significant portion of the development costs of our product candidates and to expand our sales and marketing infrastructure. However, we may need substantial additional funding for these purposes and may be unable to raise capital when needed or on acceptable terms, which would force us to delay, reduce or eliminate our development programs or commercialization efforts.

As of December 31, 2010, we had $50.9 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 and product returns of our currently marketed products and any additional products that we may market in the future;
- the scope, progress, results and costs of development activities for our current product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, additional product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of our product candidates and products;
- the extent to which we acquire or invest in products, businesses and technologies;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products and product candidates; and
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending claims related to intellectual property owned by or licensed to us.

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;

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commercializing marketed products; and

developing product candidates, including conducting clinical trials.

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

advance the development of our product candidates; and

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

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

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

Our financial statements have been prepared in accordance with GAAP. 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. Our estimates, or the assumptions underlying them, may prove to be incorrect.

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

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

seasonality of the respiratory ailment season, which historically results in higher sales of our respiratory products during the first and fourth quarters of the calendar year;

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;

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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.

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

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

Risks Relating to Common Stock

Our stock price is subject to fluctuation, which may cause an investment in our stock to suffer a decline in value.

The market price of our common stock may fluctuate significantly in response to factors that are beyond our control. The stock market in general has recently experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical and biotechnology companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of our common stock.

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

- the results of discovery, preclinical studies and clinical trials;
- significant acquisitions, strategic partnerships, joint ventures or capital commitments.
- the entry into, amendment or termination of key agreements, including licensing and collaboration agreements;
- the results and timing of regulatory reviews relating to the approval of product candidates;
- the initiation of material developments in or conclusion of litigation to enforce or defend intellectual property rights;
- failure of any product candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect research and development expenditures;
- issues in manufacturing products or product candidates;

recall or withdrawal of a product or products;

the loss of key employees;

the acquisition, development or introduction of technologies, product candidates or products;

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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, 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 or nominating and compensation committees comprised solely of independent directors. We cannot be certain that the interests of Chiesi will be consistent with the interests of our other stockholders. In addition, Chiesi s majority ownership of and control over our company may have the effect of delaying or preventing a change in control, merger or tender offer, which could deprive our stockholders of an opportunity to receive a premium for their shares of common stock and may negatively affect the market price of our common stock. Moreover, Chiesi, either alone or with other existing stockholders (including members of our management), could (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

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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. Proceedings in the USPTO to uphold the claims of the 796 Patent were prosecuted from 2007 to 2010 by the 796 Patent owner, J-Med Pharmaceuticals, Inc. In light of our decision to cease marketing and distributing ALLERX as of December 31, 2010, we no longer consider this litigation material.

On June 13, 2008, counsel for Vision Pharma, LLC, or 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 covered our later formulation of ALLERX 10 Dose Pack and ALLERX 30 Dose Pack, as well as ALLERX Dose Pack PE and ALLERX Dose Pack PE 30. Proceedings in the USPTO to uphold the claims of the 372 Patent were prosecuted from 2008 -2010 by the patent owner, Pharmaceutical Innovations, LLC, or Pharmaceutical Innovations. In light of our decision to cease marketing and distributing ALLERX as of December 31, 2010, we no longer consider this litigation material.

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, 2011 are as follows:

Name	Age	Position
Craig A. Collard	44	President and Chief Executive Officer
Steven M. Lutz	44	Executive Vice President, Manufacturing and Trade
Vincent T. Morgus	45	Executive Vice President, Finance and Chief Financial Officer
Andrew K. W. Powell	53	Executive Vice President, General Counsel and Secretary
Joshua B. Franklin	41	Vice President, Sales and Marketing
Alan T. Roberts	44	Vice President, Scientific Affairs

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, as well as our interim chief financial officer from July 2010 through January 2011. In March 2004, Mr. Collard founded Cornerstone BioPharma Holdings, Ltd. (the assets and operations of which were restructured as Cornerstone BioPharma in May 2005), and served as its President and Chief Executive Officer and a director from March 2004 to October 2008. Before founding Cornerstone BioPharma, Mr. Collard s principal occupation was serving as President and Chief Executive Officer of Carolina Pharmaceuticals, Inc., a specialty pharmaceutical company he founded in May 2003. From August 2002 to February 2003, Mr. Collard served as Vice President of Sales for Verum Pharmaceuticals, Inc., 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.

Vincent T. Morgus was appointed as our Executive Vice President, Finance and Chief Financial Officer on February 1, 2011. Mr. Morgus joined us from Quintiles Transnational Corp., a global fully integrated biopharmaceutical services company, or Quintiles, where he had been Senior Vice President, Corporate Development since September 2003. He joined Quintiles in June 1994 and progressed through a variety of financial management positions within the Quintiles organization, including Vice President, Finance of Quintiles Americas and Chief Financial Officer of Quintiles Informatics. Prior to working at Quintiles, Mr. Morgus held Controller positions at Q+E Software, Inc. and DaVinci Systems Corporation. Mr. Morgus started his career as an auditor for Arthur Andersen in

Northern California and is licensed as a certified public accountant in North Carolina and Pennsylvania. Mr. Morgus earned his Master s degree in Business Administration from the University of North Carolina s Kenan-Flagler Business School and his Bachelor of Science from the Pennsylvania State University s Smeal College of Business.

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Andrew K. W. Powell, Esq. has served as our Executive Vice President, General Counsel and Secretary since November 2009. Mr. Powell has practiced law for more than 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. Mr. Powell holds a B.A. from the University of North Carolina at Chapel Hill and a J.D. from Stanford Law School.

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

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PART II

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

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

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

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

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

On February 28, 2011, the closing price per share of our common stock as reported on the NASDAQ Capital Market was $5.39, and we had approximately 139 stockholders of record. This number does not include beneficial owners for whom shares are held by nominees in street name.

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

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Performance Graph

The following graph compares our cumulative total stockholder return from December 31, 2005 with those of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes that U.S. $100 was invested on December 31, 2005 in (1) our common stock, (2) the NASDAQ Composite Index and (3) the NASDAQ Biotechnology Index. The measurement points utilized in the graph consist of the last trading day in each calendar year, which closely approximates the last day of our respective fiscal year. The historical stock performance presented below is not intended to and may not be indicative of future stock performance.

Comparison of 5-Year Cumulative Total Return
among Cornerstone Therapeutics Inc. (known as Critical Therapeutics, Inc. prior to October 31, 2008),
the NASDAQ Composite Index and the NASDAQ Biotechnology Index

	12/31/05	12/31/06	12/31/07	12/31/08	12/31/09	12/31/10
CRTX	$ 100	$ 28	$ 18	$ 4	$ 8	$ 8
NASDAQ Composite Index	$ 100	$ 110	$ 120	$ 72	$ 103	$ 120
NASDAQ Biotech Index	$ 100	$ 101	$ 106	$ 92	$ 107	$ 123

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

Not applicable.

Issuer Purchases of Equity Securities

Not applicable.

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

The selected statement of income (loss) data and balance sheet data with respect to the years ended December 31, 2010, 2009, 2008, 2007 and 2006 set forth below are derived from our financial statements. As discussed elsewhere in this annual report, our financial statements for periods prior to October 31, 2008 reflect the historical results of Cornerstone BioPharma, and not Critical Therapeutics, and our financial statements for all subsequent periods reflect the results of the combined company. The selected financial data set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations contained in Item 7 below, and our financial statements and the notes contained in Item 8 below. Historical results are not necessarily indicative of our future results.

	Year Ended December 31,				
	2010	2009	2008	2007	2006
	(In thousands, except per share and share amounts)				
Statement of Income(Loss) Data:					
Net revenues	$ 125,317	$ 109,564	64,867	28,071	22,117
Costs and expenses:					
Cost of product sales(1)	32,313	19,457	5,951	3,300	2,151
Selling, general and administrative	53,198	45,731	27,082	15,205	14,438
Royalties	12,702	18,775	16,193	3,409	1,663
Research and development	4,488	3,608	3,679	556	249
Amortization of product rights	14,728	6,115	1,334	3,160	2,646
Total costs and expenses	117,429	93,686	54,239	25,630	21,147
Income from operations	7,888	15,878	10,628	2,441	970
Other expense, net	(110)	(128)	(1,221)	(1,741)	(1,275)
Income (loss) before income taxes	7,778	15,750	9,407	700	(305)
Provision for income taxes	(1,609)	(5,547)	(414)	(130)	
Net income (loss)	$ 6,169	$ 10,203	$ 8,993	$ 570	$ (305)
Net income (loss) per share, basic	$ 0.24	$ 0.58	$ 1.29	$ 0.10	$ (0.01)
Net income (loss) per share, diluted	$ 0.24	$ 0.54	$ 1.14	$ 0.08	$ (0.01)
Weighted-average common shares, basic	25,412,636	17,651,668	6,951,896	5,934,496	5,957,458
Weighted-average common shares, diluted	26,036,544	18,776,588	7,861,119	6,751,127	5,957,458

(1) Excludes amortization of product rights.

	December, 31				
	2010	2009	2008	2007	2006
			(In thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 50,945	$ 18,853	$ 9,286	$ 241	$ 116
Accounts receivable, net	76,476	16,548	12,987	3,505	1,799
Inventories, net	15,174	18,106	11,222	2,998	1,847
Working capital	61,165	28,312	3,157	(5,131)	(9,230)
Total assets	290,138	203,322	69,889	15,909	10,582
Deferred revenue	57,194				
Debt obligations, including current portion(1)	1,597	2,409	4,856	14,768	12,886
Total stockholders equity (deficit)	172,398	163,868	29,426	(12,295)	(13,844)
Shares of common stock outstanding	25,473	25,023	12,024	5,935	5,935

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

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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 products for the respiratory and related markets.

Our strategy is to:

- Leverage commercial capabilities by promoting respiratory and related products to high prescribing physicians through our respiratory sales force and to hospital-based healthcare professionals through our hospital sales force;
- Acquire rights to existing patent- or trade secret-protected, branded products, which can be promoted through the same channels to generate on-going high-value earnings streams;
- Advance our development projects and further build a robust pipeline; and
- Generate revenues by marketing approved generic products through our wholly owned subsidiary, Aristos.

We believe that if we implement this strategy successfully, we can deliver consistent long-term earnings growth.

2010 Highlights

Our performance for the year ended December 31, 2010 reflects the continued execution of our strategy. The proportion of our sales generated by strategic products increased over the prior year. Also, we focused our business development efforts on identifying products and companies that meet our strategic acquisition criteria. Finally, we advanced our development pipeline candidates CRTX 067, CRTX 072, and CRTX 073 and commenced preliminary development on CRTX 809. As we committed, we also ceased manufacturing and distribution of our marketed unapproved products from which we had historically derived a significant part of our revenues.

The following summarizes certain key financial results for the year ended December 31, 2010:

- Overall, cash and cash equivalents increased $32.1 million or 170% to $50.9 million as of December 31, 2010 compared to $18.9 million as of December 31, 2009;

Net revenues increased $15.8 million, or 14%, from $109.6 million in 2009 to $125.3 million in 2010; the percentage of net revenues generated from strategic products increased from 36% in 2009 to 60% in 2010;

Income from operations decreased $8.0 million, or 50%, from $15.9 million in 2009 to $7.9 million in 2010 on a GAAP basis, and decreased $3.1 million, or 11%, from $27.0 million in 2009 to $24.0 million in 2010 on a non-GAAP basis; and

Net income decreased $4.0 million, or 40%, from $10.2 million in 2009 to $6.2 million in 2010 on a GAAP basis, and increased $1.5 million, or 8%, to $18.9 million on a non-GAAP basis.

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Opportunities and Trends

We generate revenue by promoting our products to targeted physicians whose practices focus on the treatment of respiratory disorders. Primarily, these physicians are specialists. However, we continually identify and target high decile primary care physicians who are treating patients with respiratory ailments.

We will continue to direct our marketing efforts on targeted physicians in order to understand unmet patient needs in the respiratory area. By understanding these needs, we believe that we can systematically focus our efforts on acquiring or developing products that meet these needs. Also, we believe there are opportunities to acquire companies whose products or other assets may enhance our growth opportunities.

As of December 31, 2010, our working capital was $61.2 million, which represents a $32.9 million increase over our December 31, 2009 working capital of $28.2 million. The primary driver of the increase was a $32.0 million increase in available cash to $50.9 million as of December 31, 2010. Also, our relationship with Chiesi as a commercial partner continues to strengthen. In what we view as a challenging economic environment, we believe these two attributes, available cash and the Chiesi relationship, uniquely position us among our peers to capitalize on potential growth opportunities.

In summary, during 2011, we plan to continue to implement our strategy of combining organic growth, strategic acquisitions and product development. We plan to evaluate 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 products through our respiratory and hospital sales forces;

Acquisition of rights to proprietary respiratory or hospital products that align with our strategy and that offer potential for sustainable growth; and

Progress in the development of our product candidates, including receiving marketing approval by the FDA for CRTX 067 in 2011.

Meanwhile, our recent results reflect our diminished reliance on marketed unapproved products to generate revenues, and this trend will continue. In December 2010, we sold our remaining inventory of these products, which included ALLERX Dose Pack products and the HYOMAX product family. Revenue related to these sales was deferred due to our inability to reasonably estimate returns as a result of large channel inventory levels and extended payment terms given related to certain sales. As a result, revenue from the sales of these products will be recorded at the later of when cash payment is received or the risk of product returns has been substantially eliminated, which we expect will be when the product is sold to the end-user based upon prescriptions filled. For this reason, net product sales for these products will continue to be recognized after 2010 even though we are no longer manufacturing and distributing these products. Our net sales of ALLERX Dose Pack products and the HYOMAX family of products were $37.4 million, $59.9 million and $49.4 million in 2010, 2009 and 2008, respectively.

On November 22, 2010, the Company announced that it was complying with a request from the FDA that the industry voluntarily remove all products containing propoxyphene from the U.S. market. Net product sales from the Company s three propoxyphene products were $11.8 million, $9.6 million and $5.5 million in 2010, 2009, and 2008, respectively.

During 2010, we continued our intentional, strategic shift away from marketed unapproved products in order to focus on the branded approved products and, as of December 31, 2010, we are no longer manufacturing or distributing any marketed unapproved products. Because we have historically derived significant revenues from sales of marketed

unapproved products, we expect that our net product sales will begin to decline once all of our deferred revenue related to recent sales of these products has been recognized. We plan to replace these revenues, as well as revenues from other products we withdrew from the market in 2010, with increased revenues from our branded approved products, particularly CUROSURF and ZYFLO CR, and with revenues from our cough/cold product candidate, CRTX 067, for which we are targeting FDA approval during 2011, and from any other approved products which we can acquire and commercialize.

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

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Results of Operations

Comparison of the Years Ended December 31, 2010 and 2009

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	
	2010	2009	$	%
Net Product Sales				
CUROSURF	$ 33,621	$ 10,463	$ 23,158	221%
ZYFLO product family	30,619	17,959	12,660	70
FACTIVE	5,126	1,178	3,948	335
SPECTRACEF product family	5,327	9,390	(4,063)	(43)
ALLERX Dose Pack products	27,305	31,707	(4,402)	(14)
HYOMAX product family	10,071	28,148	(18,077)	(64)
Other products	11,675	10,443	1,232	12
Total net product sales	123,744	109,288	14,456	13
License and royalty agreement revenues	1,573	276	1,297	470
Net revenues	125,317	109,564	15,753	14
Cost of product sales (exclusive of amortization of product rights)	32,313	19,457	12,856	66
Selling, general and administrative	53,198	45,731	7,467	16
Royalties	12,702	18,775	(6,073)	(32)
Research and development	4,488	3,608	880	24
Amortization of product rights	14,728	6,115	8,613	141
Income from operations	7,888	15,878	(7,990)	(50)
Total other expenses, net	(110)	(128)	(18)	(14)
Income before income taxes	7,778	15,750	(7,972)	(51)
Provision for income taxes	(1,609)	(5,547)	(3,938)	(71)
Net income	$ 6,169	$ 10,203	$ (4,034)	(40)%
Net income per share, diluted	$ 0.24	$ 0.54	$ (0.30)	(56)%
Non-GAAP income from operations(1)	$ 23,955	$ 27,034	$ (3,079)	(11)%
Non-GAAP net income(1)	$ 18,912	$ 17,432	$ 1,480	8%
Non-GAAP net income per share, diluted(1)	$ 0.73	$ 0.93	$ (0.20)	(22)%

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

Net Revenues

Net Product Sales.

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

ZYFLO CR and ZYFLO net product sales increased $12.7 million, or 70%, during 2010 compared to 2009, primarily due to the increase in our price and the steady prescription volume, which were partially offset by additional expense recorded for actual product returns related to sales made prior to our merger with Cornerstone BioPharma on October 31, 2008, which we refer to as the Merger.

FACTIVE net product sales increased $3.9 million, or 335%, during 2010 compared to 2009. This increase was primarily due to the fact that we acquired the FACTIVE product rights and related inventory

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

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

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

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

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

License and Royalty Agreement Revenues.

License and royalty agreement revenues increased $1.3 million, or 470%, during 2010 compared to 2009 primarily due to the one-time, upfront nonrefundable payment of $1.5 million we received in August 2010 in accordance with our license agreement with Targacept, Inc., or Targacept, under which we out-licensed certain rights with respect to our alpha-7 receptor technology, partially offset by a reduction in unrelated royalty revenue.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $14.7 million and $6.1 million in 2010 and 2009, respectively) increased $12.9 million, or 66% during 2010 compared to 2009.

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

	Year Ended December 31, 2010	2009	Change $	Change %
Net product sales	$ 123,744	$ 109,288	$ 14,456	13%
Cost of product sales (exclusive of amortization of product rights)	32,313	19,457	12,856	66
Gross margin	$ 91,431	$ 89,831	$ 1,600	2%
% of net product sales	74%	82%		(8%)

Gross margin for 2010 decreased eight percentage points compared to 2009 due to a relatively higher portion of our net product sales in 2010 derived from products with lower gross margins, specifically CUROSURF.

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

Royalty Expenses. Royalty expenses decreased $6.1 million, or 32%, during 2010 compared to 2009. This decrease was primarily due to lower net revenues of the HYOMAX products, partially offset by increased royalties for ZYFLO CR and FACTIVE.

Research and Development Expenses. We designate development projects to which we have allocated or plan to allocate significant research and development resources with the term CRTX and a unique number. Costs related to discontinued products and/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 2010 and 2009 and for current projects under development from project inception through December 31, 2010 (dollars in thousands):

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

Total	$ 4,488	$ 3,608	$ 880	24%

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

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

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

Provision for Income Taxes

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

Quarterly Results of Operations

See Note 15 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 2010 and 2009.

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Comparison of the Years Ended December 31, 2009 and 2008

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	
	2009	2008	$	%
Net Product Sales				
CUROSURF	$ 10,463	$	$ 10,463	NM
ZYFLO product family(1)	17,959	888	17,071	1922
FACTIVE	1,178		1,178	NM
SPECTRACEF product family	9,390	6,981	2,409	35%
ALLERX Dose Pack products	31,707	26,395	5,312	20
HYOMAX product family	28,148	22,962	5,186	23
Other products	10,443	5,979	4,464	75
Total net product sales	109,288	63,205	46,083	73
License and 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
Selling, general and administrative	45,731	27,082	18,649	69
Royalties	18,775	16,193	2,582	16
Research and development	3,608	3,679	(71)	(2)
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.

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.

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ZYFLO CR and ZYFLO net product sales increased $17.1 million, or 1922%, 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 the Merger.

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 $2.4 million, or 35%, 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.

ALLERX Dose Pack net product sales increased $5.3 million, or 20%, 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 $5.2 million, or 23%, 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 other products increased $4.5 million, or 75%, during 2009 compared to 2008 primarily due to the increase in sales of APAP 325 and APAP 500. Net product sales for APAP 325 were $3.9 million in 2009 compared to $1.2 million in 2008.

License and Royalty Agreement Revenues.

License and royalty agreement revenues decreased $1.4 million, or 83%, 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 other 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% during 2009 compared to 2008.

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

	Year Ended December 31,		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 CUROSURF, and an increase in our provision for inventory allowances of $876,000 during 2009, as compared to 2008. The increase in the provision for inventory allowances resulted from adjustments recorded to adequately state reserves related to excess inventory that, due to its expiration dating, was not sold.

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Selling, General and Administrative. Selling, general and administrative expenses increased $18.6 million, or 69%, 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; 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; 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. 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.

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.

Research and Development Expenses. The following table summarizes our research and development expenses for 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)
Other projects		713	2,013	(1,300)	(65)
Total		$ 3,608	$ 3,679	$ (71)	(2)%

Research and development expenses decreased $71,000, or 2%, 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 $1.8 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 $609,000 compared to 2008. These increases were partially offset by reductions in spending related to CRTX 068 and CRTX 062.

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 the 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 the 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 the effective tax rate was due primarily to the impact of the release of valuation allowances against

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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.

Reconciliation of Non-GAAP Financial Measures

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

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

	For the Year Ended December 31,		
	2010	2009	2008
GAAP income from operations	$ 7,888	$ 15,878	$ 10,628
Add: stock-based compensation(1)	1,339	1,478	749
Add: amortization of product rights	14,728	6,115	1,334
Add: acquisition-related expenses(2)		3,563	
Non-GAAP income from operations	$ 23,955	$ 27,034	$ 12,711
GAAP net income	$ 6,169	$ 10,203	$ 8,993
Add: stock-based compensation(1)	1,339	1,478	749
Add: amortization of product rights	14,728	6,115	1,334
Add: acquisition-related expenses(2)		3,563	
Less: tax effects related to above items(3)	(3,324)	(3,927)	(92)
Non-GAAP net income	$ 18,912	$ 17,432	$ 10,984
GAAP net income per share, diluted	$ 0.24	$ 0.54	$ 1.14
Non-GAAP net income per share, diluted	$ 0.73	$ 0.93	$ 1.40
Shares used in diluted net income per share calculation:			
GAAP net income	26,036,544	18,776,588	7,861,119
Non-GAAP net income	26,036,544	18,776,588	7,861,119

(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. During 2009, acquisition-related stock-based compensation charges included $1.8 million of charges that were included in selling, general and administrative expenses.

(3) Tax effects for 2010, 2009 and 2008 are calculated using effective tax rates of 20.7%, 35.2%, and 4.4% 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 the 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, 2010, we had $50.9 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,		
	2010	**2009**	**2008**
Cash provided by (used in):			
Operating activities	$ 32,989	$ 450	$ 12,629
Investing activities	(623)	(5,504)	(346)
Financing activities	(274)	14,621	(3,238)
Net increase in cash and cash equivalents	$ 32,092	$ 9,567	$ 9,045

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 funding working capital; selling, general and administrative expenses; and royalties.

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

Net cash provided by operating activities in 2009 reflected our net income of $10.2 million, adjusted by non-cash expenses totaling $10.7 million offset by changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling $20.4 million. Non-cash items included amortization and depreciation of $6.4 million, change in allowances for prompt payment discounts and inventory obsolescence of $4.6 million, stock-based compensation of $3.3 million and changes in deferred income tax of $3.6 million. Accounts receivable increased by $6.7 million primarily due to increased net product sales. Inventories increased by $8.2 million primarily due to the purchase of $2.8 million of FACTIVE API and finished goods and purchases of CUROSURF. Prepaid expenses, long-term accounts receivable and other assets increased by $3.1 million primarily due to voucher programs, prepayments on purchases of API not yet received into inventory, and increases in FDA

regulatory fees and in insurance premiums. Accounts payable decreased by $3.1 million primarily due to the payment of accounts payable related to the Merger and a reduction in payables related to manufacturing, product development and marketing expenses. Accrued expenses increased by $2.1 million primarily due to increased returns, rebates and chargebacks resulting from increased product sales, partially offset by a decrease in accrued bonuses. Income taxes payable (exclusive of income taxes payable assumed in the Merger) decreased by $1.3 million due to the tax benefits we recognized in 2009 related to exercises of non-qualified stock options.

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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 the 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 the 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 the 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, long-term accounts receivable and other assets (exclusive of prepaid expenses acquired in the 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 the 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 the 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 the Merger. Income taxes payable (exclusive of income taxes payable assumed in the Merger) increased by $3.1 million due to an $8.7 million increase in income before income taxes during 2008.

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

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

Net cash used in 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 the Merger of $2.1 million and net proceeds from the collection of advances to related parties of $638,000.

Net Cash (Used in) Provided by 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 the 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 the 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.

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

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

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

Funding Requirements

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

- the level of product sales and product returns of our currently marketed products and any additional products that we may market in the future;
- the scope, progress, results and costs of development activities for our current product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, additional product candidates that we pursue;
- the 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. We have no committed external sources of funds. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

As of December 31, 2010, we had $50.9 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, 2010 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Capital lease obligations	$ 265	$ 100	$ 164	$ 1	$
Operating leases(1)	3,075	627	1,113	1,183	152
Purchase obligations(2)	32,123	18,799	13,139	185	
Royalty obligations(3)	1,365	315	750	150	150
Other long-term liabilities(4)	1,500	1,500			
Total contractual obligations	$ 38,328	$ 21,341	$ 15,166	$ 1,519	$ 302

(1) Operating leases include minimum payments under leases for our facilities, automobiles and certain equipment. Our total minimum lease payments for the corporate headquarters are $482,000 in 2011, $492,000 in 2012, $536,000 in 2013, $584,000 in 2014 and $751,000 thereafter.

(2) Purchase obligations include fixed or minimum payments under manufacturing and supply agreements with third-party manufacturers of $25.5 million; clinical trial and research agreements with contract research organizations and consultants of $956,000; agreements with providers of marketing analytical services of $4.5 million; and open purchase orders for the acquisition of goods and services in the ordinary course of business of $1.2 million.

(3) Royalty obligations include minimum royalty payments due in connection with certain of our agreements. See Note 9 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 5 of our Notes to Consolidated Financial Statements of this annual report on Form 10-K for additional information.

In addition to the material contractual cash obligations included the chart above, we have committed to make potential future milestone payments to third parties as part of licensing, distribution 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 $55.0 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

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

Net Product Sales

Product Sales. We recognize revenue from our product sales upon transfer of title, which occurs when product is received by our customers. We sell our products primarily to large national wholesalers, which have the right to return the products they purchase. We estimate the amount of future returns at the time of revenue recognition. We recognize product sales net of estimated allowances for product returns, rebates, price adjustments, chargebacks, and prompt payment and other discounts. When we cannot reasonably estimate the amount of future product returns, we record revenues when the risk of product return has been substantially eliminated. As of December 31, 2010, the Company had $57.2 million of deferred revenue related to sales for which future returns could not be reasonably estimated at the time of sale. Deferred revenue is recorded net of estimated allowances for rebates, price adjustments, chargebacks, and prompt payment and other discounts. Estimated allowances are recorded and classified as accrued expenses in the accompanying consolidated balance sheet as of December 31, 2010. The deferred revenue is recognized when the product is sold through to the end user based upon prescriptions filled. To estimate product sold through to end users, we rely on third-party information, including prescription data and information obtained from significant distributors with respect to their inventory levels and sell-through to customers.

When we implement a price increase, we generally offer our existing customers an opportunity to purchase a limited quantity of product at the previous list price. Shipments resulting from these programs generally are not materially in excess of ordinary levels; therefore, we recognize the related revenue when the product is received by the customers and include the shipments in estimating our various product related allowances. In the event we determine that these shipments represent purchases of inventory in excess of ordinary levels for a given wholesaler, the potential impact on product returns exposure 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 that begins six months prior to and ends up to twelve months subsequent to expiration of the products. Our products have an 18 to 48 month

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expiration period from the date of manufacture. In determining our return allowance, we consider various relevant factors, including:

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

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

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

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

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

Based on the above factors, management determines an estimated return rate for each product and applies that rate to the quantity of units sold that is subject to future return. As of December 31, 2010, our estimated return rates for products currently subject to return ranged from 1% to 20% depending on the product.

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

If our estimates of returns differ from our actual results, there could be a material impact on our financial statements. Based on historical experience, our average actual return rates vary based on our product mix. We consider a one-percentage point variation to be a reasonably possible change in the percentage of our product returns to related gross sales on a product by product basis. A one-percentage point increase or decrease in each of the individual product s estimated product returns rate would have had an approximate $3.7 million, or 3%, effect on our net revenues recognized in 2010.

Expense recognized for product returns was $20.1 million, $13.0 million and $6.9 million in 2010, 2009 and 2008, respectively, representing 11%, 9% and 8% of gross product sales in 2010, 2009 and 2008, respectively. Expense recognized during 2010 for product returns related to current year sales was $11.3 million, or 6% of gross product sales. Expense recognized during 2010 for product returns related to sales made in prior years was $8.9 million, or 5% of gross product sales. The additional expense of $8.9 million consisted of $4.5 million, $2.2 million, $1.9 million and $1.2 million related to ALLERX Dose Pack products, SPECTRACEF, ZYFLO family of products and FACTIVE, respectively, partially offset by a $1.1 million reduction to our estimate of product returns upon the withdrawal of our propoxyphene/acetaminophen products.

The majority of additional expense recorded in 2010 for ALLERX related to an increase in actual returns of ALLERX PE and ALLERX DF products due to significant changes in market dynamics during early 2010. All sales of ALLERX PE and ALLERX DF made in 2010 were deferred due to our inability to estimate returns.

During 2010, demand for certain of our SPECTRACEF products declined due to increased competition in the antibiotic market and dilution of our sales promotion efforts as a result of the introduction of FACTIVE into our product portfolio. As a result, we increased our estimated rates for product returns for these various SPECTRACEF

products by a range of two to eight percentage points of gross product sales, depending on the specific SPECTRACEF product.

Additional expense of $1.9 million related to ZYFLO CR and ZYFLO was recorded to account for an increase in actual returns compared to management s initial estimate at the time of the Merger. The product

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returns relate to product sold by Critical Therapeutics, Inc. prior to the Merger. These returns have not affected our estimated rate of returns on sales made subsequent to the Merger.

During 2010, we increased our estimated rate of return for FACTIVE 5 by eight percentage points. This increase is due to a change in our initial estimate of product returns related to sales made by Oscient prior to our acquisition of FACTIVE product rights. In addition, we believe these product return rates will remain at the higher levels due to lower than expected sales volume.

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

Expense recognized for rebates was $4.7 million, $1.4 million and $1.7 million in 2010, 2009 and 2008, respectively, representing approximately 3%, 1% and 2% of gross product sales in 2010, 2009 and 2008, respectively. The increase in rebates as a percentage of gross product sales is primarily due to new legislation, specifically Health Care Reform.

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 estimates 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. 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 $34.5 million, $21.8 million and $8.9 million in 2010, 2009 and 2008, respectively, representing approximately 18%, 15% and 11% of gross product sales in 2010, 2009 and 2008, respectively. The increase in the expense as a percentage of gross product sales during 2010 was primarily due to increased competition for HYOMAX, increase in the number of voucher programs offered, and the addition of CUROSURF to our product portfolio, which caused higher levels of price adjustments and chargebacks. There were no current period adjustments during 2010 related to prior period provisions for price adjustments and chargebacks. We do not expect future changes in our estimates for price adjustments and chargebacks to be material.

Prompt Payment Discounts. We typically require our customers to remit payments within the first 30 or 90 days, depending on the customer and the products purchased. In addition, we offer wholesale distributors a prompt payment discount if they make payments within these deadlines. This discount is generally 2%, but may be higher in some instances due to product launches or customer and/or industry expectations. Because our wholesale distributors typically take the prompt payment discount, we accrue 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of our original sale to them, and we apply earned discounts at the time of payment. We adjust the accrual periodically to reflect actual experience. Historically, these adjustments have not been material. We do not anticipate that future changes to our estimates of prompt payment discounts will have a material impact on our net revenue.

Expense recognized for prompt payment discounts was $3.9 million, $3.1 million and $1.9 million in 2010, 2009 and 2008, 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.

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License and Royalty Agreement Revenues

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

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

Royalty agreement revenues are earned under license agreements which provide for the payment of royalties based on sales of certain licensed products. These revenues are recognized based on product sales that occurred in the relevant period. Royalty agreement revenues were $73,000, $276,000 and $1.7 million during 2010, 2009 and 2008, respectively.

Goodwill and Product Rights

At December 31, 2010, we had $13.2 million in goodwill related to the 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 a single industry and operating segment which acquires, develops and commercializes prescription pharmaceutical drugs used in the treatment of a variety of respiratory-related diseases. Accordingly, our business is classified as a single reportable segment.

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, 2010. 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

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expenses require significant judgment associated with the forecast of the performance of our products. Actual revenues and costs could vary significantly from these forecasted amounts. If actual cash flows are significantly different than our forecasted amounts, we could determine that some or all of our capitalized product rights are impaired. In the event of impairment, we would record an impairment charge, which could have a material adverse effect on our results of operations.

As of December 31, 2010, we had an aggregate of $112.3 million in capitalized product rights, which we expect to amortize over a period of four to ten years. During 2010, there were no triggering events that indicated the need to test for potential impairment.

Inventory

Inventory consists of raw materials, work in process and finished goods. Raw materials include the API for a product to be manufactured, work in process includes the bulk inventory of tablets that are in the process of being coated and/or packaged for sale, and finished goods include pharmaceutical products ready for commercial sale or distribution as samples. Inventory is stated at the lower of cost or market value with cost determined under the first-in, first-out, or FIFO, method. Our estimate of the net realizable value of our inventories is subject to judgment and estimation. The actual net realizable value of our inventories could vary significantly from our estimates and could have a material effect on our financial condition and results of operations in any reporting period. In evaluating whether inventory is stated at the lower of cost or market, we consider such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life and current and expected market conditions, including levels of competition. On a quarterly basis, we analyze our inventory levels and record allowances for inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product revenues. As of December 31, 2010, we had $17.0 million in inventory and an inventory reserve of $1.8 million.

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 the Merger, Cornerstone BioPharma s board of directors determined the underlying fair value of Cornerstone BioPharma s common stock (which was exchanged in the 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.

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The expected stock price volatility for stock option awards granted prior to the 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, 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 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, 2010, there was $2.9 million and $907,000 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 2.69 and 2.61 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 20.7%, 35.2% and 4.4% in 2010, 2009 and 2008, respectively. In 2010, the decrease in the effective tax rate was primarily attributable to the impact of our release of the valuation allowances against our deferred tax assets during 2010 as well as changes in the estimated income tax provision related to the year ended December 31, 2009. Upon release of the valuation allowances, we fully utilized our net operating loss carryforwards that were not subject to limitations, thereby reducing total income tax expense in 2010 and significantly lowering our effective tax rate.

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 determinations, we consider all available positive and negative evidence, including reversals of existing temporary differences, projected future taxable income, tax planning strategies and recent financial operations. A valuation allowance is required to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will

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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, 2010, we had approximately $72 million in deferred tax assets. We determined that a $62.9 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 the technical merits. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized. We had no unrecognized tax benefits at December 31, 2010 and do not expect to have any unrecognized tax benefits during the next twelve months.

Recent Accounting Pronouncements

There were no recent accounting pronouncements that we have not yet adopted that would have a material impact on our consolidated financial statements.

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

Interest Rate Risk

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

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

Foreign Currency Exchange Risk

The majority of our transactions occur in U.S. dollars and we do not have subsidiaries or investments in foreign countries. Therefore, we are not subject to significant foreign currency exchange risk. We currently have two development agreements denominated in foreign currencies, Euros and Swiss francs. Unfavorable fluctuations in these exchange rates could have a negative impact on our consolidated financial statements. The impact of changes in the exchange rates related to these contracts was immaterial to our consolidated financial statements for the years ended December 31, 2010, 2009, and 2008. We do not believe a fluctuation in these exchange rates would have a material impact on us. To date, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. These circumstances may change.

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

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Cornerstone Therapeutics Inc.

We have audited the accompanying consolidated balance sheets of Cornerstone Therapeutics Inc. (a Delaware corporation) as of December 31, 2010 and 2009, and the related consolidated statements of income, stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2010. Our audits of the basic financial statements included the financial statement schedule listed in the index appearing under Item 8. These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Cornerstone Therapeutics Inc. as of December 31, 2010 and 2009, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2010 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ GRANT THORNTON LLP

Raleigh, North Carolina
March 3, 2011

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CORNERSTONE THERAPEUTICS INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2010	2009
Assets		
Current assets:		
Cash and cash equivalents	$ 50,945	$ 18,853
Accounts receivable, net	76,476	16,548
Inventories, net	15,174	18,106
Prepaid and other current assets	5,111	4,808
Income tax receivable	197	
Deferred income tax asset	6,599	3,507
Total current assets	154,502	61,822
Property and equipment, net	1,486	1,312
Product rights, net	112,328	126,806
Goodwill	13,231	13,231
Amounts due from related parties	38	38
Long-term accounts receivable and other assets	8,553	113
Total assets	$ 290,138	$ 203,322
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 7,671	$ 7,172
Accrued expenses	46,599	23,703
Current portion of license agreement liability	1,368	1,019
Current portion of capital lease	83	10
Current portion of deferred revenue	37,616	
Income taxes payable		1,606
Total current liabilities	93,337	33,510
License agreement liability, less current portion		1,341
Capital lease, less current portion	146	39
Deferred revenue, less current portion	19,578	
Deferred income tax liability	4,679	4,564
Total liabilities	117,740	39,454
Commitments and contingencies, Note 9		
Stockholders equity		
Preferred stock $0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding		

Common stock $0.001 par value, 90,000,000 shares authorized; 25,472,963 and 25,022,644 shares issued and outstanding as of December 31, 2010 and December 31, 2009, respectively	25	25
Additional paid-in capital	160,106	157,745
Retained earnings	12,267	6,098
Total stockholders equity	172,398	163,868
Total liabilities and stockholders equity	$ 290,138	$ 203,322

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,		
	2010	**2009**	**2008**
Net revenues	$ 125,317	$ 109,564	$ 64,867
Costs and expenses:			
Cost of product sales (exclusive of amortization of product rights)	32,313	19,457	5,951
Selling, general and administrative	53,198	45,731	27,082
Royalties	12,702	18,775	16,193
Research and development	4,488	3,608	3,679
Amortization of product rights	14,728	6,115	1,334
Total costs and expenses	117,429	93,686	54,239
Income from operations	7,888	15,878	10,628
Other expenses, net:			
Interest expense, net	(85)	(128)	(1,211)
Loss on marketable security			(8)
Other expenses	(25)		(2)
Total other expenses, net	(110)	(128)	(1,221)
Income before income taxes	7,778	15,750	9,407
Provision for income taxes	(1,609)	(5,547)	(414)
Net income	$ 6,169	$ 10,203	$ 8,993
Net income per share, basic	$ 0.24	$ 0.58	$ 1.29
Net income per share, diluted	$ 0.24	$ 0.54	$ 1.14
Weighted-average common shares, basic	&nbs		