CORNERSTONE THERAPEUTICS INC
Form 10-K
March 26, 2009

Table of Contents

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

Form 10-K

ANNUAL REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2008

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

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

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

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

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant as of June 30, 2008 was approximately $12,823,867 based on a price per share of $3.70, the last reported sale price of the registrant s common stock on the NASDAQ Stock Market on that date (as adjusted for the 10-to-1 reverse split of the registrant s common stock effected on October 31, 2008).

As of March 20, 2009, the registrant had 12,499,102 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant s proxy statement for the registrant s 2009 annual meeting of stockholders currently expected to be held on May 28, 2009, 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, 2008, are incorporated by reference into

Part III of this report.

CORNERSTONE THERAPEUTICS INC.

ANNUAL REPORT
ON FORM 10-K

INDEX

Table of Contents

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, financial position, future revenues and projected costs; our management s prospects, plans and objectives; and any other statements about management s future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use words such as anticipate, believe, could, estimate, expect, intend, may, plan, project, should, target, will, 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 and risks relating to our ability to realize anticipated synergies and cost savings from our merger with Cornerstone BioPharma Holdings, Inc., or Cornerstone BioPharma; our ability to develop and maintain the necessary sales, marketing, supply chain, distribution and manufacturing capabilities to commercialize our products, including difficulties relating to the manufacture of ZYFLO CR® tablets; the possibility that the Food and Drug Administration, or FDA, will take enforcement action against us or one or more of our marketed drugs which do not have FDA-approved marketing applications; patient, physician and third-party payor acceptance of our products as safe and effective therapeutic products; our heavy dependence on the commercial success of a relatively small number of currently marketed products; our ability to obtain and maintain regulatory approvals to market and sell our products; our ability to enter into additional strategic licensing, collaboration or co-promotion transactions on favorable terms, if at all; our ability to maintain compliance with NASDAQ listing requirements; adverse side effects experienced by patients taking our products; difficulties relating to clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the results of preclinical studies and clinical trials with respect to our products under development and whether such results will be indicative of results obtained in later clinical trials; our ability to satisfy FDA and other regulatory requirements; and our ability to obtain, maintain and enforce patent and other intellectual property protection for our products and product candidates. 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. 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 future acquisitions, mergers, dispositions, joint ventures or investments we may make.

ITEM 1. *BUSINESS*

Background

Cornerstone Therapeutics Inc. is a specialty pharmaceutical company focused on acquiring, developing and commercializing prescription products for the respiratory market. We were incorporated in Delaware on July 14, 2000 as Medicept, Inc. and changed our name to Critical Therapeutics, Inc., or Critical Therapeutics, in March 2001. We completed an initial public offering of our common stock in June 2004, and our common stock is currently traded on the NASDAQ Capital Market. On October 31, 2008, we completed our merger with Cornerstone BioPharma. Following the closing of the merger, former Cornerstone BioPharma

Table of Contents

stockholders owned approximately 70%, and former Critical Therapeutics stockholders owned approximately 30%, of our common stock, after giving effect to shares issuable pursuant to outstanding options and warrants held by Cornerstone BioPharma s stockholders immediately prior to the effective time of the merger, but without giving effect to any shares issuable pursuant to options and warrants held by Critical Therapeutics stockholders immediately prior to the effective time of the merger. In connection with the completion of the merger, on October 31, 2008, we changed our name to Cornerstone Therapeutics Inc.

Because former Cornerstone BioPharma stockholders owned, immediately following the merger, approximately 70% of the combined company on a fully diluted basis and as a result of certain other factors, Cornerstone BioPharma was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition in accordance with accounting principles generally accepted in the United States, 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 and ZYFLO®, the immediate-release formulation of zileuton) prior to the completion of the merger.

Overview

Our goal is to become a leading specialty pharmaceutical company that acquires, develops and commercializes significant products primarily for the respiratory market. Key elements of our strategy to achieve this goal include the following:

In-license or acquire rights to under-promoted, patent-protected, branded respiratory pharmaceutical products, or late stage product candidates;

Implement life cycle management strategies to maximize the potential value and competitive position of our currently marketed products, newly acquired products and product candidates that are currently in development;

Grow product revenue through our specialty sales force which is focused on the respiratory market; and

Maintain and strengthen the intellectual property position of our currently marketed products, newly acquired products and our product candidates.

Table of Contents

We currently market nine product lines in the United States. The table below provides information on the products that we actively promote.

Promoted Product Lines	Active Pharmaceutical Ingredient(s)	Primary Indication
SPECTRACEF 200 mg	Cefditoren	Treatment of mild to moderate infections that are caused by susceptible strains of microorganisms in community-acquired pneumonia, acute bacterial exacerbation of chronic bronchitis, pharyngitis and tonsillitis and uncomplicated skin and skin-structure infections
SPECTRACEF 400 mg	Cefditoren	Treatment of acute bacterial exacerbation of chronic bronchitis; community-acquired pneumonia
ZYFLO CR	Zileuton	Prevention and chronic treatment of asthma in adults and children 12 years of age or older
ALLERX 10 Dose Pack/ ALLERX 30 Dose Pack	AM dose: Pseudoephedrine and methscopolamine PM dose: Phenylephrine, chlorpheniramine and methscopolamine	Temporary relief of symptoms associated with allergic rhinitis
ALLERX Dose Pack DF	AM dose: Chlorpheniramine and methscopolamine PM dose: Chlorpheniramine and methscopolamine	Temporary relief of symptoms associated with allergic rhinitis
ALLERX Dose Pack PE	AM dose: Phenylephrine and methscopolamine PM dose: Phenylephrine, chlorpheniramine and methscopolamine	Temporary relief of symptoms associated with allergic rhinitis

We also generate revenue from the sale of marketed products that we do not promote. BALACET® 325 and propoxyphene napsylate 100 mg and acetaminophen 325 mg, or APAP 325, are promoted by a third party. We have four product lines that include generic products that we market through Aristos Pharmaceuticals, Inc., or Aristos, one of our wholly owned subsidiaries. We formed Aristos to launch authorized generic versions of our products that become subject to generic competition and to acquire or in-license generic versions of products with little or no generic competition that our management believes offer attractive returns on investment, regardless of whether such products are used to treat respiratory ailments.

Our product development pipeline includes two SPECTRACEF® line extensions: a once daily dosage tablet, or SPECTRACEF Once Daily, and an oral suspension for the pediatric market, or SPECTRACEF Suspension. Our product development pipeline also includes the following three additional product candidates: an anticholinergic, or drying agent, and antihistamine combination product candidate for the treatment of symptoms of allergic rhinitis and two antitussive, or cough suppressant, and antihistamine combination product candidates. We have initiated a process to seek potential collaborators for the future clinical development and commercialization of Critical Therapeutics

historical projects for the alpha-7 nicotinic acetylcholine receptor, or alpha-7 receptor, zileuton injection and R(+) isomer of zileuton.

Our Promoted Products

We promote our SPECTRACEF product line, ZYFLO CR and our ALLERX® Dose Pack family of products, or ALLERX Dose Pack products, through our own direct sales force because we believe these products are most responsive to promotional efforts. Our SPECTRACEF product line currently includes SPECTRACEF 200 mg and SPECTRACEF 400 mg, which are oral antibiotics indicated for the treatment of

Table of Contents

mild to moderate infections caused by pathogens associated with particular respiratory tract infections. For convenience, we sometimes refer to SPECTRACEF 200 mg and 400 mg collectively as the SPECTRACEF products. ZYFLO CR is a leukotriene synthesis inhibitor that is indicated for the prevention and chronic treatment of asthma in adults and children 12 years of age and older. Our ALLERX Dose Pack products include our three products, which are oral tablets indicated for the temporary relief of symptoms associated with allergic rhinitis.

SPECTRACEF

Overview. SPECTRACEF, an antibiotic administered orally in tablet form, is a third generation cephalosporin with the active pharmaceutical ingredient, or API, cefditoren pivoxil, a semi-synthetic cephalosporin. SPECTRACEF is currently available in 200 mg and 400 mg strengths. SPECTRACEF 400 mg is a single 400 mg tablet, twice-daily dosage of SPECTRACEF, which is indicated for the treatment of mild to moderate infections in adults and adolescents 12 years of age or older that are caused by pathogens associated with particular respiratory tract infections, including community-acquired pneumonia and acute bacterial exacerbation of chronic bronchitis. We received approval for SPECTRACEF 400 mg in July 2008 and launched it in October 2008. We believe that patients will find taking one 400 mg tablet twice daily to be more convenient than taking two SPECTRACEF 200 mg tablets twice daily. 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. Our net sales of SPECTRACEF were $7.0 million in 2008 and $6.9 million in 2007.

Market Opportunity and Other Treatment Options. The U.S. oral antibiotic market is fairly fragmented, with approximately 40 branded products and more than 40 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 2008, the U.S. oral solid antibiotic market generated approximately 224 million prescriptions, including approximately 46 million for extended spectrum macrolides, such as generic formulations of Pfizer Inc. s Zithromax® (azithromycin) and Abbott Laboratories , or Abbott, Biaxin® (clarithromycin); approximately 39 million for quinolones, such as Ortho-McNeil-Janssen Pharmaceuticals, Inc. s Levaquin® (levofloxacin) and generic formulations of Bayer Schering AG s Cipro® (ciprofloxacin); and approximately 7.7 million for second and third generation cephalosporins, such as SPECTRACEF, Shionogi USA, Inc. s Cedax® (ceftibuten), Lupin Pharmaceuticals, Inc. s, or Lupin Pharmaceuticals, Suprax® and generic formulations of Abbott s Omnicef® (cefdinir) and GlaxoSmithKline plc s, or GSK, Ceftin® (cefuroxime). The only branded second or third generation oral solid cephalosporin products currently without generic competition in the United States are SPECTRACEF, Cedax and Suprax.

Macrolides generally are broad spectrum, have a low incidence of side effects and have convenient dosing regimens. However, macrolides can be associated with severe allergic reactions and interactions with many other commonly prescribed drugs that can affect potency. Quinolones generally are considered safe and efficacious overall and have convenient dosing regimens. Quinolones, however, have multiple interactions with commonly prescribed drugs, cannot be used in children and have been associated with tendon rupture and photosensitivity adverse reactions. Cephalosporins, including SPECTRACEF, generally cause few side effects. Common side effects are gastrointestinal in nature and are mild and transient.

We believe that SPECTRACEF currently is the only branded second or third generation oral solid cephalosporin product being actively promoted to health care providers in the adult respiratory market, although Suprax is being promoted within the pediatric market by Lupin Pharmaceuticals specialty sales force, and Suprax is being promoted by Ascend Therapeutics, Inc. s specialty sales force to obstetricians and gynecologists pursuant to a co-promotion agreement with Lupin Pharmaceuticals.

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

Table of Contents

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 both an issued U.S. patent with claims to the composition of matter of the API in SPECTRACEF, cefditoren pivoxil, and 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 expires in April 2009 and the formulation patent expires in 2016. We have also licensed from Meiji the U.S. trademark rights to SPECTRACEF.

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 because of its twice-daily, two tablets per dose dosing regimen, as compared to ZYFLO s four-times daily dosing regimen, which we believe may increase patient drug compliance.

Our net sales of ZYFLO CR in 2008 and 2007 were $13.9 million and $2.3 million, respectively; our net sales of ZYFLO in 2008 and 2007 were $1.1 million and $8.7 million, respectively. Of the net sales of ZYFLO CR and ZYFLO in 2008, only $888,000, which is the net sales of these products after the closing of our merger on October 31, 2008, is included in net revenues in our financial statements because net revenues from these products prior to the closing of the merger were earned by Critical Therapeutics, not Cornerstone BioPharma.

Market Opportunity and Other Treatment Options. 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 the first half of 2008 in the United States approximately 7.6% of the population, or approximately 23 million people, had asthma and approximately 3.9% of the people, or 12 million people, had asthma attacks.

There is no one ideal treatment for asthma, and there is no cure. Currently, patients are treated with a combination of products that are designed primarily to manage their disease symptoms by opening the airways in the lungs and reducing inflammation. Typical treatments include bronchodilatory drugs, such as Teva Specialty Pharmaceuticals LLC s ProAir® HFA (albuterol sulfate) Inhalation Aerosol and Schering-Plough Corporation s Proventil® HFA (albuterol sulfate) Inhalation Aerosol; leukotriene receptor antagonists, or LTRAs, such as Merck & Co., Inc. s Singulair® (montelukast sodium); inhaled corticosteroids, such as GSK s Flovent®; and combination products, such as GSK s Advair Diskus® (fluticasone propionate and salmetorol inhalation powder), which is a combination of an inhaled corticosteroid and a long-acting bronchodilator, and AstraZeneca PLC s Symbicort®, a twice-daily asthma therapy combining budesonide, an inhaled corticosteroid, and formoterol, a long-acting beta2-agonist.

In June 2007, the National Heart, Lung, and Blood Institute, released an updated version of the Guidelines for the Diagnosis and Management of Asthma. In these guidelines, zileuton is specifically mentioned in steps three and four in the treatment protocol as an alternative option in the treatment of asthma. This is the first time zileuton has been mentioned in these guidelines, and we believe this may provide additional scientific credibility to ZYFLO CR in the marketplace.

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

Table of Contents

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.

Our post hoc analysis of the data suggested there was a greater airway response benefit in asthma patients with less than 50% of expected airway function, and a six-fold decrease in the need for steroid rescue medication in these patients compared to placebo. In these placebo-controlled clinical trials, 1.9% of patients taking ZYFLO experienced an increase in a liver enzyme called alanine transaminase, or ALT, greater than three times the level normally seen in the bloodstream compared to 0.2% of patients receiving placebo. These enzyme levels resolved or returned towards normal in approximately 50% of the patients who continued therapy and all of the patients who discontinued the therapy.

In addition, prior to FDA approval, a long-term, safety surveillance trial was conducted in 2,947 patients. In this safety trial, 4.6% of patients taking ZYFLO experienced ALT levels greater than three times the level normally seen in the bloodstream compared to 1.1% of patients receiving placebo, with 61.0% of the patients experiencing such elevated ALT levels in the first two months of dosing. After two months of treatment, the rate of ALT levels greater than three times the level normally seen in the bloodstream stabilized at an average of 0.3% per month for patients taking a combination of ZYFLO and their usual asthma medications compared to 0.11% per month for patients taking a combination of placebo and their usual asthma medications. This trial also demonstrated that ALT levels returned to below two times the level normally seen in the bloodstream in both the patients who continued and those who discontinued the therapy. In these trials, one patient developed symptomatic hepatitis with jaundice, which resolved upon discontinuation of therapy, and three patients developed mild elevations in bilirubin.

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

- In a three-month pivotal efficacy trial, in which 397 patients received either ZYFLO CR or placebo, patients taking ZYFLO CR demonstrated statistically significant improvements over placebo in objective measures of asthma control. In the trial, patients taking ZYFLO CR showed a reduced need for bronchodilatory drugs as a rescue medication to alleviate uncontrolled symptoms. In this trial, 2.5% of the patients taking ZYFLO CR experienced ALT levels greater than or equal to three times the level normally seen in the bloodstream, compared to 0.5% of the patients taking placebo.
- In a six-month safety trial, in which 706 patients received either a combination of ZYFLO CR and their usual asthma medications or a combination of placebo and their usual asthma medications, 1.78% of the patients taking ZYFLO CR and their usual asthma medications experienced ALT levels greater than or equal to three times the level normally seen in the bloodstream, compared to 0.65% of the patients taking placebo and their usual asthma medications.

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

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

Table of Contents

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

ALLERX DOSE PACKS

Overview. Our ALLERX Dose Pack products are oral tablets indicated for the temporary relief of symptoms associated with allergic rhinitis. Each ALLERX Dose Pack product contains the antihistamine chlorpheniramine, a choice of decongestant, including an option without a decongestant, and methscopolamine, an anticholinergic, which provides additional symptomatic relief by drying up the mucosal secretions associated with allergic rhinitis. Our net sales of ALLERX Dose Pack products were $26.4 million in 2008 and $13.5 million in 2007.

We market our ALLERX Dose Pack products without their having an FDA-approved marketing application. These products are subject to the risk that the FDA will take enforcement action which would preclude our marketing them until the FDA has approved NDAs or ANDAs for them. For a more complete discussion regarding FDA drug approval requirements, please see Item 1. Business Regulatory Matters in this annual report on Form 10-K and Item 1A. Risk Factors Some of our specialty pharmaceutical products are now being marketed without approved NDAs or ANDAs in this annual report on Form 10-K.

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

According to the Centers for Disease Control and Prevention, allergic rhinitis is believed to be responsible for approximately 14.1 million physician visits annually. According to a January 2006 Allergies in America survey, approximately 69% of patients with allergic rhinitis had taken medication for their nasal allergies in the prior four weeks, including 45% who took prescription medication. The survey also reported that 40% of patients surveyed indicated that nasal allergies had a lot or a moderate amount of impact on their daily life, compared with only 33% of patients who indicated that nasal allergies had little or no impact on their daily life.

First generation prescription antihistamine and antihistamine combination products include Capellon Pharmaceuticals, Ltd. s, or Capellon, Rescon® (phenylephrine, chlorpheniramine and methscopolamine) and Laser Pharmaceuticals, LLC s Dallergy® (phenylephrine, chlorpheniramine and methscopolamine). Over-the-counter products include well known brands such as McNeil-PPC, Inc. s Benadryl® (diphenhydramine) and Schering-Plough Corporation s Chlor-Trimeton® (chlorpheniramine). According to Wolters Kluwer Health, in 2008, oral solid first generation antihistamine and antihistamine combination products generated approximately six million prescriptions.

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

We currently market the following ALLERX Dose Pack products.

ALLERX 10 Dose Pack/ALLERX 30 Dose Pack. These ALLERX Dose Pack products are available in 10-day and 30-day regimens and consist of a morning, or AM, dose and an evening, or PM, dose. The AM dose contains 120 mg of the decongestant pseudophedrine, which also helps patients stay alert during the day, and 2.5 mg of the anticholinergic methscopolamine. The PM dose contains 10 mg of the decongestant phenylephrine, 8 mg of the antihistamine chlorpheniramine, which helps patients sleep better at night by relieving their symptoms and making them drowsy, and 2.5 mg of methscopolamine.

ALLERX Dose Pack DF/ALLERX Dose Pack DF 30. ALLERX Dose Pack DF is a decongestant-free dosing regimen suitable for patients who cannot tolerate a decongestant but need the antihistamine and anticholinergic to relieve their allergic rhinitis symptoms other than congestion. ALLERX Dose Pack DF is available in 10-day and 30-day regimens and consists of an AM dose and a PM dose. The AM dose contains

Table of Contents

4 mg of the antihistamine chlorpheniramine and 2.5 mg of the anticholinergic methscopolamine. The PM dose contains 8 mg of chlorpheniramine and 2.5 mg of methscopolamine.

ALLERX Dose Pack PE/ALLERX Dose Pack PE 30. ALLERX Dose Pack PE substitutes the decongestant phenylephrine for pseudoephedrine in the AM dose. ALLERX Dose Pack PE is available in 10-day and 30-day regimens and consists of an AM dose and a PM dose. The AM dose contains 40 mg of phenylephrine and 2.5 mg of the anticholinergic methscopolamine. The PM dose contains 10 mg of phenylephrine, 8 mg of the antihistamine chlorpheniramine and 2.5 mg of methscopolamine.

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

In addition, we have applied for U.S. patents that, if issued, would include claims to ALLERX Dose Pack DF s and ALLERX Dose Pack DF 30 s AM and PM dosing regimen and method of treating a rhinitic condition using an antihistamine and an anticholinergic in both doses. This patent application has been published and is currently pending. If issued, these patents would expire in 2026.

Other Products

Our current, more important marketed products that we do not promote are described below.

HYOMAX

Overview. The HYOMAX® line of products consists of generic formulations of four antispasmodic medications containing the API hyoscyamine sulfate, an anticholinergic, which may be prescribed for functional intestinal disorders to reduce symptoms such as those seen in mild dysenteries and diverticulitis. The HYOMAX line of products can also be used to control gastric secretion, visceral spasm and hypermotility in cystitis, pylorospasm and associated abdominal cramps. Along with appropriate analgesics, HYOMAX products may be prescribed for symptomatic relief of biliary and renal colic and as a anticholinergic in the relief of symptoms of acute rhinitis. HYOMAX products may also be used as adjunctive therapy in the treatment of peptic ulcer and irritable bowel syndrome, or IBS; acute enterocolitis; and other functional gastrointestinal disorders. We launched our first HYOMAX product, HYOMAX SL 0.125 mg tablets, in May 2008, followed by HYOMAX SR 0.375 mg tablets and HYOMAX FT 0.125 mg chewable melt tablets in June 2008 and HYOMAX DT 0.125 mg immediate release/0.25 mg sustained release tablets in July 2008. Our net sales of HYOMAX products in 2008 were $23.0 million. We market our HYOMAX products without their having an FDA-approved marketing application. These products are subject to the risk that the FDA will take enforcement action which would preclude our marketing them until the FDA has approved NDAs or ANDAs for them. For a more complete discussion regarding FDA drug approval requirements, please see Item 1. Business Regulatory Matters in this annual report on Form 10-K and Item 1A. Risk Factors Some of our specialty pharmaceutical products are now being marketed without approved NDAs or ANDAs in this annual report on Form 10-K. Our HYOMAX line of products is marketed through our Aristos subsidiary.

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

Table of Contents

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

The U.S. antispasmodic market is fairly fragmented with approximately 25 branded products and 20 generic products. According to Wolters Kluwer Health, in 2008, in the United States the antispasmodic market generated approximately 25 million prescriptions, including approximately 16.2 million for urinary incontinence antispasmodics, such as Pfizer Inc. s Detrol® LA (tolterodine tartrate), Astellas Pharmaceuticals, Inc. and GSK s VESIcare® (solifenacin) and the generic formulations of Ortho-McNeil-Janssen Pharmaceuticals, Inc. s Ditropan® and Ditropan XL® (oxybutynin); approximately four million for synthetic gastrointestinal antispasmodics, such as the generic formulations of Axcan Pharma Inc. s Bentyl® (dicyclomine) and Bradley Pharmaceuticals, Inc. s Pamine® (methscopolamine bromide); and approximately 3.7 million for belladonna and derivatives gastrointestinal antispasmodics, such as the HYOMAX products, and generic formulations of Alaven Pharmaceutical LLC s Levsin® (hyoscyamine sulfate) and Levbid® (hyoscyamine sulfate) products and of PBM Pharmaceuticals, Inc. s Donnatal® (belladonna alkaloids/phenobarbital). All brands in the belladonna and derivatives gastrointestinal antispasmodics market have a generic formulation.

Benefits of HYOMAX. Once absorbed, hyoscyamine sulfate, the API in the HYOMAX products, disappears rapidly from the blood and is distributed throughout the entire body. The majority of hyoscyamine sulfate is excreted in the urine unchanged within the first 12 hours and only traces of hyoscyamine sulfate are found in the breast milk of nursing mothers. The HYOMAX line of products offers patients a cost-effective treatment option for a variety of gastrointestinal problems, such as IBS and urinary incontinence and may be preferred by physicians concerned about the potential serious side effects associated with newer products such as Novartis AG s Zelnorm® (tegaserod maleate) product, which Novartis voluntarily withdrew from the market in 2007.

Proprietary Rights. We have an exclusive license from Sovereign Pharmaceuticals, Ltd., or Sovereign, to market and distribute three hyoscyamine sulfate products in the United States through April 2011. We market and distribute HYOMAX DT tablets in the United States pursuant to a verbal agreement between Capellon, a wholly owned subsidiary of Sovereign, and us.

PROPOXYPHENE/ACETAMINOPHEN PRODUCTS

Our propoxyphene/acetaminophen products include BALACET 325, APAP 325 and APAP 500. We acquired the rights to each of these products from Vintage Pharmaceuticals, LLC, or Vintage.

BALACET 325. BALACET 325 is indicated for the relief of mild to moderate pain, either when pain is present alone or when it is accompanied by a fever. BALACET 325 contains 100 mg of propoxyphene napsylate and 325 mg of acetaminophen. We licensed rights to the formulation of BALACET 325 from Vintage in 2004. BALACET 325 is currently promoted by Atley Pharmaceuticals, Inc., or Atley Pharmaceuticals, under a co-promotion agreement with us.

APAP 325. APAP 325 is a generic formulation of BALACET 325 and is indicated for the relief of mild to moderate pain. Each tablet contains 100 mg of propoxyphene napsylate and 325 mg of acetaminophen. Atley Pharmaceuticals currently promotes APAP 325 under a co-promotion agreement with us.

APAP 500. APAP 500 is a generic formulation of Xanodyne Pharmaceuticals, Inc. s Darvocet A500® and indicated for the relief of mild to moderate pain. Each tablet contains 100 mg of propoxyphene napsylate and 500 mg of acetaminophen.

The most commonly reported side effects with our propoxyphene/acetaminophen products are dizziness, sedation, nausea, and vomiting. Additionally, concerns have been raised regarding the potential toxicity and addictiveness of propoxyphene and the known liver toxicity of acetaminophen. These concerns are more fully

Table of Contents

discussed in Item 1A. Risk Factors Concerns regarding the potential toxicity and addictiveness of propoxyphene and the known liver toxicity of acetaminophen may limit market acceptance of our propoxyphene/acetaminophen line of products or cause the FDA to remove these products from the market. in this annual report on Form 10-K.

Product Development Pipeline

Our product development pipeline consists of two SPECTRACEF line extensions and a portfolio of additional product candidates based on marketed drug compounds. The following table sets forth additional information regarding our product candidates:

Product Candidate	Regulatory Status	Therapeutic Class	Method of Administration	Primary Indication(s)
Spectracef Line Extensions				
SPECTRACEF Once Daily	sNDA submission targeted in 2011	Antibiotic	Oral tablet Once-daily Dosing	Acute bacterial exacerbations of chronic bronchitis with COPD
SPECTRACEF Suspension	NDA submission targeted in 2011	Antibiotic	Oral suspension	Pharyngitis and tonsillitis; acute otitis media
Other Product Candidates				
CRTX 058	NDA submission targeted in 2011	Anticholinergic and antihistamine combination	Oral tablet	Temporary relief of symptoms associated with allergic rhinitis
CRTX 067	Regulatory submission targeted in 2009	Antitussive and antihistamine combination	Oral suspension	Temporary relief of symptoms associated with cough and upper respiratory symptoms associated with allergies or a cold
CRTX 069	Regulatory submission targeted in 2009	Antitussive and antihistamine combination	Oral suspension	Temporary relief of symptoms associated with cough and upper respiratory symptoms associated with allergies or a cold

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

SPECTRACEF Line Extensions

Overview. SPECTRACEF is an integral part of our current sales strategy, as well as our sales growth strategy for the future. To protect and expand SPECTRACEF s market share, we developed SPECTRACEF 400 mg, a higher dose tablet for the adult market, and are developing SPECTRACEF Once Daily, a new oral solid dosage form, and SPECTRACEF Suspension, an oral suspension for the pediatric market.

SPECTRACEF Once Daily. SPECTRACEF Once Daily is a single tablet, once-daily dosage of SPECTRACEF. We filed an investigational NDA, or IND, with the FDA in July 2008 for SPECTRACEF Once Daily, which has since been cleared by the FDA, and commenced a clinical trial in the fourth quarter of 2008

Table of Contents

to evaluate the pharmacokinetic profile of a formulation of SPECTRACEF Once Daily developed by MOVA Pharmaceutical Corporation. If the results of this pharmacokinetic trial are favorable, we expect to commence two clinical trials in the fourth quarter of 2009 to evaluate the safety and efficacy of this product candidate designed to form the basis for a supplemental NDA, or sNDA, submission to the FDA in 2011 for the treatment of acute bacterial exacerbations of chronic bronchitis with COPD. We anticipate that, if approved based on the results of these clinical trials, the FDA will grant SPECTRACEF Once Daily a three-year period of marketing exclusivity under the Hatch-Waxman Act.

We believe that the once-daily dosage of this product candidate would be more convenient for patients than taking SPECTRACEF twice daily and would increase compliance. Among oral solid cephalosporins, only Cedax and Suprax have a once-daily dosage. Most macrolides and quinolones also have a once-daily dosage option.

SPECTRACEF Suspension. SPECTRACEF Suspension is an oral, liquid suspension of SPECTRACEF. We expect to commence clinical trials in 2010 for use of this product candidate by children with acute otitis media. A number of clinical trials for use of this product candidate by children with pharyngitis or tonsillitis were previously conducted. Two of these clinical trials compared the safety and efficacy of orally administered cefditoren pivoxil with an FDA-approved product, penicillin VK, using a non-inferiority design. In each of these trials, cefditoren pivoxil was well tolerated with no significant adverse events reported. In the first trial, both treatment regimens were effective in resolving the clinical signs and symptoms of streptococcal pharyngitis or tonsillitis, but cefditoren pivoxil was statistically superior to penicillin VK in eradicating *Streptococcus pyogenes*. In the second trial, cefditoren pivoxil was equivalent to penicillin VK in resolving the clinical signs and symptoms of streptococcal pharyngitis or tonsillitis and in eradicating *Streptococcus pyogenes*. We expect to submit an NDA in 2011 for use of this product candidate by children with pharyngitis, tonsillitis or acute otitis media. We anticipate that, if approved based on the results of these clinical trials, the FDA will grant SPECTRACEF Suspension a three-year period of marketing exclusivity under the Hatch-Waxman Act for acute otitis media.

According to Wolters Kluwer Health, second and third generation oral cephalosporin suspensions generated approximately 7.4 million prescriptions in 2008 and approximately $702 million in sales, including suspension products containing cefdinir that generated approximately 5.4 million prescriptions and approximately $521 million in sales.

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

Other Product Candidates

Anticholinergic and Antihistamine Combination Product Candidate CRTX 058

Overview and Development Status. CRTX 058 is an anticholinergic and antihistamine combination product candidate that we are developing for the treatment of symptoms of allergic rhinitis. We plan to file an IND and to commence a clinical trial for CRTX 058 in 2009 and submit an NDA in 2011. If approved, we believe this anticholinergic therapy would be the first of its kind with an indication for the treatment of symptoms of allergic rhinitis.

Market Opportunity and Current Treatment Options. 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

Table of Contents

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 1.5 million prescriptions in 2008, representing a growth rate of three percent compared to 2007. In addition, second and third generation antihistamine and antihistamine combination products generated a total of approximately 37 million prescriptions in 2008.

Current treatments for the symptoms of rhinitis, including allergic rhinitis, consist of both prescription and over-the-counter products. Prescription products include large second generation antihistamine branded families of products, such as Sanofi-Aventis U.S. LLC s Allegra® (fexofenadine); third generation antihistamine branded families of products, such as UCB, Inc. and Sanofi-Aventis U.S. LLC s Xyzal® (levocetirizine) and Schering-Plough Corporation s Clarinex® (desloratadine); and first generation antihistamine and antihistamine combination products, most of which are generic formulations. Over-the-counter products include first generation antihistamines, such as Benadryl and Chlor-Trimeton, and second generation antihistamines, such as Schering-Plough Corporation s Claritin® (loratadine) and McNeil-PPC, Inc. s Zyrtec® (cetirizine).

Benefits of CRTX 058. If approved, CRTX 058 will provide drying through the anticholinergic, as well as an antihistamine to provide further relief of symptoms of allergic rhinitis, such as itchy or watery eyes and sneezing.

We anticipate that, if approved based on the results of clinical trials that we plan to conduct, the FDA will grant CRTX 058 a three-year period of marketing exclusivity under the Hatch-Waxman Act. In addition, we believe that the FDA would require other products containing this anticholinergic ingredient and which do not have FDA approval to be removed from the market after a grace period. In such event, we believe that CRTX 058 would be the only approved anticholinergic product containing this ingredient for the treatment of symptoms of allergic rhinitis on the market.

Proprietary Rights. We have licensed from Neos Therapeutics, L.P., or Neos, the rights to market CRTX 058 utilizing Neos s Dynamic Variable Release® technology. Dynamic Variable Release technology is covered under a pending U.S. patent application that if issued would expire in 2024. This licensed technology allows us to formulate CRTX 058 with one or more APIs that require immediate activation followed by extended release of the remaining APIs.

Antitussive and Antihistamine Combination Product Candidates CRTX 067 and CRTX 069

Overview and Development Status. CRTX 067 and CRTX 069 are antitussive and antihistamine combination product candidates currently in development. We expect that both of these product candidates will require only pharmacokinetic studies for approval. We are targeting submission of applications for marketing approval for these product candidates in 2009 and, if approved, commercial launch of the product candidates in late 2010 or early 2011. If approved, these product candidates will compete directly in the narcotic antitussive market.

Market Opportunity and Current Treatment Options. Cough can adversely affect quality of life, leading patients to seek medical attention. Health care providers have a variety of treatment options. Non-productive cough is commonly treated with antitussive and antitussive combinations that do not contain an expectorant, such as guaifenesin. Antitussive combination products that treat non-productive coughs typically combine an antitussive, including codeine, dextromethorphan or hydrocodone, with antihistamines, including brompheniramine or chlorpheniramine, or decongestants, including pseudoephedrine or phenylephrine. Dextromethorphan, a non-narcotic antitussive is available in both over-the-counter and prescription formulations. Codeine and hydrocodone are narcotic antitussives and are only sold in prescription formulations.

Table of Contents

According to Wolters Kluwer Health, in 2008, there were over 30 million prescriptions generated for oral antitussive and antitussive combinations. Nearly 10 million of these prescriptions were for products that only contained a narcotic antitussive and an antihistamine.

Benefits of CRTX 067 and CRTX 069. Most antitussive and antitussive combination products that are currently marketed are in an immediate-release formulation, meaning they must be dosed every four to six hours, which can be inconvenient. For example, patients may not be able to sleep through the night because their antitussive is not effective for more than four hours. We believe that CRTX 067 and CRTX 069 could improve patients quality of life by providing more convenient twice-daily, longer lasting dosing.

Proprietary Rights. We have licensed the rights to market CRTX 067 and CRTX 069 utilizing Neos s Dynamic Variable Release technology and Dynamic Time Release Suspension® technology and Coating Place, Inc. s, or Coating Place, drug resin complex technology. We expect that these licensed technologies will allow us to formulate CRTX 067 and CRTX 069 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 Dynamic Variable Release technology is covered under a pending U.S. patent application that if issued would expire in 2024. Neos s Dynamic Time Release Suspension technology is covered under a pending U.S. patent application that if issued would expire in 2025. Coating Place s drug resin complex technology is covered under a pending U.S. patent application that if issued would expire in 2025.

Other Technology Assets

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

- the development of a small molecule product candidate targeting the alpha-7 receptor;
- the development of an injectable form of zileuton initially for use in emergency room or urgent care centers for patients who suffer acute exacerbations of asthma;
- the examination of the pharmacokinetic and pharmacodynamic profile of the R(+) isomer of zileuton to determine if there are potential dosing improvements for patients from this isomer; and
- the development, in collaboration with MedImmune, Inc., or MedImmune, a subsidiary of AstraZeneca PLC, of monoclonal antibodies directed toward a cytokine called HMGB1, which we believe may be an important target for the development of products to treat diseases mediated by the body s inflammatory response.

Alpha-7 Program

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

Stimulation of the vagus nerve, a nerve that links the brain with the major organs of the body, causes the release of a chemical neurotransmitter called acetylcholine. Acetylcholine has been shown to inhibit the release of cytokines that

play a fundamental role in the inflammatory response, including TNF alpha. Research indicates that acetylcholine exerts anti-inflammatory activity by stimulating alpha-7 receptor on cells involved in the inflammatory process. We believe the discovery of the role of this receptor in inflammation has led to a new opportunity for the development of products to treat diseases in which inflammation plays a role. Our alpha-7 program has been directed towards the development of a small molecule product candidate that inhibits the inflammatory response by stimulating the alpha-7 receptor on human inflammatory cells.

Table of Contents

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

Zileuton Injection

We believe zileuton injection is a promising adjunctive treatment for use in emergency room and urgent care centers for patients who suffer acute exacerbations of asthma. We believe acute exacerbations of asthma are a significant unmet medical need that occur in asthma patients who are poorly controlled on their existing medications. We believe zileuton injection could offer a new treatment option for acute asthma patients in the emergency department that can be added to existing therapies in order to improve pulmonary function by controlling both bronchospasm and pulmonary inflammation.

We believe that these exploratory analyses and the tolerability of zileuton injection may support a clinical trial in an acute population as a potential next step in the development process. We have initiated a process to seek to enter into a collaboration agreement for the future clinical development and commercialization of zileuton injection.

R(+) Isomer of Zileuton

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

We are currently seeking a potential collaboration partner for the R(+) isomer of zileuton project.

HMGB1 Program

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

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

As part of the MedImmune collaboration, the research programs are currently aimed at generating antibodies that can neutralize circulating HMGB1 prior to it binding to its receptor. Fully human antibodies directed towards HMGB1, including fully human antibodies identified as part of the MedImmune collaboration, are currently in preclinical

development. In December 2005, MedImmune agreed that proof of concept had been achieved for two preclinical models with human anti-HMGB1 monoclonal antibodies. These antibodies are now undergoing further evaluation with the goal of selecting candidates for use in clinical testing. While we previously had research responsibilities under our collaboration agreement with MedImmune, MedImmune is responsible for conducting all future research activities necessary to advance

Table of Contents

potential product candidates into Phase I clinical trials. As of March 15, 2009, no decision to select a clinical candidate has been made.

Sales and Marketing; Co-promotion Agreements

Sales and Marketing

We have built a commercial organization, consisting at March 15, 2009 of a respiratory-focused sales team that includes 61 sales representatives, six sales managers and one national sales director. Our sales team is 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.

Our sales representatives 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.

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 or expected to be obtained in the near future, revenues expand or we obtain additional funding.

We seek to differentiate our products from our competitors by emphasizing the clinical advantages and favorable side effect profile for patients who are suffering from respiratory diseases or allergies. Our marketing programs to support our products include: patient co-payment assistance, health care provider education, information to further support patient compliance and participation in national medical conventions. In addition, we have established 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 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 Agreement for ZYFLO CR. On March 13, 2007, we entered into an agreement with DEY under which we and DEY agreed to jointly co-promote ZYFLO CR and ZYFLO. Under the co-promotion and marketing services agreement, we granted DEY an exclusive right to promote and detail ZYFLO CR and ZYFLO in the United States, together with us and our affiliates, for asthma and, subject to FDA approval, other respiratory conditions. Both we and DEY have agreed to use diligent efforts to promote the applicable products in the United States during the term of the co-promotion agreement. In addition, DEY has agreed to provide a minimum number of details per month for ZYFLO CR in the second position to office-based physicians and other health care professionals, including a minimum number of details delivered to respiratory specialists, such as allergists and pulmonologists. We agreed to provide a minimum number of details per month for ZYFLO CR in the first position. From 2008 through 2010, we and DEY each have agreed to contribute 50% of approved out-of-pocket promotional expenses for ZYFLO CR that are accrued or paid to third parties. We and DEY each agreed to contribute a minimum of $3.0 million per year for these promotional expenses. We record any co-promotion fees paid to DEY as sales and marketing expenses.

Under the co-promotion agreement, we record all quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, up to $1.95 million. We pay DEY a portion of quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, in excess of $1.95 million. Following the commercial launch of ZYFLO CR in September 2007 through December 31, 2010, we have agreed to pay DEY 35% of quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, in excess of $1.95 million. From January 1, 2011 through

Table of Contents

December 31, 2013, we have agreed to pay DEY 20% of quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, in excess of $1.95 million.

The co-promotion agreement has a term expiring on December 31, 2013, which may be extended by mutual agreement of the parties. Beginning on September 25, 2010, 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 ZYFLO CR cumulative net sales for any four consecutive calendar quarters after commercial launch of ZYFLO CR are less than $25 million. ZYFLO CR cumulative net sales for the four consecutive calendar quarters ended December 31, 2008 were less than $25 million, but we have not received any notice from DEY expressing DEY s intention to exercise its termination right.

DEY has agreed not to manufacture, detail, sell, market or promote any product containing zileuton as one of the APIs for sale in the United States until the later of one year after expiration or termination of the co-promotion agreement or March 15, 2012. However, if an 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 $25 million or upon the occurrence of a material uncured breach by us.

Co-promotion Agreement with Atley Pharmaceuticals. In April 2007, we entered into a co-promotion agreement with Atley Pharmaceuticals to co-promote BALACET 325. In July 2008, we and Atley Pharmaceuticals agreed to amend the agreement to include APAP 325. Under the agreement, we pay Atley Pharmaceuticals fees based on a percentage of the net profits from sales of BALACET 325 and APAP 325 above a specified baseline within assigned sales territories. The parties have agreed to revise the baseline semi-annually to ensure that the baseline is attainable using commercially reasonable efforts.

Atley Pharmaceuticals sales representatives are mainly located in the southeastern, southwestern and midwestern United States. Atley Pharmaceuticals is required under the co-promotion agreement to maintain a trained sales force of at least 40 representatives to detail BALACET 325 and APAP 325 and an incentive compensation plan to encourage superior performance by its sales representatives. Atley Pharmaceuticals promotes BALACET 325 and APAP 325 to pain specialists and primary care providers and other specialties within Atley Pharmaceuticals assigned sales territories.

The co-promotion agreement expires on April 2, 2010, unless extended by mutual agreement of the parties. Either party may terminate the co-promotion agreement without cause upon 60-days advance notice or upon the failure of the parties to agree on a revised specified baseline during the semi-annual review process. If Atley Pharmaceuticals terminates the co-promotion agreement based upon our breach of such agreement, we terminate the co-promotion agreement without cause, or either party terminates because the parties cannot agree upon a revised specified baseline, then Atley Pharmaceuticals is entitled to receive a termination fee for the six months following such termination, paid on a quarterly basis, equal to the average monthly detailing fee paid by us to Atley Pharmaceuticals during the six months immediately preceding such termination.

Trade, Distribution and Reimbursement

Trade Sales and Distribution

Our customers consist of drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies in the United States. We primarily sell products directly to drug wholesalers, which in turn distribute the products to retail

drug stores, mass merchandisers and grocery store pharmacies. Our top three

Table of Contents

customers, which represented 86% of gross product sales in 2008, are all drug wholesalers and are listed below:

Customer	2008	2007
Cardinal Health	40%	43%
McKesson Corporation	31%	34%
AmerisourceBergen Corporation	15%	14%

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 significantly 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 as orders are placed through our customer service center.

Reimbursement

In the U.S. market, sales of pharmaceutical products depend in part on the availability of reimbursement to the patient from third-party payors, such as government health administration authorities, managed care organizations, or MCOs, and private insurance plans. All of our products are generally covered by managed care and private insurance plans. The status or tier within each plan varies, but coverage for SPECTRACEF is similar to other products within the same class of drugs. For example, SPECTRACEF is covered by private insurance plans similar to other marketed, branded cephalosporins. We believe that in most managed care formularies ZYFLO CR and ZYFLO have been placed in formulary positions that require a higher co-payment for patients prescribed the product. In some cases, MCOs, may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for ZYFLO CR. Some Medicare Part D plans also cover some or all of our products, but the amount and level of coverage varies from plan to plan. We also participate in the Medicaid Drug Rebate Program with the Centers for Medicare & Medicaid Services and submit all of our products for inclusion in this program. Coverage of our products under individual state Medicaid plans varies from state to state. Third-party payors are increasingly challenging the prices charged for pharmaceutical products and reviewing different cost savings efforts, which could affect the reimbursement available for our products.

Manufacturing

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

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

We place orders pursuant to supply agreements or purchase order arrangements with third-party manufacturers and packagers for each of our marketed products. Depending on the finished product presentation, some of our manufacturers also package the product. In other cases, the manufacturer supplies

Table of Contents

the bulk form of the product and we package the product through a separate third party. Important information about our material manufacturing and packaging agreements is summarized in the following table.

Product	Manufacturer/Packager
SPECTRACEF	
API (cefditoren pivoxil)	Meiji
200 mg tablets	Meiji
400 mg tablets	Meiji
SPECTRACEF packaging	Meiji
ZYFLO/ZYFLO CR	
API (zileuton)	Shasun
ZYFLO tablets	Patheon
ZYFLO CR tablet cores	Jagotec
ZYFLO CR tablet coating and packaging	Patheon
ALLERX	
Bulk tablets for Dose Pack family of products	Sovereign
ALLERX Packaging	Legacy, Carton Services
BALACET 325, APAP 500 and APAP 325	Vintage
HYOMAX	Sovereign

Certain of our products, including ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D, RESPIVENT-D, BALACET 325, APAP 325 and APAP 500, contain controlled substances, which are regulated by the U.S. Drug Enforcement Administration, or DEA, under the Controlled Substances Act. DEA quota requirements limit the amount of controlled substance drug products a manufacturer can manufacture and the amount of API it can use to manufacture those products. We rely on Sovereign, the manufacturer of bulk tablets for ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D and RESPIVENT-D, Legacy Pharmaceutical Packaging, LLC, or Legacy, and Carton Service, Inc., or Carton Service, the manufacturers of trade and sample packaging for ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D and RESPIVENT-D, and Vintage, the manufacturer and packager of BALACET 325, APAP 325 and APAP 500, to annually request and obtain from the DEA the quota allocation needed to meet our production requirements. If our manufacturers are unsuccessful in obtaining quotas, our supply chain for controlled substance products could be at risk. We and our suppliers attempt to manage this risk through accurate product planning and timely quota submissions with appropriate allocation justifications to the DEA.

We and our manufacturers and packagers are subject to the FDA s current Good Manufacturing Practice, or cGMP, requirements and other applicable laws and regulations administered by the FDA, the DEA and other regulatory authorities.

While some of our products do not have an alternative manufacturer qualified due to exclusivity provisions in the respective licensing agreements or based on other commercial considerations, we believe there are other suppliers that could serve as replacements for the current manufacturers if the need arose. However, qualifying such a replacement manufacturer with the FDA could take a significant amount of time, and, as a result, we would not be able to guarantee an uninterrupted supply of the affected product to our customers.

ZYFLO CR Supply Chain Issues

During 2008, we experienced difficulties in the supply for ZYFLO CR, including an aggregate of eight batches of ZYFLO CR that could not be released into our commercial supply chain, consisting of one batch of ZYFLO CR that did not meet our product release specifications and an additional seven batches of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. In conjunction with our three third-party manufacturers for zileuton API, tablet cores and coating and release, we initiated an investigation to determine the cause of this issue and we believe that

Table of Contents

we have resolved the supply chain issue. If we are not able to supply ZYFLO CR at a commercially acceptable cost and level, we could experience difficulties in maintaining or increasing market share for ZYFLO CR.

Meiji SPECTRACEF License and Supply Agreement

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

Shasun Agreement for Manufacturing and Supply of Zileuton API

Shasun Pharma Solutions, or Shasun, manufactures all of our commercial supplies of the zileuton API pursuant to an agreement dated February 8, 2005. 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 and December 31, 2010. The agreement will automatically extend for successive one-year periods after December 31, 2010, unless Shasun provides us with 18-months prior written notice of cancellation.

Jagotec Manufacture and Supply Agreement for ZYFLO CR

Jagotec AG, or Jagotec, a subsidiary of SkyePharma PLC, manufactures all of our bulk, uncoated tablets of ZYFLO CR pursuant to a manufacture and supply agreement dated August 20, 2007. We have agreed to purchase from Jagotec a minimum of 20 million ZYFLO CR tablet cores in each of the four 12-month periods starting May 30, 2008. The agreement s initial term extends to May 22, 2012, and will automatically continue thereafter, unless we provide Jagotec with 24-months prior written notice of termination or Jagotec provides us with 36-months prior written notice of termination.

Patheon Manufacturing Services Agreement for ZYFLO CR

Patheon Pharmaceuticals, Inc., or Patheon, coats, conducts quality control and quality assurance and stability testing and packages commercial supplies of ZYFLO CR for us using uncoated ZYFLO CR tablets we supply to Patheon. We have agreed to purchase from Patheon at least 50% of our requirements for such manufacturing services for ZYFLO CR for sale in the United States each year during the term of this agreement. The agreement s initial term extends to May 9, 2010, and will automatically continue for successive one-year periods thereafter, unless we provide Patheon with 12-months prior written notice of termination or Patheon provides us with 18-months prior written notice of termination.

Patheon Commercial Manufacturing Agreement ZYFLO Immediate Release Tablets

Patheon also manufactures all of our ZYFLO immediate release tablets pursuant to a commercial manufacturing agreement. We have agreed to purchase from Patheon at least 50% of our commercial supplies of ZYFLO immediate-release tablets for sale in the United States each year for the term of the agreement. The agreement s current term extends to September 15, 2009, and will automatically continue for successive one-year periods thereafter, unless we provide Patheon with 12-months prior written notice of termination or Patheon provides us with 18-months prior written notice of termination.

Vintage Manufacturing Agreement for BALACET 325, APAP 325 and APAP 500

Vintage manufactures all of our requirements of BALACET 325, APAP 325 and APAP 500 pursuant to an exclusive manufacturing agreement that we entered into in July 2004. The term of the agreement expires in June 2010 and will be automatically renewed for successive one-year terms unless either party provides written notice of termination at

least one year prior to the end of the then current term.

Sovereign Pharmaceuticals, Ltd. Manufacturing of HYOMAX Product Line

Sovereign manufactures all of our requirements for three of our HYOMAX products pursuant to an exclusive supply and marketing agreement that we entered into in May 2008. The term of the agreement expires in April 2011 and will be automatically renewed for successive one-year terms unless either party provides written notice of termination at least 90 days prior to the end of the then current term. Additionally, we purchase all of our requirements for HYOMAX DT tablets pursuant to purchase orders we place from time

Table of Contents

to time with Sovereign, which manufactures and supplies the HYOMAX DT tablets to us pursuant to an agreement between Sovereign and Capellon to which we are not a party.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business and obtaining, where possible, assignment of invention agreements from employees and consultants. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

Patents

As of February 28, 2009, we owned or exclusively licensed for one or more indications or formulations a total of 21 issued U.S. patents, 50 issued foreign patents, 25 pending U.S. patent applications and 53 pending foreign patent applications These patents and patent applications include patents and patent applications with claims directed to composition of matter, formulations of our products and product candidates and methods of use of our products and product candidates to treat particular indications.

The following table shows our U.S. patents and pending U.S. patent applications relating to SPECTRACEF, ZYFLO CR and ALLERX as of February 28, 2009:

Patents

Number	Issued Patents	Product(s)	Expiration
Licensed Patents			
4,839,350	Cephalosporin compounds and the production thereof	SPECTRACEF	04/07/2009
4,873,259	Indole, Benzofuran, Benzothiophene Containing Lipoxygenase Inhibiting Compounds	ZYFLO CR and ZYFLO	12/10/2010
5,422,123	Tablets with controlled-rate release of active substances	ZYFLO CR	06/06/2012
5,958,915	Antibacterial composition for oral administration	SPECTRACEF	10/14/2016
6,270,796	Antihistamine/ decongestant regimens for treating rhinitis	ALLERX Dose Pack(1)	10/29/2017
6,843,372	Antihistamine/ decongestant regimens for treating rhinitis	ALLERX Dose Pack PE, ALLERX 10 Dose Pack, ALLERX 30 Dose Pack	05/04/2021

Patent Applications

Number	Pending Patents	Product	Expiration

20040115272	Amorphous cefditoren pivoxil composition and process for producing the same	SPECTRACEF	04/26/2022
20080015241	All day rhinitic condition treatment regimen	ALLERX Dose Pack DF	07/13/2026
20080185313	Medicament regimen for treating bronchitis or lower respiratory tract condition	None	02/05/2027
20080311196	All day rhinitic condition treatment regimen	ALLERX Dose Pack DF	07/13/2026

Table of Contents

(1) AlleRx Dose Pack was reformulated in March 2008 and is currently marketed under Patent No. 6,843,372

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

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

The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. Our success depends, in part, on our ability to protect proprietary products, methods and technologies that we develop under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from using our inventions and proprietary information. If any parties should successfully claim that our proprietary products, methods and technologies infringe upon their intellectual property rights, we might be forced to pay damages, and a court could require us to stop the infringing activity. We do not know if our pending patent applications will result in issued patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

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

Trade Secrets

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

Trademarks

We use trademarks on all of our marketed branded products and select generic products, and believe that having distinctive marks is an important factor in marketing these products. We have U.S. trademark registrations, issued by the United States Patent and Trademark Office, for our ZYFLO CR, ZYFLO, ALLERX, DECONSAL®,

RESPIVENT, HYOMAX and BALACET trademarks, among others. SPECTRACEF is owned by Meiji and licensed to us for sales and marketing purposes in the United States.

Table of Contents

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.

Meiji SPECTRACEF License and Supply Agreement

Overview. On October 12, 2006, we entered into a license and supply agreement, as subsequently amended and supplemented, with Meiji that grants us an exclusive, nonassignable U.S. license to manufacture and sell SPECTRACEF, using cefditoren pivoxil supplied by Meiji, for our currently approved therapeutic indications and to use Meiji s SPECTRACEF trademark in connection with the sale and promotion of SPECTRACEF for our currently approved therapeutic indications. The agreement also extends these rights to additional products and additional therapeutic indications of products containing cefditoren pivoxil supplied by Meiji that are to be jointly developed by Meiji and us and which we and Meiji agree to have covered by the agreement. We and Meiji have agreed that the agreement will apply to SPECTRACEF Suspension and SPECTRACEF Once Daily once we receive the necessary FDA approvals for these SPECTRACEF line extensions.

Fees, Milestones and Royalties. In consideration for the licenses Meiji granted to us, we agreed to pay Meiji a nonrefundable license fee of $6 million in six installments over a period of five years from the date of the agreement. Under certain circumstances, we will be released from our obligation to make any further license fee payments if a 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 ten years from the date the particular product is launched by us.

Exclusive Supplier and Minimum Purchase Obligation. Under the license and supply agreement, Meiji is our exclusive supplier of cefditoren pivoxil and, through October 2018, of SPECTRACEF 400 mg so long as Meiji is able to supply 100% of our requirements for SPECTRACEF 400 mg. Additionally, Meiji will be a non-exclusive supplier of SPECTRACEF 200 mg through October 2018. We are required to purchase from Meiji combined amounts of the API cefditoren pivoxil, SPECTRACEF 200 mg, SPECTRACEF 400 mg and sample packs of SPECTRACEF 400 mg exceeding $15.0 million for the first year beginning October 2008, $20.0 million for year two, $25.0 million for year three, $30.0 million for year four and $35.0 million for year five. If we do not meet our minimum purchase requirement in a given year, we must pay Meiji an amount equal to 50% of the shortfall in that year. We expect to exceed the minimum purchase requirements. If we are unable to meet the minimum purchase requirements, the parties will discuss in good faith measures they can take to address the situation. These minimum purchase requirements cease to apply if a generic cefditoren product is launched in the United States prior to October 12, 2011.

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

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

Table of Contents

indication and agree on whether the license and supply agreement will cover the new product or therapeutic indication and on the allocation of expenses between the parties related to the joint development.

Abbott Zileuton License Agreements

Overview. In December 2003, we acquired an exclusive worldwide license, under patent rights and know-how controlled by Abbott, to develop, make, use and sell controlled-release and injectable formulations of zileuton for all clinical indications, except for the treatment of children under age seven and use in cardiovascular and vascular devices. This license included an exclusive sublicense of Abbott s rights in proprietary controlled-release technology originally licensed to Abbott by Jagotec. 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, 2008, aggregate milestone payments of up to $6.5 million remain under the December 2003 license. In connection with a milestone payment(s) due to Abbott on the second anniversary of FDA approval of the ZYFLO CR NDA, we have accrued $1.5 million as of December 31, 2008. 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 ten years from the first commercial sale of a licensed product in each country. Upon the expiration of our obligation to pay royalties for licensed products in a given country, the license will become perpetual, irrevocable and fully paid up with respect to licensed products in that country. If we decide to sublicense rights under the license, we must first enter into good faith negotiations with Abbott for the commercialization rights to the licensed product. Abbott waived its right of first negotiation with respect to our co-promotion arrangement with DEY for ZYFLO CR.

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

Jagotec Consent to Abbott Sublicense of Zileuton

In December 2003, we entered into an agreement with Jagotec under which Jagotec consented to Abbott s sublicense to us of rights to make, use and sell ZYFLO CR covered by Jagotec s patent rights and know-how. In addition to an upfront fee, we agreed to make aggregate milestone payments to Jagotec of up to $6.6 million upon the achievement of various development and commercialization milestones. As of December 31, 2008, aggregate milestone payments of up to $1.6 million remain under this agreement. In connection with a milestone payment(s) due to Jagotec on the second anniversary of FDA approval of the ZYFLO CR NDA, we have accrued $368,000 as of December 31, 2008. In addition, we agreed to pay royalties to Jagotec based on the net sales of the product by us and our affiliates. We also agreed to pay royalties to Jagotec under the license agreement between Jagotec and Abbott based on the net sales of the product by us and our affiliates. In addition, we agreed to pay Jagotec fees if we sublicense our rights under the licensed patent rights and know-how. Except for a termination right provided to a party in connection with a breach by the other party, the term of this agreement is perpetual.

Pharmaceutical Innovations ALLERX 372 Patent License Agreement

Overview. On August 31, 2006, we entered into a license agreement with Pharmaceutical Innovations that, as subsequently amended, provides for an exclusive license in the United States and Puerto Rico and a nonexclusive license in all other markets to manufacture, package, market, distribute and otherwise exploit

Table of Contents

ALLERX Dose Pack products that are covered by claims under the 372 Patent, by corresponding foreign patents and foreign patent applications and by certain Pharmaceutical Innovations know-how related to those ALLERX Dose Pack products. We also have the right to sublicense our rights under the license agreement to third parties. The 372 Patent expires May 4, 2021. On June 13, 2008, the U.S. Patent and Trademark Office received a request from Vision to re-examine the 372 Patent. On August 21, 2008, the U.S. Patent and Trademark Office ordered the re-examination of the 372 Patent. These re-examination proceedings are more fully discussed in Item 3, Legal Proceedings of this annual report on Form 10-K.

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

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

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

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

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

Term and Termination. The agreement expires on the earlier of March 19, 2013 or FDA approval of the NDA for the licensed product. We may terminate the agreement with 90-days prior written notice if Neos fails to meet any milestones or quality targets determined in the development plan and may terminate the agreement immediately if Neos s manufacturing site is revoked as a cGMP manufacturing facility by the FDA. We also may immediately terminate the agreement if the product is unable to achieve a suitable pharmacokinetic profile as determined by the bioavailability study in the development plan or if we receive a complete response letter from the FDA with respect to the licensed product. If the NDA 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.

Table of Contents

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

Overview. In February 2008, we entered into a development and manufacturing agreement with Neos and Coating Place pursuant to which we obtained an exclusive license under Neos s patent-pending Dynamic Variable Release technology and patent-pending Dynamic Time Release Suspension technology and Coating Place s patent-pending drug resin complex technology to develop, manufacture and commercialize antitussive and antihistamine combination products 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 products 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 products. The parties have agreed to share equally the Prescription Drug User Fee Act, or PDUFA, fees for licensed products.

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

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

Neos Products Development Agreement

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

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

manufacturing agreement, we will be obligated to pay royalties determined as a percentage of the net sales of any licensed product.

Term and Termination. The agreement expires on December 31, 2026. This agreement may be terminated upon written notice by either party to the other that federal or state regulatory authorities with jurisdiction over a party and the products has effected, or will effect at a time certain, changes to the regulations or have instituted one or more enforcement actions that can, in the determination of the relevant

Table of Contents

party, be reasonably expected to result in the commercial infeasibility of the objectives of the agreement. The agreement may also be terminated upon written notice by us to Neos if we determine that continued investment in the development or commercialization of the products is not commercially advisable.

Sovereign Supply and Marketing Agreement for Sovereign s Hyoscyamine Products

In May 2008, Aristos entered into a supply and marketing agreement with Sovereign pursuant to which Aristos obtained the exclusive right to market, sell and distribute in the United States three of Sovereign s generic products, each containing the API hyoscyamine, in return for a share of the net profits realized from the sale of the products. The initial term of the agreement expires April 30, 2011 and will be automatically renewed for successive one-year terms unless either party provides written notice of termination.

Vintage Asset Purchase Agreement Propoxyphene/Acetaminophen Products

In July 2004, we entered into an asset purchase agreement, as subsequently amended, with Vintage, pursuant to which we obtained the rights, title and interest to promote, market, sell, distribute and manufacture BALACET 325 and APAP 500. In addition, Vintage granted us the right to market and sell an authorized generic version of BALACET 325. We are obligated to pay Vintage a royalty equal to a percentage of the net sales of BALACET 325, APAP 500 and APAP 325 each calendar quarter.

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

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

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

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

Fees and Royalty Payments Under Sponsored Research Agreements. In connection with the July 2001 sponsored research and license agreement, we agreed to make payments to The Feinstein Institute ranging from $50,000 to $200,000 for each additional distinguishable product depending on whether it was covered by the licensed patent rights or by the licensed know-how. In connection with the January 2003 sponsored research and license agreement,

we agreed to pay additional amounts in connection with the filing of any U.S. patent application or issuance of a U.S. patent relating to the field of cholinergic anti-inflammatory technology. We also agreed to make aggregate milestone payments to The Feinstein Institute of up to $1.5 million in both cash and shares of our common stock upon the achievement of specified development and regulatory approval milestones with respect to any licensed product. In addition, under each of these agreements, we agreed to pay The Feinstein Institute royalties based on the net sales of a licensed product by us and our affiliates until the later of ten years from the first commercial sale of licensed products in a given country and the expiration of the patent rights covering the licensed product in that country. Under the

Table of Contents

January 2003 sponsored research and license agreement, we agreed to pay minimum annual royalties beginning in 2008 to The Feinstein Institute, regardless of whether we sell any licensed products, of $100,000 in 2008, which minimum annual royalties amount will increase by $50,000 annually to a maximum of $400,000 in 2014, with a minimum annual royalty payment of $400,000 thereafter payable through the expiration of the patent in 2023. We also agreed to pay The Feinstein Institute certain fees if we sublicense our rights under the licensed patent rights and know-how under either agreement.

MedImmune License and Collaboration Agreement HMGB1 Pharmaceuticals

Overview. In July 2003, we entered into an exclusive license and collaboration agreement with MedImmune to jointly develop products directed towards HMGB1. This agreement was amended in December 2005. Under the terms of the agreement, we granted MedImmune an exclusive worldwide license, under patent rights and know-how controlled by us, to make, use and sell products, including antibodies, that bind to, inhibit or inactivate HMGB1 and are used in the treatment or prevention, but not the diagnosis, of diseases, disorders and medical conditions.

We and MedImmune determine the extent of the collaboration on research and development matters each year upon the renewal of a rolling three-year research plan. We are currently working with MedImmune to evaluate the potential of a series of fully human monoclonal antibodies as agents for development as therapeutic antibodies to enable them to enter clinical development. Under the terms of the agreement, MedImmune agreed to fund and expend efforts to research and develop at least one HMGB1-inhibiting product for two indications through specified clinical phases.

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

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

Beckman Coulter License Agreement HMGB1 Diagnostic Products

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

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

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

Table of Contents

SetPoint Vagus Nerve Technology License

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

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

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

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

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

Competition

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

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, our programs or advantageous to our business. In many cases, products that compete with our currently marketed products and product candidates have well known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. The principal competitors to our products are more fully discussed in Item 1A. Risk Factors We face competition, which may result in others discovering, developing or commercializing products before or more successfully than us in this annual report on Form 10-K. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and

established companies.

Our ability to remain competitive in the marketplace is also impacted by our ability to compete successfully with other specialty pharmaceutical companies for product and product candidate acquisition and in-licensing opportunities. These established companies may have a competitive advantage over us due to their size and financial resources.

Table of Contents

The key competitive factors affecting the success of all of our products and product candidates, if approved, are and are likely to continue to be efficacy, safety, convenience, price, the availability of patent protection or regulatory marketing exclusivity, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our 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 competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products. In addition, our ability to compete may be affected because in some cases insurers or other third-party payors seek to encourage the use of generic products, which may have the effect of making branded products less attractive, from a cost perspective, to buyers. Accordingly, even if our product candidates achieve initial market acceptance, competitive products may render our products obsolete or noncompetitive. If our product candidates are rendered obsolete, we may not be able to recover the expenses of developing and commercializing those product candidates.

Marketed Products

Our currently marketed products face significant competition from a wide range of branded and generic products for the same therapeutic indications. 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. The specific competitive conditions affecting SPECTRACEF, ZYFLO CR and the ALLERX Dose Pack products are more fully discussed above under the caption Marketed Products in this Item 1 of this annual report on Form 10-K. Our generic products are also subject to competition from equivalent generic products introduced by other pharmaceutical companies. Such competition may adversely impact the sales volume and pricing of our generic products and our ability to profitably market these products.

Product Candidates

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. The competitive conditions affecting the products in our product pipeline is more fully discussed above under the caption Product Development Pipeline in this Item 1 of this annual report on Form 10-K.

Regulatory Matters

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

FDA Regulation of Drug Products

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

Table of Contents

have obtained the FDA approval for them. As a matter of the FDA enforcement discretion, the FDA has tolerated some such drugs remaining on the market without having first received FDA marketing approval, but the FDA is under no obligation to continue to refrain from enforcement action and can take enforcement action at any time.

Depending on the drug for which approval is sought, the FDA marketing approval can be issued either as approval of an NDA or an ANDA.

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

- pre-clinical laboratory tests, animal studies and formulation studies;
- submission to the FDA of an investigational new drug exemption, or IND, for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an the FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP; and
- FDA review and approval of the NDA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulations, as well as animal studies. The results of these pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the clinical trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding the FDA concerns or questions before clinical trials can proceed. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials. Once an IND is in effect, each clinical trial to be conducted under the IND must be submitted to the FDA, which may or may not allow the trial to proceed.

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

Assuming successful completion of the required clinical testing, the results of the pre-clinical trials and the clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA in the form 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 though the sponsor provides the requested or other information or data, the FDA may ultimately decide that the NDA does not satisfy the regulatory criteria for approval.

Supplemental New Drug Applications. We plan line extensions of certain of our products with approved NDAs, such as new formulations including extended release formulations, new labeling claims and new indications. Before we can market these products, we must submit for FDA review an 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.

If NDA approval is received for a new drug containing an API that was previously approved by the FDA but the NDA is for a drug that includes an innovation over the previously approved drug, for example, a NDA approval for a new indication or formulation of the drug with the same API, and if such NDA approval was dependent upon the submission to the FDA of new clinical investigations, other than bioavailability studies, then the Hatch-Waxman Act prohibits the FDA from making effective the approval of an ANDA or 505(b)(2) NDA for a generic version of such drug for a period of three years from the date of the NDA approval. This three-year exclusivity, however, only covers the innovation associated with the NDA to which it attaches. Thus, the three-year exclusivity does not prohibit the FDA, with limited exceptions, from approving ANDAs or 505(b)(2) NDAs for drugs containing the same API but without the new innovation.

Some of our product candidates may be eligible for submission of applications for approval that require less information than the NDAs discussed above. There are two such pathways to approval: Abbreviated New Drug Applications 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, such as 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 submit studies showing that the product is bioequivalent to the listed drug. Drugs are bioequivalent if the rate and extent of absorption of the drug does 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 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. 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 18-month period of market exclusivity. The regulations governing marketing exclusivity and patent protection are complex, and it is often

Table of Contents

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.

Regulation of Controlled Substances

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

In addition, a DEA quota system controls and limits the availability and production of certain controlled substances, including propoxyphene, pseudoephedrine and hydrocodone that are used in our products and product candidates. The DEA annually establishes aggregate quotas for how much of each controlled substance may be produced based on the DEA s estimate of the quantity needed to meet legitimate scientific and medical needs. The limited aggregate amounts of these substances that the DEA allows to be produced in the United States each year are allocated among individual companies, which must submit applications annually to the DEA for individual production and procurement quotas. A manufacturer must receive an annual quota from the DEA in order to produce or procure any controlled substance

product. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, and it has substantial discretion over whether to make such adjustments. Our contract

Table of Contents

manufacturers quotas may not be sufficient for us to meet commercial demand for our products or complete clinical trials of our product candidates. Any delay or refusal by the DEA in establishing our contract manufacturers 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 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 are subject to state regulation on distribution of these products.

Hazardous Materials

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

Pharmaceutical Pricing and Reimbursement

Our ability to commercialize our products successfully depends in significant part on the availability of adequate coverage and reimbursement from third-party payors, including governmental payors such as the Medicare and Medicaid programs, MCOs and private health insurers. Third-party payors are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products, in addition to the costs required to obtain FDA approvals. Even with these studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may decide not to provide coverage and reimbursement for our products, in whole or in part. If third-party payors approve coverage and reimbursement, the resulting payment rates may not be sufficient for us to sell our products at a profit.

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

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

- controls on government funded reimbursement for drugs;
- controls on payments to health care providers that affect demand for drug products;
- challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;

weakening of restrictions on imports of drugs; and

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

Under the Medicare Part D prescription drug benefit, which took effect in January 2006, Medicare beneficiaries can obtain prescription drug coverage from private plans that are permitted to limit the number of prescription drugs that are covered on their formularies in each therapeutic category and class. Under this program, our products may be excluded from formularies and may be subject to significant price competition

Table of Contents

that depresses the prices we are able to charge. We believe that it is likely that private managed care plans will follow Medicare coverage and reimbursement policies.

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

We may also face competition for our products from lower-priced products from foreign countries that have placed price controls on pharmaceutical products. Proposed federal legislative changes may expand consumers ability to import lower-priced versions of competing products from Canada and other countries. In August 2007, the U.S. House of Representatives passed a measure that would permit more imports of prescription drugs, but the United States Senate has not yet approved it. If this proposal or similar proposals become law, our products may be subjected to increased price competition from lower priced imported drugs. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our own products could negatively impact our business and prospects.

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

Fraud and Abuse Regulation

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

Federal Anti-Kickback Law. The anti-kickback law contained in the federal Social Security Act is a criminal statute that makes it a felony for individuals or entities knowingly and willfully to offer or pay, or to solicit or receive, direct or indirect remuneration, in order to induce the purchase, order, lease, or recommending of items or services, or the referral of patients for services, that are reimbursed under a federal health care program, including Medicare and Medicaid. The term remuneration has been interpreted broadly and includes both direct and indirect compensation and other items and services of value. Both the party offering or paying remuneration and the recipient may be found to have violated the statute. Courts have interpreted the anti-kickback law to cover any arrangement where one purpose of the remuneration is to induce purchases or referrals, regardless of whether there are also legitimate purposes for the arrangement. There are narrow exemptions and regulatory safe harbors, but many legitimate transactions fall outside of the scope of any exemption or safe harbor, although that does not necessarily mean the arrangement will be subject to penalties

under the anti-kickback statute. Penalties for federal anti-kickback violations are severe, including up to five years imprisonment, individual and corporate criminal fines, exclusion from participation in federal health care programs and civil monetary penalties in the form of treble damages plus $50,000 for each violation of the statute.

Table of Contents

State Laws. Various states have enacted laws and regulations comparable to the federal fraud and abuse laws and regulations. These state laws and regulations may apply to items or services reimbursed by any third-party payor, including private, commercial insurers and other payors. Moreover, these laws and regulations vary significantly from state to state and, in some cases, are broader than the federal laws and regulations. These differences increase the costs of compliance and the risk that the same arrangements may be subject to different compliance standards in different states.

Employees

As of March 15, 2009, we had 107 full-time employees, 77 of whom were engaged in marketing and sales, four of whom were engaged in research, development and regulatory affairs, and 26 of whom were engaged in management, administration and finance. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages. We believe that relations with our employees are good.

Available Information

We maintain a web site with the address www.crtx.com. We are not including the information contained on our web site as part of, or incorporating it by reference into, this annual report. We make available, free of charge, on or through our web site our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as practicable after such material is electronically filed with or furnished to the SEC. In addition, we intend to post on our web site all disclosures that are required by applicable law, the rules of the SEC or NASDAQ listing standards concerning any amendment to, or waiver from, our code of business conduct and ethics.

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 Cornerstone Therapeutics 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 expect to derive substantially all of our revenues from sales of the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products and the propoxyphene/acetaminophen products.

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenues from sales of the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products and the propoxyphene/acetaminophen products. If commercial, regulatory or other developments adversely affect our ability to market these products or if demand for these products is reduced, our business, financial condition and operating results could be materially harmed. Until one or more of our product candidates receives FDA approval and is successfully commercialized, the success of our business and operating results will depend substantially on the demand for and continued marketability of these products.

The commercial success of our currently marketed products and any additional products that we successfully develop 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;

Table of Contents

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.

For example, the SPECTRACEF products and the SPECTRACEF line extensions are indicated for the treatment of respiratory infections. Products used to treat respiratory infections are, from time to time, subject to negative publicity, including with respect to antibiotic resistance and overuse.

In the year ended December 31, 2008, we experienced supply chain issues in manufacturing ZYFLO CR. If we are unable to manufacture or release ZYFLO CR on a timely and consistent basis, some physicians may prescribe ZYFLO to ensure that their patients with asthma continue to have access to zileuton as a treatment option. ZYFLO, which is dosed four times per day, contains the same zileuton API as ZYFLO CR, which is dosed two tablets twice daily.

Despite being approved by the FDA since 1996, ZYFLO did not achieve broad market acceptance. We experienced difficulty expanding the prescriber and patient bases for ZYFLO, in part, we believe, because it requires dosing of one tablet four times per day, which some physicians and patients may find inconvenient or difficult to comply with compared to other available asthma therapies that require dosing only once or twice daily. If any existing negative perceptions about ZYFLO persist, we will have difficulty achieving market acceptance for ZYFLO CR.

In addition, if physicians do not prescribe ZYFLO CR for the recommended dosing regimen of two tablets twice daily, or if patients do not comply with the dosing schedule and take less than the prescribed number of tablets, sales of ZYFLO CR will be limited and our revenues will be adversely affected.

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 also 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

Table of Contents

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 and any other zileuton product candidates that we successfully develop and commercialize, which could limit their commercial acceptance.

In March 2008, the FDA issued an early communication regarding an ongoing safety review of the leukotriene montelukast relating to suicide and other behavior related adverse events. In that communication, the FDA stated that it was also reviewing the safety of other leukotriene medications. On May 27, 2008, we received a request from the FDA that we gather and provide to the FDA data from the clinical trial database to evaluate behavior-related adverse events for ZYFLO and ZYFLO CR. On January 13, 2009, the FDA announced that company data 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 the company studies it reviewed were not designed to detect those events. The FDA also indicated that it is continuing to review clinical trial data to assess other mood and behavioral adverse events related to such drugs and it had not yet reached a definitive conclusion regarding the clinical trial data on mood and behavioral adverse events associated with such drugs. Depending on the results of such analyses and the FDA s review, the FDA could request that we revise the labeling of ZYFLO and ZYFLO CR to include statements regarding the potential for other mood and behavior-related changes associated with the use of zileuton. If the FDA requests that we add these statements or similar statements to package inserts, sales of these products could suffer.

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

Periodically, there is negative publicity related to the potential toxicity and addictiveness of propoxyphene. Propoxyphene is one of two APIs, together with acetaminophen, in BALACET 325, APAP 325 and APAP 500. For example, the consumer advocacy organization Public Citizen filed suit in June 2008 against the FDA based on the FDA s failure to act on Public Citizen s February 2006 citizen petition that had requested that the FDA immediately begin the phased removal of all drugs containing propoxyphene from the marketplace based on propoxyphene s toxicity relative to its efficacy and its tendency to induce psychological and physical dependence. On January 30, 2009, an FDA Advisory Committee voted 14-to-12 in favor of a phased removal from the market of all drugs containing propoxyphene. If the FDA acts upon the Advisory Committee s recommendation and began the phased removal of propoxyphene products from the market, product sales of our propoxyphene/acetaminophen products would be eliminated and we would be forced to terminate our co-promotion agreement with Atley Pharmaceuticals.

In December 2006, the FDA recognized concerns about the known liver toxicity of over-the-counter pain relievers, including acetaminophen, which is found in BALACET 325, APAP 325 and APAP 500. The FDA could act on these concerns by changing its policies with respect to acetaminophen as a single ingredient and in combination with opioid products. Any such future policy change could adversely affect our ability to market our propoxyphene/acetaminophen products.

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

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

reasons.

The licensing and acquisition of pharmaceutical products, product candidates and related technologies is a competitive area, and a number of more established companies are also pursuing strategies to license or

Table of Contents

acquire products, product candidates and drug delivery and formulation technologies, which may mean fewer suitable acquisition opportunities for us, as well as higher acquisition prices. Many of our competitors have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

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

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

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

If we 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 of our sales department, including our sales force, sales management, sales logistics and sales administration, and our marketing department. As of March 15, 2009, our sales force consists of 61 sales representatives. 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 not successful in our efforts to expand our sales force and marketing capabilities, our ability to independently market and promote 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 the product candidate. However, we might not be able to enter into such an arrangement on favorable terms, if at all. Even if we are able to effectively expand our sales force and marketing capabilities, our sales force and marketing teams may not be successful in commercializing our products.

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

The development and commercialization of drugs is highly competitive. We face competition with respect to our currently marketed products, our current product candidates and any products that we may seek to develop or commercialize in the future. Our competitors include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other private and public research organizations that seek patent protection and establish collaborative arrangements for development, manufacturing and commercialization. We face significant competition for our currently marketed products. Some of our currently marketed products do not have patent protection and in

most cases face generic competition. All of these products face significant price competition from a range of branded and generic products for the same therapeutic indications.

Given that our product development approach is to develop new formulations of existing drugs, some or all of our product candidates, if approved, may face competition from other branded and generic drugs approved for the same therapeutic indications, approved drugs used off label for such indications and novel drugs in clinical development. For example, our SPECTRACEF Once Daily product candidate, which is a

Table of Contents

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

Our patents will not protect our products if competitors devise ways of making products that compete with our products without legally infringing our patents. The FDCA and FDA regulations and policies provide certain exclusivity incentives to manufacturers to create modified, non-infringing versions of a drug in order to facilitate the approval of ANDAs for generic substitutes. These same types of exclusivity incentives encourage manufacturers to submit NDAs that rely, in part, on literature and clinical data not prepared for or by such manufacturers. Manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same API, dosage form, strength, route of administration and conditions of use or labeling as our product and that the generic product is absorbed in the body at the same rate and to the same extent as our product, a comparison known as bioequivalence. Such products would be significantly less costly than our products to bring to market and could lead to the existence of multiple lower-priced competitive products, which would substantially limit our ability to obtain a return on the investments we have made in those products.

Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates. If NDA approval is received for a new drug containing an API that was previously approved by the FDA but the NDA is for a drug that includes an innovation over the previously approved drug, for example, a NDA approval for a new indication or formulation of the drug with the same API, and if such NDA approval was dependent upon the submission to the FDA of new clinical investigations, other than bioavailability studies, then the Hatch-Waxman Act prohibits the FDA from making effective the approval of an ANDA or 505(b)(2) NDA for a generic version of such drug for a period of three years from the date of the NDA approval. This three-year exclusivity, however, only covers the innovation associated with the NDA to which it attaches.

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

Our products compete, and our product candidates, if approved, will compete, principally with the following:

The SPECTRACEF products and SPECTRACEF Once Daily second and third generation cephalosporins, such as Cedax, Suprax and generic formulations of Omnicef and Ceftin; macrolides, such as generic formulations of Zithromax and Biaxin; and quinolones, such as Levaquin and generic formulations of Cipro.

SPECTRACEF Suspension Suprax and generic formulations of Omnicef and Ceftin.

ZYFLO CR and ZYFLO bronchodilatory drugs, such as ProAir HFA Inhalation Aerosol and Proventil HFA Inhalation Aerosol; LTRAs, such as Singulair; inhaled corticosteroids, such as Flovent; and combination products, such as Advair Diskus and Symbicort. In addition, we may face competition from pharmaceutical companies seeking to develop new drugs for the asthma market.

ALLERX and RESPIVENT Dose Pack Products prescription products, including first generation antihistamine and antihistamine combination products, such as Rescon and Dallergy, and over-the-counter products, such as Benadryl and Chlor-Trimeton.

HYOMAX Products belladonna and derivative antispasmodics, such as the generic formulations of Levsin, Levbid and Donnatal; urinary incontinence antispasmodics, such as Detrol LA, VESIcare and the generic formulations of Ditropan and Ditropan XL; and synthetic gastrointestinal antispasmodics, such as the generic formulations of Bentyl and Pamine.

Table of Contents

BALACET 325, APAP 325 and APAP 500 generic formulations of propoxyphene and acetaminophen, the APIs in BALACET 325, APAP 325 and APAP 500, and many other drugs on the market or in development for the treatment of mild to moderate pain.

Anticholinergic and Antihistamine Combination Product Candidates second generation antihistamines, such as Allegra; third generation antihistamines, such as Xyzal and Clarinex; first generation antihistamine and antihistamine combination products, most of which are generic formulations; and over-the-counter antihistamines, such as Claritin, Zyrtec, Benadryl and Chlor-Trimeton.

Antitussive and Antihistamine Combination Product Candidates various narcotic and non-narcotic antitussives, such as King Pharmaceuticals, Inc. s Tussigon® (hydrocodone and homatropine), Mallinckrodt Brand Pharmaceuticals, Inc. s TussiCaps® (hydrocodone polistirex and chlorpheniramine polistirex), UCB, Inc. s Tussionex® (hydrocodone polistirex and chlorpheniramine polistirex) and generic formulations of Wyeth s Phenergan® with codeine (codeine and promethazine); over-the-counter antitussives, such as Reckitt Benckiser Inc. s Delsym® (dextromethorphan polistirex), Schering-Plough Corporation s Coricidin HBP® Cough & Cold (dextromethorphan and chlorpheniramine); and prescription antitussives, such as Sciele Pharma, Inc. s Rondec® DM Syrup (dextromethorphan, phenylephrine and chlorpheniramine) and Meda Pharmaceuticals Inc. s Tussi-12D® (carbetapentane, pyrilamine and phenylephrine).

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

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

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

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

on several factors, including the number of competitors, the price of the branded product and the pricing strategy of the new competitors. Our inability to introduce additional generic products or our withdrawal of existing generic products from the market due to increased competition would have a material adverse effect on our financial condition and results of operations.

Table of Contents

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

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

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

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

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

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

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 $15.0 million for the first year beginning with the commercial launch in October 2008 of SPECTRACEF 400 mg manufactured by Meiji, $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. If our SPECTRACEF products do not achieve the level of sales we anticipate, we may not be able to use all of the cefditoren pivoxil we have purchased. We are using our current inventory of cefditoren pivoxil for formulation, development and manufacture of the currently marketed SPECTRACEF products as well as the SPECTRACEF line extensions.

We are also subject to minimum purchase obligations under supply agreements, which require us to buy inventory of the tablet cores for ZYFLO CR. We have committed to purchase a minimum of 20 million ZYFLO CR tablet cores from Jagotec in each of the four 12-month periods starting May 30, 2008. If ZYFLO CR does not achieve the level of demand we anticipate, we may not be able to use the inventory we are required to purchase. Based on our current expectations regarding demand for ZYFLO CR, we expect that inventory levels could increase substantially in the future as a result of minimum purchase obligations under supply agreements with third-party manufacturers and orders we have submitted to date.

Table of Contents

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.

In the year ended December 31, 2008, we experienced difficulties in the supply for ZYFLO CR, including an aggregate of eight batches of ZYFLO CR that could not be released into our commercial supply chain, consisting of one batch of ZYFLO CR that did not meet our product release specifications and an additional seven batches of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. We cannot assure you that we will not have similar manufacturing issues in producing ZYFLO CR or our other products in the future.

Our ability to maintain optimal inventory levels also depends on the performance of third-party contract manufacturers. In some instances, third-party manufacturers have encountered difficulties obtaining raw materials needed to manufacture our products as a result of DEA regulations and because of the limited number of suppliers of pseudoephedrine, hyoscyamine sulfate, and methscopolamine nitrate. Although these difficulties have not had a material adverse impact on us, such problems could have a material adverse impact on us in the future. 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 products or the quotas are not sufficient, we may be unable to meet commercial demand for the products.

Certain of our products, including ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D, RESPIVENT-D, BALACET 325, APAP 325 and APAP 500, contain controlled substances, which are regulated by the DEA under the Controlled Substances Act. DEA quota requirements limit the amount of controlled substance drug products a manufacturer can manufacture and the amount of API it can use to manufacture those products. We rely on Sovereign, the manufacturer of bulk tablets for ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D and RESPIVENT-D, Legacy and Carton Service, the manufacturers of trade and sample packaging for ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D and RESPIVENT-D, and Vintage, the manufacturer and packager of BALACET 325, APAP 325 and APAP 500, to annually request and obtain from the DEA the quota allocation needed to meet our production requirements. If our manufacturers are unsuccessful in obtaining quotas, our supply chain for controlled substance products could be at risk.

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

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

Table of Contents

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

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

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

injury to our reputation;

the withdrawal of clinical trial participants;

the withdrawal of a product from the market;

costs to defend the related litigation;

substantial monetary awards to clinical trial participants or patients;

diversion of management time and attention;

loss of revenue; and

inability to commercialize the products that we may develop.

The consumer advocacy organization Public Citizen filed suit in June 2008 against the FDA based on the FDA s failure to act on Public Citizen s February 2006 citizen petition that had requested that the FDA immediately begin the phased removal of all drugs containing propoxyphene from the marketplace based on propoxyphene s toxicity relative to its efficacy and its tendency to induce psychological and physical dependence. On January 30, 2009, an FDA Advisory Committee voted 14-to-12 in favor of a phased removal of all drugs containing propoxyphene. Propoxyphene is one of two APIs, together with acetaminophen, in BALACET 325, APAP 325 and APAP 500. In addition, in December 2006, the FDA recognized concerns about the known liver toxicity of over-the-counter pain relievers, including acetaminophen, which is found in BALACET 325, APAP 325 and APAP 500. While we are not aware of any pending or threatened product liability claims against us related to propxyphene or acetaminophen, we cannot assure you that such claims will not arise in the future.

Our contracts with wholesalers and other customers require us to carry product liability insurance. We have product liability insurance coverage with a $10 million annual aggregate limit and a $10 million individual claim limit, and which is subject to a per claim deductible and a policy aggregate deductible. The annual cost of this products liability insurance was approximately $265,000 for the policy year beginning September 13, 2008. The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Risks Relating to Product Development and Regulatory Matters

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

Our product candidates are still in various stages of development. Our product development pipeline includes the following two SPECTRACEF line extensions: SPECTRACEF Once Daily, a once daily dosage tablet, and SPECTRACEF Suspension, an oral suspension for the pediatric market. Our product development pipeline also includes the following three additional product candidates: CRTX 058, an anticholinergic and antihistamine combination product candidate for the treatment of symptoms of allergic rhinitis; CRTX 067, an antitussive and antihistamine combination product candidate; and CRTX 069, also an antitussive and

Table of Contents

antihistamine combination product candidate. All of our product candidates remain subject to pharmaceutical formulation development and clinical testing necessary to obtain the regulatory approvals or clearances required for commercial sale. Depending on the nature of the product candidate, to demonstrate a product candidate s safety and efficacy, we and our collaborators generally must either demonstrate bioequivalence with a drug already approved by the FDA or complete human clinical trials. We may not be able to obtain permission from the FDA, institutional review boards, or IRBs, or other authorities to commence or complete necessary clinical trials. If permitted, such clinical testing may not prove that our product candidates are safe and effective to the extent necessary to permit us to obtain marketing approvals or clearances from regulatory authorities. One or more of our product candidates may not exhibit the expected therapeutic results in humans, may cause harmful side effects or may have other unexpected characteristics that may delay or preclude submission and regulatory approval or clearance, or cause imposition of burdensome post-approval requirements or limit commercial use if approved or cleared. For example, our antitussive and antihistamine combination product candidates, CRTX 067 and CRTX 069, contain a narcotic antitussive, which has been associated with abuse and can lead to serious illness, injury or death if improperly used. Furthermore, we, one of our collaborators, IRBs or regulatory agencies may order a clinical hold or suspend or terminate clinical trials at any time if it is believed that the subjects or patients participating in such trials are being exposed to unacceptable health risks or for other reasons.

For example, Guidance for Industry issued by the FDA in 2007 regarding, among other things, the design of clinical trials of 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 in such cases, we believe this FDA guidance may make placebo-controlled trials more difficult to design and complete, 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 be unable to obtain regulatory approval and commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay the receipt of any revenues from product sales.

We currently expect to commence clinical trials with respect to SPECTRACEF Once Daily in 2009, SPECTRACEF Suspension in 2010, our anticholinergic and antihistamine combination product candidate CRTX 058 in 2009 and our antitussive and antihistamine combination product candidates CRTX 067 and CRTX 069 in 2009. 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 or 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 approvals from regulators, IRBs or other governing entities at clinical sites selected for participation in our clinical trials;

Table of Contents

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

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

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

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

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

- serious and unexpected drug-related side effects experienced by participants in past clinical trials for the same or a different indication; or

- exposure of participants to unacceptable health risks.

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

Delays in patient enrollment and the related increase in costs also could cause us to decide to discontinue a clinical trial prior to completion. For example, in March 2008, we discontinued our Phase IV clinical trial for ZYFLO CR designed to generate data in the current patient treatment setting because patient enrollment was significantly slower than we had anticipated. We initiated the trial in July 2007 and had enrolled only approximately 25% of the patients prior to discontinuing the trial. We had planned to use data from this trial to support ZYFLO CR s market position, and we may have increased difficulty promoting ZYFLO CR to physicians without this data.

We expect to rely on academic institutions and contract research organizations to 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.

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

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

Table of Contents

complete. Clinical data is often susceptible to varying interpretations, and many companies that have believed their products performed satisfactorily in clinical trials were nonetheless unable to obtain FDA approval for their product candidates. Similarly, even if clinical trials of a product candidate are successful in one indication, clinical trials of that product candidate for other indications may be unsuccessful. One or more of our clinical trials could fail at any stage of testing.

We expect to submit an NDA to the FDA in 2011 for SPECTRACEF Suspension for use of this product candidate by children with pharyngitis, tonsillitis or otitis media. TAP Pharmaceutical Products, Inc. or TAP, conducted all of the preclinical studies and clinical trials of the oral suspension formulation of SPECTRACEF before we licensed the rights to SPECTRACEF from Meiji. We intend to rely on the results of these prior clinical trials to support our NDA for SPECTRACEF Suspension for pharyngitis and tonsillitis. TAP conducted its clinical trials of the oral suspension formulation of SPECTRACEF using a non-inferiority design, meaning that the objective was to demonstrate that the safety and effectiveness of SPECTRACEF Suspension is not inferior relative to the control drug. However, current FDA guidelines request superiority design clinical trials, meaning that the objective of the clinical trials is to demonstrate that the test drug s safety and effectiveness are superior to the control drug. If the FDA does not permit us to rely on the prior clinical data for SPECTRACEF Suspension, we would be required to repeat some or all of the clinical trials, which would lead to unanticipated costs and delays. Problems with the previous trials, such as incomplete, outdated or otherwise unacceptable data also 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 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.

Product development costs also will increase if we experience delays in testing or obtaining approvals. Significant clinical trial delays also could shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved and the nature of the disease or condition to be treated. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations or medical and technical developments during the review process may delay the approval or cause the rejection of an application. The FDA has substantial discretion in the approval process and may 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.

Our limited experience in obtaining regulatory approvals could delay, limit or prevent such approvals for our product candidates.

We have only limited experience in preparing and submitting the applications necessary to gain regulatory approvals and expect to rely on third-party contract research organizations to assist us in this

Table of Contents

process. We acquired the rights to most of our currently marketed products and product candidates through four licensing transactions, two related to ZYFLO CR and ZYFLO in 2003 and 2004 respectively, one for the ALLERX Dose Pack products in February 2005 and one for SPECTRACEF in October 2006. Personnel who are no longer with Cornerstone obtained approval to market ZYFLO and ZYFLO CR in the United States from the FDA in September 2005 and May 2007, respectively. The FDA approved our sNDA for SPECTRACEF 400 mg in July 2008 and we launched this product in October 2008. We do not have other experience gaining FDA approval of product candidates.

Our limited experience in this regard could delay or limit approval of our product candidates if we are unable to effectively manage the applicable regulatory process with either the FDA or foreign regulatory authorities. In addition, significant errors or ineffective management of the regulatory process could prevent approval of a product candidate, especially given the substantial discretion that the FDA and foreign regulatory authorities have in this process.

Some of our specialty pharmaceutical products are now being marketed without approved NDAs or ANDAs.

Even though the FDCA requires pre-marketing approval of all new drugs, as a matter of history and regulatory policy, the FDA has historically refrained from taking enforcement action against some marketed, unapproved new drugs. The FDA has adopted a risk-based enforcement policy concerning these unapproved drugs. Although the FDA considers all such drugs to require its approval, FDA enforcement against such products as unapproved drugs prioritizes products that pose potential safety risks, lack evidence of effectiveness, prevent patients from seeking effective therapies or are marketed fraudulently. In addition, the FDA is less likely to exercise enforcement discretion regarding unapproved new drugs if it finds that the marketer and its manufacturers are also allegedly in non-compliance with cGMP requirements. Also, the FDA has indicated that approval of an NDA for one drug within a class of drugs marketed without FDA approval may also trigger agency enforcement of the new drug requirements against all other drugs within that class that have not been so approved. While the FDA generally provides sponsors with a one-year grace period during which time they are permitted to continue selling the unapproved drug, it is not statutorily required to do so and could ask or require that the products be removed from the market immediately. Although we may be given the benefit of a grace period to submit a marketing application before the agency would take enforcement action, the time it takes us to complete the necessary clinical trials and submit an NDA or ANDA to the FDA may exceed this time period, which would result in an interruption of sales of our products.

As of March 15, 2009, our only products that are subject to approved NDAs or ANDAs are the SPECTRACEF products, ZYFLO CR, ZYFLO and our propoxyphene/acetaminophen products. Our net revenues from the sale of unapproved products were $15.4 million, or 55% of total net revenues, in the year ended December 31, 2007, and $49.8 million, or 77% of total net revenues, in the year ended December 31, 2008. All of our other products are marketed in the United States without an FDA-approved marketing application.

Our net revenues from sales of the ALLERX Dose Pack products were $13.5 million in the year ended December 31, 2007 and $26.4 million in the year ended December 31, 2008. Our net revenues from sales of our HYOMAX products, which we launched beginning in May 2008, were $23.0 million in the year ended December 31, 2008. If the FDA required us to remove our unapproved products from the market, particularly our ALLERX Dose Pack family of products and our HYOMAX line of products, our revenue from product sales would be significantly reduced. For example, when the FDA announced in May 2007 that it was directing that all non-approved extended-release guaifenesin products, including Cornerstone s DECONSAL II product, be removed from the market within 180 days, the FDA noted that Adams Respiratory Therapeutics, Inc., or Adams, was the only company to date that had obtained FDA approval for timed-release products containing guaifenesin. Our net revenues from sales of DECONSAL II were $177,000 in 2007 and $1.2 million in 2006.

Table of Contents

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

Our sales of currently marketed products are, and any future sales of our product candidates will be, dependent, in part, on the availability of coverage and reimbursement from third-party payors, including government health care programs such as Medicare and Medicaid, and private insurance plans. All of our products are generally covered by managed care and private insurance plans. Generally, the status or tier within managed care formularies, which are lists of approved products developed by MCOs varies but coverage is similar to other products within the same class of drugs. For example, the SPECTRACEF products are covered by private insurance plans, similar to other marketed, branded cephalosporins. However, the position of ZYFLO CR may make it more difficult to expand the current market share for this product. In most instances, ZYFLO CR and ZYFLO have been placed in formulary positions that require a higher co-payment for patients. 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 ZYFLO CR. Some Medicare Part D plans also cover some or all of our products, but the amount and level of coverage varies from plan to plan. We also participate in the Medicaid Drug Rebate program with the Centers for Medicare & Medicaid Services and submit all of our products for inclusion in this program. Coverage of our products under individual state Medicaid plans varies from state to state.

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

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

If we succeed in bringing additional products to the market, these products may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow us to sell our product candidates on a competitive basis to a sufficient patient population. Because our product candidates are in the development stage, we do not know whether payors will cover the products and the level of reimbursement, if any, we will receive for these product candidates if they are successfully developed, and we are unable at this time to determine the cost-effectiveness of these product candidates. We may need to conduct expensive pharmacoeconomic trials in order

to demonstrate the cost-effectiveness of 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

Table of Contents

limited. If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce use of our products or cause us to reduce the price of our products.

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

We and our products 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. The manufacturer and the manufacturing facilities used to make our products and product candidates are also subject to comprehensive regulatory requirements. The FDA periodically inspects sponsors, marketers and manufacturers for compliance with these requirements. Additional, potentially costly, requirements may apply to specific products as a condition of FDA approval or subsequent regulatory developments. For example, as part of the approval of the NDA for ZYFLO CR in May 2007, the FDA required us to conduct a pediatric clinical trial of ZYFLO CR as a post-approval commitment and report the results to the FDA by June 2010. If we do not successfully begin and complete this clinical trial in the time required by the FDA, our ability to market and sell ZYFLO CR may be hindered, and our business may be harmed as a result.

Discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in:

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.

State and federal pharmaceutical marketing and promotional compliance and reporting requirements may expose us to regulatory and legal action by government authorities.

In recent years, several states, including California, Maine, Massachusetts, Minnesota, Nevada, Vermont and West Virginia, as well as the District of Columbia, have enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs or file periodic reports with the state on sales and marketing activities and expenditures, including but not limited to, the provision of gifts to healthcare practitioners. For example, a California statute effective July 1, 2005 requires pharmaceutical companies to adopt and post on their public web site a comprehensive compliance program that complies with

Table of Contents

the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals and the Office of Inspector General of the Department of Health and Human Services Compliance Program Guidance for Pharmaceutical Manufacturers. In addition, such a compliance program must establish a specific annual dollar limit on gifts or other items given to individual health care professionals in California. Other states have also enacted statutes of varying scope that impose reporting and disclosure requirements on pharmaceutical companies pertaining to drug pricing. Similar legislation is being considered in a number of other states and the U.S. Congress is also considering legislation that would require drug manufacturers to report to the federal government their payments and other transfers of value to physicians.

Many of the existing requirements are new and have not been definitively interpreted by state authorities or courts, and available guidance is limited. Unless and until we are in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity, all of which could materially harm our business.

We may be subject to investigations or other inquiries concerning our compliance with reporting obligations under federal health care program pharmaceutical pricing requirements.

There have been a number of government enforcement actions under the federal health care programs, primarily Medicare and Medicaid, against numerous pharmaceutical companies alleging that the reporting of prices for pharmaceutical products has resulted in false and overstated prices, such as average wholesale and best price, which are alleged to have improperly inflated the reimbursements paid by Medicare, state Medicaid programs and other payors to health care providers who prescribed and administered those products or pharmacies that dispensed those products. These actions have been brought by both the federal government and individual states. Failure to comply with these government health care program pharmaceutical pricing requirements may lead to federal or state investigations, criminal or civil liability, exclusion from government health care programs, contractual damages and otherwise materially harm our reputation, business and prospects.

Our corporate compliance and corporate governance programs cannot guarantee that we are in compliance with all potentially applicable regulations.

The development, manufacturing, pricing, marketing, sales and reimbursement of our products and product candidates, together with our general operations, are subject to extensive regulation by federal, state and other authorities within the United States. We are a relatively small company and had approximately 107 employees as of March 15, 2009. We rely heavily on third parties to conduct many important functions. We have developed and instituted a corporate compliance program designed to comply with current best practices for pharmaceutical companies and continue to update the program in response to newly implemented and changing regulatory requirements. However, our compliance program does not and cannot guarantee that we are in compliance with all potentially applicable federal and state regulations. If we fail to comply with any of these regulations, we may be subject to a range of enforcement actions, including significant fines, litigation or other sanctions. Any action against us for a violation of these regulations, even if we successfully defend against such actions, could cause us to incur significant legal expenses, divert our management s attention and harm our reputation.

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

Health care providers, physicians and others play a primary role in the recommendation and prescription of our products. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we will market, sell and distribute our products. Applicable federal and state health care

laws and regulations, include, but are not limited to, the following:

The federal anti-kickback statute is a criminal statute that makes it a felony for individuals or entities knowingly and willfully to offer or pay, or to solicit or receive, direct or indirect remuneration, in order to induce the purchase, order, lease, or recommending of items or services, or the referral of patients

Table of Contents

for services, that are reimbursed under a federal health care program, including Medicare and Medicaid;

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

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

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

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

We are a participant in the Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as amended, effective in 1993. Under the Medicaid rebate program, we pay a rebate for each unit of our product reimbursed by Medicaid. The amount of the rebate for each product is set by law. We are also required to pay certain statutorily defined rebates on Medicaid purchases for reimbursement on prescription drugs under state Medicaid plans. Both the federal government and state governments have initiated investigations into the rebate practices of many pharmaceutical companies to ensure compliance with these rebate programs. Any investigation of our rebate practices could be costly, could divert the attention of our management and could damage our reputation.

Efforts to help ensure that our business arrangements comply with these extensive federal and state health care fraud and abuse laws could be costly. It is possible that governmental authorities may conclude that our business practices do not comply with current or future statutes or regulations involving applicable fraud and abuse or other health care laws and regulations. If our past or present operations, including activities conducted by our sales team or agents, are found to be in violation of any of these laws or any other applicable governmental regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government health care programs and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we do business is found not to be in compliance with applicable laws, they may also be subject to criminal, civil or administrative sanctions, including exclusions from government health care programs.

Many aspects of the above-described laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations, which increases the risk of potential violations. In addition, these laws and their interpretations are subject to change. Any action against us for violation of these laws, even if we successfully defend against 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.

Recent proposed legislation may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could force us to lower the prices of our products and impair our ability to derive revenue from our products.

Legislation has been introduced in the United States Congress that, if enacted, would permit more widespread re-importation of FDA-approved drugs from foreign countries into the United States. This could

Table of Contents

include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. While we do not currently sell any of our products outside the United States, legislation or other factors that increase such sales by our direct competitors could adversely affect our pricing and revenues. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue generated from our product sales.

Risks Relating to Our Dependence on Third Parties

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

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

We obtain all of our BALACET 325, APAP 500 and APAP 325 supply from Vintage, which has the exclusive right to supply all of our requirements for these products. Meiji has the exclusive right to supply all of our requirements for cefditoren pivoxil, the API in SPECTRACEF. We acquire all of our requirements for the HYOMAX line of products and all of the bulk tablets for our ALLERX Dose Pack products from Sovereign. We also have qualified two packagers of the ALLERX product line.

We have contracted with Shasun for commercial production of the zileuton API, subject to specified limitations, through December 31, 2010. Zileuton API is used in our FDA-approved oral zileuton products, ZYFLO CR and ZYFLO, as well as in our zileuton injection product candidate. Our only source of supply for zileuton API is Shasun, which manufactures the zileuton API in the United Kingdom. In addition, there is only one qualified supplier of a chemical known as 2-ABT, which is one of the starting materials for zileuton, and if that manufacturer stops manufacturing 2-ABT, is unable to manufacture 2-ABT or is unwilling to manufacture 2-ABT on commercially reasonable terms or at all, Shasun may be unable to manufacture API for us.

We have contracted with Jagotec for the manufacture of core tablets for ZYFLO CR for commercial sale. Our only source of supply for the core tablets of ZYFLO CR is Jagotec, which manufactures them in France. We have contracted with Patheon to coat and package the core tablets of ZYFLO CR for commercial sale. Patheon is currently our only source of finished ZYFLO CR tablets. We have contracted with Patheon to manufacture ZYFLO tablets for commercial sale. Patheon is currently our only source of finished ZYFLO tablets.

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

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

We may not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. If we were required to change manufacturers, we would be required to obtain FDA approval of an sNDA covering the new manufacturing site. In addition, we would be required to conduct additional clinical bioequivalence trials to demonstrate that the products manufactured by the new manufacturer are equivalent to the products manufactured by the current manufacturer, which could take 12 to 18 months or possibly longer. The technical transfer of manufacturing capabilities can be difficult. For example, in the second quarter of

Table of Contents

2007, we initiated the qualification process for two new manufacturing sites for the five different tablet formulations that are used in the various AM/PM dosing combinations in the different ALLERX Dose Pack products in order to have additional manufacturing capacity and to mitigate the risks associated with relying on a single supplier. Both facilities initially encountered difficulties in developing stable tablet formulations, which were later resolved. Any delays associated with the approval of an sNDA covering a new manufacturer or conducting additional clinical bioequivalence trials 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 are aware that Patheon, the owner of the Puerto Rico-based manufacturing plant for SPECTRACEF 200 mg, has decided to close this plant. We plan to obtain commercial supplies of SPECTRACEF 200 mg and SPECTRACEF 400 mg from Meiji, whose plant in Spain is approved by the FDA to manufacture these products. We believe that the closing of Patheon s Puerto Rico plant could delay the research formulation development of SPECTRACEF line extensions.

We also rely on third-party manufacturers to purchase the necessary raw materials to manufacture our products, with the exception of cefditoren pivoxil, the API in SPECTRACEF, which we are required to purchase from Meiji. In some instances, third-party manufacturers have encountered difficulties obtaining raw materials needed to manufacture our products as a result of DEA regulations and because of the limited number of suppliers of pseudoephedrine, hyoscyamine sulfate, and methscopolamine nitrate. Although these difficulties have not had a material adverse impact on us, such problems could have a material adverse impact on us in the future. In addition, supply interruptions or delays could occur that require us or our manufacturers to obtain substitute materials or products, which would require additional regulatory approvals. Changes in our raw material suppliers could result in delays in production, higher raw material costs and loss of sales and customers because regulatory authorities must generally approve raw material sources for pharmaceutical products. Any significant supply interruption could have a material adverse effect on our business, financial condition and results of operation.

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

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

Our third-party manufacturers may not be able to comply with cGMP regulations or other United States regulatory requirements or similar regulatory requirements outside the United States. DEA regulations also

Table of Contents

govern facilities where controlled substances are manufactured. Our third-party manufacturers are subject to DEA registration requirements and unannounced inspections by the FDA, the DEA, state regulators and similar regulators outside the United States. 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 these regulations. We cannot assure you that our current quality assurance program is reasonably designed to, or would, discover all instances of non-compliance by our third-party manufacturers with these regulations. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including:

fines;

injunctions;

civil penalties;

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

delays, suspension or withdrawal of approvals;

suspension of manufacturing operations;

license revocation;

seizures or recalls of products or product candidates;

operating restrictions; and

criminal prosecutions.

Any of these sanctions could significantly and adversely affect supplies of our products and product candidates.

Difficulties relating to the supply chain for ZYFLO CR tablets could significantly inhibit our ability to meet, or prevent us from meeting, commercial demand for the product.

During 2008, we experienced difficulties in the supply for ZYFLO CR, including an aggregate of eight batches of ZYFLO CR that could not be released into our commercial supply chain, consisting of one batch of ZYFLO CR that did not meet our product release specifications and an additional seven batches of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. In conjunction with our three third-party manufacturers for zileuton API, tablet cores and coating and release, we initiated an investigation to determine the cause of this issue and we believe that we have resolved the supply chain issue. Any delays or difficulties associated with our supply chain for ZYFLO CR could adversely affect our production schedule or increase our production costs and could ultimately lead to a shortage of supply in the market. If we are not able to supply ZYFLO CR at a commercially acceptable cost and level, we could experience difficulties in maintaining or increasing market share for ZYFLO CR.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.

We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Reliance on these third parties for clinical development activities reduces our control over these activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Furthermore,

Table of Contents

these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

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

We may seek to enter into co-promotion arrangements to enhance our promotional efforts and, therefore, sales of our products. By entering into agreements with pharmaceutical companies that have experienced sales forces with strong management support, we can reach health care providers in areas where we have limited or no sales force representation, thus expanding the reach of our sales and marketing programs.

We also seek to enter into co-promotion arrangements for the marketing of products that are not aligned with our respiratory focus and, therefore, are not promoted by our sales force. For example, in July 2007, Atley Pharmaceuticals began marketing and promoting BALACET 325 to pain specialists and other high prescribers of pain products through a co-promotion agreement. We rely on MedImmune for the commercialization of any anti-HMGB1 products that are developed under our exclusive license and collaboration agreement with MedImmune, and we plan to rely on Beckman Coulter for the commercialization of any diagnostic assay for HMGB1. We may not be successful in entering into additional marketing arrangements in the future and, even if successful, we may not be able to enter into these arrangements on terms that are favorable to us. In addition, we may have limited or no control over the sales, marketing and distribution activities of these third parties. If these third parties are not successful in commercializing the products covered by these arrangements, our future revenues may suffer.

We rely on DEY to jointly promote and market ZYFLO CR. DEY initiated promotional detailing activities for ZYFLO CR in September 2007 after initiating promotional detailing for ZYFLO in April 2007. After September 27, 2010, DEY may terminate the co-promotion agreement with six-months prior written notice. In addition, DEY has the right to terminate the co-promotion agreement with two-months prior written notice if ZYFLO CR cumulative net sales, as defined in the co-promotion agreement, for any four consecutive calendar quarters after commercial launch of ZYFLO CR are less than $25 million. The ZYFLO CR cumulative net sales, as defined in the co-promotion agreement, for the four consecutive calendar quarters ended December 31, 2008 were less than $25 million. Each party has the right to terminate the co-promotion agreement upon the occurrence of a material uncured breach by the other party. Both parties have agreed to use diligent efforts to promote the applicable products in the United States during the term of the co-promotion agreement. In particular, both parties have agreed to provide a minimum number of details per month for ZYFLO CR.

If DEY were to terminate or breach the co-promotion agreement, and we were unable to enter into a similar co-promotion agreement with another qualified party in a timely manner or devote sufficient financial resources or capabilities to independently promoting and marketing ZYFLO CR, then our sales of ZYFLO CR would be limited and we would not be able to generate significant revenues from product sales. In addition, DEY may choose not to devote time, effort or resources to the promotion and marketing of ZYFLO CR beyond the minimum required by the terms of the co-promotion agreement. DEY is a subsidiary of Mylan. Mylan acquired DEY in October 2007 as part of its acquisition of Merck KGaA s generic business, of which DEY was a part. We cannot predict what impact Mylan s acquisition of DEY may have on our co-promotion arrangement. Any decision by DEY or Mylan not to devote sufficient resources to the co-promotion arrangement or any future reduction in efforts under the co-promotion arrangement, including as a result of the sale or potential sale of DEY by Mylan, would limit our ability to generate significant revenues from product sales. Furthermore, if DEY does not have sufficient sales capabilities, then DEY may not be able to meet its minimum detailing obligations under the co-promotion agreement.

55

Table of Contents

The concentration of our product sales to only a few wholesale distributors increases the risk that we will not be able to effectively distribute our products if we need to replace any of these customers, which would cause our sales to decline.

The majority of our sales are to a small number of pharmaceutical wholesale distributors, which in turn sell our products primarily to retail pharmacies, which ultimately dispense our products to the end consumers. Sales to our three primary wholesale distributors, AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation, collectively accounted for at least 86% of our gross product sales during 2008.

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 recent significant consolidation in the wholesale drug distribution industry, including through mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large wholesale distributors control a significant share of the market.

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.

If any of the third parties that we rely upon for assistance in researching, developing, manufacturing, promoting and distributing our products and product candidates defaults on or is unable to refinance at maturity its third party indebtedness, our operating performance would be adversely affected.

The full impact of the credit crunch that is currently affecting the national and international credit markets has yet to be fully established and therefore the possibility remains that credit conditions, as well as a slowdown or recession in economic growth, could adversely affect the third parties upon whom we rely for researching, developing, manufacturing, promoting and distributing our products and product candidates. We believe that some of the third parties upon which we rely, including Neos, 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.

Table of Contents

We depend on MedImmune and Beckman Coulter and expect to depend on additional collaborators in the future for a portion of our revenues and to develop, conduct clinical trials with, obtain regulatory approvals for, and manufacture, market and sell some of our product candidates. These collaborations may not be successful.

We have entered into and may in the future enter into collaboration arrangements on a selective basis. For example, we have determined as a strategic matter to seek to enter into collaboration arrangements with respect to the development of our alpha-7 product candidates and our zileuton injection product candidate.

We are relying on MedImmune to fund the development of and to commercialize product candidates in our HMGB1 program. We are relying on Beckman Coulter to fund the development and to commercialize diagnostics in our HMGB1 program. Payments due to us under the collaboration agreements with MedImmune and Beckman Coulter are generally based on the achievement of specific development and commercialization milestones that may not be met. In addition, the collaboration agreements entitle us to royalty payments that are based on the sales of products developed and marketed through the collaborations. These future royalty payments may not materialize or may be less than expected if the related products are not successfully developed or marketed or if we are forced to license intellectual property to continue to generate revenues.

Our collaboration agreement with MedImmune generally is terminable by MedImmune at any time upon six-months notice or upon our material uncured breach of the agreement. The parties agreed to work exclusively in the development and commercialization of HMGB1-inhibiting products for a period of four years, and, after such time, we have agreed to work exclusively with MedImmune in the development of HMGB1-inhibiting products for the remaining term of the agreement. If MedImmune were to terminate or breach this arrangement, and we were unable to enter into a similar collaboration agreement with another qualified third party in a timely manner or devote sufficient financial resources or capabilities to continue development and commercialization on our own, the development and commercialization of the HMGB1 program likely would be delayed, curtailed or terminated, which could harm our future prospects.

In June 2007, AstraZeneca PLC completed its acquisition of MedImmune and MedImmune became a wholly owned subsidiary of AstraZeneca. We cannot predict what impact this transaction may have on our HMGB1 collaboration with MedImmune. If MedImmune does not devote sufficient time and resources to our collaboration or changes the focus of its programs, it could delay or prevent the achievement of clinical, regulatory and commercial milestones and prevent us from realizing the potential commercial benefits of the collaboration.

Our license agreement with Beckman Coulter generally is terminable by Beckman Coulter on 90-days written notice. If Beckman Coulter were to terminate or materially breach the license agreement, and we were unable to enter into a similar agreement with another qualified third party in a timely manner or devote sufficient financial resources or capabilities to continue development and commercialization on our own, the development and commercialization of a diagnostic based on the detection of HMGB1 likely would be delayed, curtailed or terminated.

In addition, our collaborations with MedImmune and Beckman Coulter and any future third-party collaborative arrangements may not be scientifically or commercially successful. Factors that may affect the success of collaborations include the following:

- Collaborators may be pursuing alternative technologies or developing alternative products, either on their own or in collaboration with others, that may be competitive with the product on which they are collaborating with us or that could affect our collaborators commitment to us;

- Reductions in marketing or sales efforts or a discontinuation of marketing or sales of our products by our collaborators would reduce our revenues, which we expect will be based on a percentage of net sales by

collaborators;

Collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the business and financial communities;

Table of Contents

Collaborators may not devote sufficient time and resources to any collaboration with us, which could prevent us from realizing the potential commercial benefits of that collaboration; and

Collaborators may pursue higher priority programs or change the focus of their development programs, which could affect their commitments to us.

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or the commercialization of the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration of our collaboration agreements would adversely affect us financially and could harm our business reputation.

Risks Relating to Intellectual Property and Licenses

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

Our success depends in part on our ability to obtain and maintain protection for the intellectual property covering or incorporated into our technology and products, whether such technology is owned by us or licensed to us by third parties. Patent protection in the pharmaceutical field is highly uncertain and involves complex legal and scientific questions. We and our licensors may not be able to obtain additional issued patents relating to our respective technology or products. Even if issued, patents issued to us or our licensors may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the longevity of the patent protection we may have for our products. For example, two United States patents exclusively licensed to us have been challenged by third parties in re-examination proceedings before the United States Patent and Trademark Office. While we no longer rely on one of the patents to protect any of our products, we believe that the other United States patent being re-examined, the 372 Patent, covers ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX Dose Pack PE and ALLERX Dose Pack PE 30. In addition, Breckenridge filed suit on November 10, 2008, against Cornerstone BioPharma, Inc. in the United States District Court for the District of Maryland seeking, among other things, a declaratory judgment that the 372 Patent is invalid. The re-examination proceedings before the United States Patent and Trademark Office and the Breckenridge litigation are described in greater detail below under the caption Legal Proceedings in Part I, Item 3. If the United States Patent and Trademark Office or the United States District Court for the District of Maryland finds that some or all of the claims under the 372 Patent are invalid, our sales of the ALLERX Dose Pack products and our future operating and financial results could be adversely affected. Additionally, changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

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

application covering our product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the United States Patent and Trademark Office to determine priority of invention in the United States. These proceedings are costly and time-consuming, and it is possible that our efforts could be unsuccessful, resulting in a loss of our United States patent protection. In addition, United States patents generally expire, regardless of the date of issue, 20 years from the earliest claimed non-provisional filing date. Because the timing for submission of our applications to the FDA for regulatory approval of our product candidates is uncertain and, once submitted, the FDA regulatory process and timing for regulatory approval with respect to our product candidates is unpredictable, our estimates regarding the

Table of Contents

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 Pharmaceutical Innovations for ALLERX Dose Pack and ALLERX Dose Pack PE, Pharmaceutical Innovations 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 Pharmaceutical Innovations fails to do so. In addition, both Pharmaceutical Innovations and we have 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 SPECTRACEF and in the SPECTRACEF line extension product candidates will expire in April 2009, and the composition of matter patent for the API in ZYFLO CR and ZYFLO will expire in December 2010 and none of our other current products or current product candidates have, or will have, composition of matter patent protection.

Some of our currently marketed products do not have patent protection and in most cases such products face generic competition. In addition, although we own or exclusively license United States patents and patent applications with claims directed to the pharmaceutical formulations of our product candidates, methods of use of our product candidates to treat particular conditions, delivery systems for our product candidates, delivery profiles of our product candidates and methods for producing our product candidates, patent protection is not available for composition of matter claims directed to the APIs of any of our products or product candidates other than the SPECTRACEF products, the SPECTRACEF line extensions, ZYFLO CR and ZYFLO. The SPECTRACEF composition of matter United States patent expires in April 2009. The composition of matter United States patent for zileuton that is used in ZYFLO CR and ZYFLO will expire in December 2010.

Because the composition of matter patent for the API in SPECTRACEF expires in April 2009 and for the API in ZYFLO CR and ZYFLO expires in December 2010, 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.

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

Table of Contents

patients may not readily associate our trademark with the applicable product or API. In addition, prescriptions written for a branded product are typically filled with the generic version at the pharmacy if an approved generic is available, resulting in a significant loss in sales of the branded product, including for indications for which the generic version has not been approved for marketing by the FDA. Competitors also may use marks or names that are similar to our trademarks. If we initiate legal proceedings to seek to protect our trademarks, the costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful.

Competitors may also seek to cancel our similar trademarks based on the competitor s prior use. For example, on May 15, 2008, the United States Patent and Trademark Office sent written notice to us that Bausch & Lomb Incorporated, or Bausch & Lomb, filed a cancellation proceeding with respect to the ALLERX registration, 3,384,232 (serial number 77120121), seeking to cancel the ALLERX registration based on Bausch & Lomb s claims that such registration dilutes the distinctive quality of Bausch & Lomb s Alrex® trademark and that Bausch & Lomb is likely to be damaged by the ALLERX registration. We responded to the Trademark Trial and Appeal Board, or TTAB, on June 24, 2008 opposing the claims by Bausch & Lomb. On February 10, 2009, the TTAB suspended proceedings for a period of six months to allow the parties to negotiate a possible settlement of the cancellation proceeding. If the settlement discussions do not provide a prior resolution, we could take numerous courses of action, including continuing to oppose the claims, undertaking action to cancel Bausch & Lomb s registration of its Alrex® trademark, or entering into discovery. If the United States Patent and Trademark Office cancels the ALLERX registration, we will be required to cease marketing products under that brand, which could adversely affect sales of the ALLERX Dose Pack products and our future operating and financial results.

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

We have acquired intellectual property rights relating to all of our 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. For example, we acquired from Meiji the exclusive United States rights to market, develop and commercialize SPECTRACEF. Pursuant to our agreement with Meiji, we obtained an exclusive license to use know-how and trademarks to commercialize SPECTRACEF and any other pharmaceutical product, such as SPECTRACEF Suspension, containing the API cefditoren pivoxil in the United States.

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. For example, we have entered into an agreement with Neos and Coating Place directed to commercialization of certain antitussive and antihistamine combination products, which obligates us to use commercially reasonable efforts to carry out development and regulatory activities within timelines specified in such development agreement. Under this agreement, we are obligated to use commercially reasonable efforts to develop and commercially launch products containing an antitussive and antihistamine in the United States as soon as practicable, and thereafter to maximize sales of such licensed product in the United States. If we fail to comply with these obligations or otherwise breach the license agreement, Neos or Coating Place may have the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could prevent or impede our ability to market any product that is covered by the licensed patents. Even if we contest any such termination or claim and are ultimately successful, we could suffer adverse consequences to our operations and business interests.

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

Table of Contents

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

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

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

As a result of patent infringement or other similar claims or to avoid potential claims, we or our potential future collaborators may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. For example, our MedImmune collaboration agreement provides that a portion of the royalties payable to us by MedImmune for licenses to our intellectual property may be offset by amounts paid by MedImmune to third parties who have competing or superior intellectual property positions in the relevant fields, which could result in significant reductions in our revenues. 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 United States Patent and Trademark Office, 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.

Table of Contents

Risks Relating to Financial Results

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

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

As of December 31, 2008, we had approximately $9.3 million of cash and cash equivalents on hand and available borrowing capacity of $3.9 million under our $4.0 million revolving line of credit. Based on our current operating plans, we believe that our existing cash and cash equivalents, revenue from product sales and borrowing availability under our revolving line of credit are sufficient to continue to fund our existing level of operating expenses and capital expenditure requirements for the foreseeable future.

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

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

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

To the extent that our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all. Our only committed external source of funds is borrowing availability under our revolving line of credit, which is personally guaranteed by our President and Chief Executive Officer. Our ability to borrow under the revolving line of credit is subject to our satisfaction of specified conditions.

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

Table of Contents

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 have incurred significant losses and may incur losses in the future.

Critical Therapeutics experienced significant operating losses in each year from its inception in 2000 until its merger with Cornerstone BioPharma, and Cornerstone BioPharma experienced operating losses from its inception in 2004 and has only been profitable beginning in 2007. As a combined company, we may be unable to sustain and increase our profitability, even if we are able to commercialize additional products. To date, we have financed our operations primarily with revenue from product sales and borrowings. We have devoted substantially all of our efforts to:

establishing a sales and marketing infrastructure;

acquiring marketed products, product candidates and related technologies;

commercializing marketed products; and

developing product candidates, including conducting clinical trials.

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

seek FDA approval for the SPECTRACEF line extensions;

advance the development of other product candidates, including our anticholinergic and antihistamine combination product candidate and antitussive and antihistamine combination product candidates;

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

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

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

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

successfully completing clinical trials of our product candidates;

obtaining and maintaining regulatory approval for these product candidates; and

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

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

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

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, stockholders deficit, 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.

Table of Contents

Actual sales allowances may exceed our estimates for a variety of reasons, including unanticipated competition, regulatory actions or changes in one or more of our contractual relationships. We cannot assure you, therefore, that any of our estimates, or the assumptions underlying them, will be correct.

Our short operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We have a short operating history. Cornerstone BioPharma commenced active operations in 2004. Excluding ZYFLO CR and ZYFLO, Cornerstone acquired most of its currently marketed products and product candidates through two licensing transactions, one for the ALLERX Dose Pack products in February 2005 and the other for SPECTRACEF in October 2006, after these products were already being marketed by other companies. Excluding approvals to market ZYFLO and ZYFLO CR obtained by Critical Therapeutics personnel who are no longer with Cornerstone and the approval for SPECTRACEF 400 mg, for which the FDA approved Cornerstone s sNDA in July 2008 and which we launched in October 2008, we have not received approval from the FDA for any of our products or demonstrated our ability to obtain regulatory approval for any drugs that we have developed or are developing. In addition, we have not demonstrated our ability to initiate sales and marketing activities for successful commercialization of a newly approved product. As a relatively new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors.

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:

- new product launches, which could increase revenues but also increase sales and marketing expenses;
- acquisition activity;
- one-time charges, such as for inventory expiration or product quality issues;
- increases in research and development expenses resulting from the acquisition of a product candidate that requires significant additional development;
- changes in the competitive, regulatory or reimbursement environment, 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; and
- price erosion and customer consolidation.

Additionally, the ongoing integration of the Cornerstone BioPharma and Critical Therapeutics businesses following our merger could cause disruptions to our ongoing operations and be distracting to our management, which could

cause fluctuations in our operating results. We may never fully realize the benefits or synergies from the merger that we have anticipated. If we are unable to successfully integrate our business operations following the consummation of the merger, our results of operations and financial condition could be materially and adversely affected.

Table of Contents

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

We depend to a great extent on the principal members of our management and scientific staff. The loss of the services of any of our key personnel, in particular, Craig Collard, President and Chief Executive Officer, Brian Dickson, M.D., Chief Medical Officer, and David Price, Executive Vice President of Finance and Chief Financial Officer, might significantly delay or prevent the achievement of our development and commercialization objectives and could cause us to incur additional costs to recruit replacements. Each member of our executive management team may terminate his or her employment at any time. We do not maintain key person life insurance with respect to any of our executives. Furthermore, if we decide to recruit new executive personnel, we will incur additional costs.

We may experience turnover amongst our board of directors. If our board were to fail to satisfy the requirements of relevant rules and regulations of the SEC and NASDAQ relating to director independence or membership on board committees, this could result in the delisting of our common stock from NASDAQ or could adversely affect investors confidence in us and our ability to access the capital markets. If we are unable to attract and retain qualified directors, the achievement of our corporate objectives could be significantly delayed or may not occur.

We identified a material weakness in our internal control over financial reporting as of December 31, 2008 that has not yet been effectively remediated. If we fail to achieve and maintain effective internal control over financial reporting and disclosure controls and procedures, we could face difficulties in preparing timely and accurate financial statements and periodic reports, which could result in a loss of investor confidence in the information that we report and a decline in our stock price, and could impair our ability to raise additional funds to the extent needed to meet our future capital requirements.

In connection with the preparation of our financial statements as of and for the year ended December 31, 2008, we identified a material weakness in our internal control over financial reporting as discussed in Item 9A(T), Controls and Procedures, of this annual report on Form 10-K. As discussed in Item 9A(T), as a result of this material weakness, our chief executive officer and chief financial officer concluded that, as December 31, 2008, our disclosure controls and procedures were not effective. While we are in the process of implementing steps to remedy this material weakness, we may not be successful in doing so. In addition, we or our independent registered public accounting firm may identify additional material weaknesses in our internal control over financial reporting in the future, including in connection with our management s ongoing assessment of our internal control over financial reporting, which is discussed in Item 9A(T). Any failure or difficulties in promptly and effectively remediating our presently identified

material weakness, or any material weaknesses that we or our independent registered public accounting firm may identify in the future, could result in our inability to prevent or detect material misstatements in our financial statements and cause us to fail to meet our periodic reporting obligations. As a result, our management may not be able to provide an

Table of Contents

unqualified assessment of our internal control over financial reporting as of December 31, 2009 or beyond, and our chief executive officer and chief financial officer may not be able to conclude, on a quarterly basis, that our disclosure controls and procedures are effective. In addition, our independent registered public accounting firm may not be able to provide an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2009 or beyond. Any material weakness, or any remediation thereof that is ultimately unsuccessful, could also cause investors to lose confidence in the accuracy and completeness of our financial statements and periodic reports, which in turn could harm our business, lead to a decline in our stock price and impair our ability to raise additional funds to the extent needed to meet our future capital requirements.

Our management will be required to devote substantial time to comply with public company regulations.

As a public company, we will incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and NASDAQ, impose various requirements on public companies, including with respect to corporate governance practices. Some of our management and other personnel do not have substantial experience complying with the requirements applicable to public companies and will need to devote a substantial amount of time to these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

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

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

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 results of current and any future clinical trials;

Table of Contents

the entry into, or termination of, key agreements, including key strategic alliance 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 any of our 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;

the results of clinical trials conducted by others on products that would compete with our product candidates;

issues in manufacturing our product candidates or any approved products;

the loss of key employees;

the introduction of technological innovations or new commercial products by our competitors;

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

future sales of our common stock;

changes in the structure of health care payment systems; and

period-to-period fluctuations in our financial results.

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.

If we fail to continue to meet all applicable continued listing requirements of The NASDAQ Capital Market and NASDAQ determines to delist our common stock, the market liquidity and market price of our common stock could decline.

Our common stock is currently listed on The NASDAQ Capital Market. In order to maintain that listing, we must satisfy minimum financial and other listing requirements. If we fail to continue to meet all applicable listing requirements of The NASDAQ Capital Market and NASDAQ determines to delist our common stock, an active trading market for our common stock may not be sustained and the market price of our common stock could decline. If an active trading market for our common stock is not sustained, it will be difficult for our stockholders to sell shares of our common stock without further depressing the market price of our common stock or at all. A delisting of our common stock also could make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

If our quarterly results of operations fluctuate, this fluctuation may subject our stock price to volatility, which may cause an investment in our stock to suffer a decline in value.

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. A number of factors, many of which are not within our control, could subject our operating results and stock price to volatility, including:

- variations in the amount and timing of sales of the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products, our propoxyphene/acetaminophen products, and other products due to changes in product pricing, changes in the prevalence of disease conditions from quarter to quarter or other factors;

- the timing of operating expenses, including selling and marketing expenses and the costs of maintaining a direct sales force;

Table of Contents

the availability and timely delivery of a sufficient supply of the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products, our propoxyphene/acetaminophen products, and other products;

the amount of rebates, discounts and chargebacks to wholesalers, Medicaid, federal and state healthcare programs, and MCOs related to the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products, our propoxyphene/acetaminophen products, and other products;

the amount and timing of product returns for the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products, our propoxyphene/acetaminophen products, and other products;

achievement of, or the failure to achieve, milestones under our development agreement with MedImmune, our license agreement with Beckman Coulter and, to the extent applicable, other licensing and collaboration agreements;

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

production problems occurring at our third-party manufacturers;

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

general and industry-specific economic conditions that may affect our research and development expenditures.

Due to the possibility of significant fluctuations, we do not believe that quarterly comparisons of our operating results will necessarily be indicative of our future operating performance. If our quarterly operating results fail to meet the expectations of stock market analysts and investors, the price of our common stock may decline.

If significant business or product announcements by us or our competitors cause fluctuations in our stock price, an investment in our stock may suffer a decline in value.

The market price of our common stock may be subject to substantial volatility as a result of announcements by us or other companies in our industry, including our collaborators. Announcements that may subject the price of our common stock to substantial volatility include announcements regarding:

our operating results, including the amount and timing of sales of our products, including the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products, our propoxyphene/acetaminophen products, and other products;

the availability and timely delivery of a sufficient supply of our products, including the SPECTRACEF products, ZYFLO CR, the ALLERX Dose Pack products, the HYOMAX line of products, our propoxyphene/acetaminophen products, and other products;

Our licensing and collaboration agreements and the products or product candidates that are the subject of those agreements;

the results of discovery, preclinical studies and clinical trials by us or our competitors;

the acquisition of technologies, product candidates or products by us or our competitors;

the development of new technologies, product candidates or products by us or our competitors;

regulatory actions with respect to our product candidates or products or those of our competitors; and

significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors.

Table of Contents

Insiders have substantial control 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 of December 31, 2008, our directors, executive officers and 10% or greater stockholders, together with their affiliates, to our knowledge, beneficially owned, in the aggregate, approximately 52% of our outstanding common stock. As a result, our directors, executive officers and 10% or greater stockholders, together with their affiliates, if acting together, may have the ability to affect the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control the company s management and affairs. Accordingly, this concentration of ownership may harm the value of the company s common stock by:

delaying, deferring or preventing a change in control;

impeding a merger, consolidation, takeover or other business combination; or

discouraging a potential acquirer from making an acquisition proposal or otherwise attempting to obtain control.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or frustrate attempts by our stockholders to change our management or board of directors and hinder efforts by a third party to acquire a controlling interest in our company.

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our charter documents may make a change in control more difficult, even if the stockholders desire a change in control. For example, anti-takeover provisions include provisions in our bylaws and certificate of incorporation providing that, except as otherwise required by law, special meetings of the stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president (if the president is different than the chief executive officer) or the board of directors, and that stockholders may not take action by written consent and provisions in our bylaws providing for the classification of the board of directors. Additionally, the board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the terms of those shares of stock without any further action by the stockholders. The rights of holders of the common stock are subject to the rights of the holders of any preferred stock that the company issues. As a result, our issuance of preferred stock could cause the market value of the common stock to decline and could make it more difficult for a third party to acquire a majority of our outstanding voting stock.

Delaware law also prohibits a corporation from engaging in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. The board of directors may use this provision to prevent changes in management. Also, under applicable Delaware law, the board of directors may adopt additional anti-takeover measures in the future.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

Not applicable.

ITEM 2. *PROPERTIES*

We lease approximately 15,000 square feet of office space in Cary, North Carolina. The lease expires on March 16, 2016, and we have an option to extend the term of the lease for an additional five years through March 2021. Initial

annual base rent under the lease is approximately $350,000 with annual rent increases of approximately 3%. In addition to rent, we are obligated to pay certain operating expenses and taxes. We believe our facilities are sufficient to meet our needs for the foreseeable future.

ITEM 3. ***LEGAL PROCEEDINGS***

In November 2006, we were named as a defendant in an action filed in New York County, New York by Adams captioned *Adams Respiratory Therapeutics, Inc. (f/k/a Adams Laboratories, Inc.) v. Cornerstone BioPharma, Inc. and Carolina Pharmaceuticals, Inc.*, Supreme Court of the State of New York, New York

Table of Contents

County, Index No. 603969/2006. The complaint alleged breach of contract concerning a settlement agreement between Adams and us dated January 14, 2005. The complaint also alleged claims concerning the settlement agreement for failure to pay the agreed amount, fraudulent misrepresentation and negligent misrepresentation. We filed an answer to the complaint in which we denied the material allegations of the complaint and asserted counterclaims against Adams for breach of contract concerning the settlement agreement. Following mediation in March 2008, we reached an agreement with Adams to settle all matters, which resulted in the execution of a new settlement agreement in May 2008. We and Carolina Pharmaceuticals, Inc. completed payment of the $1.5 million settlement amount to Reckitt Benckiser Inc., the parent of Adams, on or about September 30, 2008, and the litigation was dismissed with prejudice on October 6, 2008.

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 U.S. Patent and Trademark Office ordered a re-examination of the 796 patent as a result of a third-party request for ex parte re-examination. We and J-Med Pharmaceuticals, Inc., or J-Med, the licensor of the 796 Patent, have asserted infringements of the 796 Patent in litigation with each of Everton Pharmaceuticals, LLC, or Everton, Breckenridge and Vision, and manufacturers and related parties of each, alleging that those parties had infringed the 796 Patent by making, using, selling, offering for sale or importing into the United States pharmaceutical products intended as generic equivalents to the former formulation of ALLERX 10 Dose Pack and ALLERX 30 Dose Pack protected under claims in the 796 Patent. Everton and Breckenridge entered into settlement agreements in January 2007 and July 2007, respectively, and agreed to cease selling the infringing products. In October 2007, we and J-Med filed an action in the U.S. District Court for the Eastern District of North Carolina against Vision and Nexgen Pharma, Inc. captioned *Cornerstone BioPharma, Inc. and J-Med Pharmaceuticals, Inc. v. Vision Pharma, LLC and Nexgen Pharma, Inc.*, No. 5:07-CV-00389-F. In this action, we and J-Med alleged that the product known as VisRx infringes the 796 Patent. On November 19, 2007, we and J-Med filed an amended complaint asserting claims against Vision s principals, Sander Busman, Thomas DeStefano and Michael McAloose. On November 30, 2007, defendants moved to stay the litigation pending the re-examination of the 796 Patent. The Court granted defendants motion and stayed the litigation pending the re-examination of the 796 Patent on February 15, 2008.

In proceedings before a re-examination examiner in the U.S. Patent and Trademark Office, the examiner rejected claims of the 796 Patent as failing to satisfy novelty and non-obviousness criteria for U.S. patent claims. J-Med appealed to the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences, or Board of Patent Appeals, on June 13, 2008, seeking reversal of the examiner s rejections. On the same date, J-Med filed additional documents with the U.S. Patent and Trademark Office for review by the examiner. If the examiner does not reverse his prior rejections, then the Board of Patent Appeals will act on the case and can take various actions, including affirming or reversing the examiner s rejections in whole or part, or introducing new grounds of rejection of the 796 Patent claims. If the Board of Patent Appeals thereafter affirms the examiner s rejections, J-Med can take various further actions, including requesting reconsideration by the Board of Patent Appeals, filing a further appeal to the U.S. Court of Appeals for the Federal Circuit or instituting a reissue of the 796 Patent with narrowed claims. The further proceedings involving the 796 Patent therefore may be lengthy in duration, and may result in invalidation of some or all of the claims of the 796 Patent.

On June 13, 2008, counsel for Vision filed in the U.S. Patent and Trademark Office a request for re-examination of certain claims under the 372 Patent, which we believe covers ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX Dose Pack PE and ALLERX Dose Pack PE 30. Our counsel reviewed the request for re-examination and the patents and publications cited by counsel for Vision, and our counsel have concluded that valid arguments exist for distinguishing the claims of the 372 Patent over the references cited in the request for re-examination. On August 21, 2008, the U.S. Patent and Trademark Office determined that a substantial new question of patentability was raised by the patents and publications cited by Vision. We will have the opportunity in coordination with the patent owner, Pharmaceutical Innovations, to present substantive arguments supporting the patentability of the claims issued in the

372 Patent. If the re-examination examiner in the U.S. Patent and Trademark Office rejects claims of the 372 Patent, Pharmaceutical Innovations may appeal to the Board of Patent Appeals to seek reversal of the examiner s rejections. If Pharmaceutical

Table of Contents

Innovations does not receive relief from the Board of Patent Appeals, Pharmaceutical Innovations could file a further appeal to the U.S. Court of Appeals for the Federal Circuit or could institute a reissue of the 372 Patent with narrowed claims. The further proceedings involving the 372 Patent therefore may be lengthy in duration, and may result in invalidation of some or all of the claims of the 372 Patent.

In February 2008, we filed a notice of opposition before the TTAB in relation to Application No. 77/226,994 filed in the U.S. Patent and Trademark Office by Vision, seeking registration of the mark VisRx. The opposition proceeding is captioned *Cornerstone BioPharma, Inc. v. Vision Pharma, LLC*, Opposition No. 91182604. In April 2008, Vision filed an Answer to Notice of Opposition and Counterclaims in which it requested cancellation of U.S. Registrations No. 3,384,232 and 2,448,112 for the mark ALLERX owned by us. Vision did not request monetary relief. We responded to Vision s counterclaims on May 16, 2008. On December 2, 2008, Vision filed a motion for judgment on the pleadings as to our opposition to Vision s application for registration of the mark VisRx. By order dated December 3, 2008, the TTAB suspended all proceedings pending disposition of Vision s motion. We responded to Vision s motion on January 9, 2009. We intend to defend our interests vigorously against the counterclaims asserted by Vision.

On May 15, 2008, the U.S. Patent and Trademark Office sent written notice to us that a cancellation proceeding had been initiated by Bausch & Lomb against the ALLERX trademark registration. The petition to cancel filed in this proceeding alleges that the ALLERX registration dilutes the distinctive quality of Bausch & Lomb s Alrex® trademark and that Bausch & Lomb is likely to be damaged by the ALLERX registration. We are currently engaged in settlement discussions with Bausch & Lomb concerning a refinement of the product description in the ALLERX trademark registration to distinguish it from the product marketed by Bausch & Lomb under the Alrex trademark. We responded to the TTAB on June 24, 2008, opposing the claims in the Bausch & Lomb cancellation petition, while concurrently continuing to seek settlement of the cancellation proceeding on favorable terms. We could take any of numerous courses of action, including continuing to oppose Bausch & Lomb s claims, undertaking action to cancel Bausch & Lomb s registration of its Alrex trademark or entering into discovery. A final decision by the TTAB could take several years.

On September 17, 2008, a purported shareholder class action lawsuit was filed by a single plaintiff against us and each of our then current directors in the Court of Chancery of the State of Delaware. The action is captioned *Jeffrey Benison IRA v. Critical Therapeutics, Inc., Trevor Phillips, Richard W. Dugan, Christopher Mirabelli, and Jean George*, Case No. 4039, Court of Chancery, State of Delaware. The plaintiff, which claimed to be one of our stockholders, brought the lawsuit on its own behalf, and sought certification of the lawsuit as a class action on behalf of all stockholders of Critical Therapeutics, except the defendants and their affiliates. The complaint alleged, among other things, that the defendants breached fiduciary duties of loyalty and good faith, including a fiduciary duty of candor, by failing to provide Critical Therapeutics stockholders with a proxy statement/prospectus adequate to enable them to cast an informed vote on the proposed merger, and by possibly failing to maximize stockholder value by entering into an agreement that effectively discourages competing offers. The complaint sought, among other things, an order (i) enjoining the defendants from proceeding with or implementing the proposed merger on the terms and under the circumstances as they then existed, (ii) invalidating the provisions of the proposed merger that purportedly improperly limited the effective exercise of the defendants continuing fiduciary duties, (iii) ordering defendants to explore alternatives and to negotiate in good faith with all bona fide interested parties, (iv) in the event the proposed merger was consummated, rescinding it and setting it aside or awarding rescissory damages, (v) awarding compensatory damages against defendants, jointly and severally, and (vi) awarding the plaintiff and the purported class their costs and fees.

On October 17, 2008, we and the other defendants entered into a memorandum of understanding with the plaintiff regarding the settlement of the lawsuit. In connection with the settlement, the parties agreed that we would make certain additional disclosures to Critical Therapeutics stockholders, which are contained in a supplement to the proxy

statement/prospectus that was mailed to Critical Therapeutics stockholders. After the completion of certain confirmatory discovery by counsel to the plaintiff, as contemplated by the memorandum of understanding, the parties entered into a stipulation and agreement of compromise, settlement and release on November 24, 2008. On December 3, 2008, the court entered a scheduling order preliminarily approving class treatment of the case and setting a briefing and hearing schedule to consider the proposed settlement of

Table of Contents

the case. On December 23, 2008, we caused a court-approved notice of pendency of class action, proposed class action determination, proposed settlement of class action, settlement hearing and right to appear to be mailed to all persons that held Critical Therapeutics stock during the period May 1, 2008 through October 31, 2008, other than the defendants and their affiliates. On February 26, 2009, the court approved the settlement resolving all of the claims that were or could have been brought in the action being settled, including all claims relating to the merger, the merger agreement and any disclosure made in connection therewith. In addition, in connection with the settlement, the court awarded plaintiff s counsel $175,000 for attorneys fees and expenses to be paid by us.

On November 10, 2008, we were named as a defendant in an action filed by Breckenridge in the United States District Court for the District of Maryland captioned *Breckenridge Pharmaceutical, Inc. v. Cornerstone BioPharma, Inc., J-Med Pharmaceuticals, Inc. and Allan M. Weinstein*, No. 8:08-CV-02999-DKC. Breckenridge seeks a declaratory judgment that the 372 Patent and U.S. Patent No. 6,651,816, or the 816 patent, are invalid. The 372 Patent is licensed to us by Pharmaceutical Innovations, an affiliate of J-Med. We do not have an interest in the 816 Patent. Breckenridge also seeks a declaratory judgment that its Allergy DN II and Allergy DN PE products do not infringe the 372 and 816 Patents. Breckenridge also seeks a declaratory judgment that our claimed copyright in the product informational inserts for ALLERX® DF and ALLERX® PE are invalid and/or not infringed by the product informational inserts for Allergy DN II and Allergy DN PE. Breckenridge does not request monetary relief. We have not yet responded to Breckenridge s complaint but we intend to defend our interests vigorously against the claims asserted by Breckenridge.

ITEM 4. ***SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS***

The following matters were submitted to a vote of our stockholders at a special meeting of stockholders held on October 31, 2008 and approved by the requisite vote of stockholders as follows:

1. To approve the issuance of our common stock pursuant to the Agreement and Plan of Merger, dated as of May 1, 2008, by and among Critical Therapeutics (now known as Cornerstone Therapeutics), Neptune Acquisition Corp., a wholly owned subsidiary of Critical Therapeutics, and Cornerstone BioPharma.

	Number of Shares	
For	**Against**	**Abstain**
27,750,431	298,459	28,100

2. To approve an amendment to our certificate of incorporation to effect a reverse split of our common stock.

	Number of Shares	
For	**Against**	**Abstain**
27,559,122	490,272	27,596

3. To approve an amendment to our certificate of incorporation to change our name to Cornerstone Therapeutics Inc.

	Number of Shares	
For	**Against**	**Abstain**
27,785,553	270,637	20,800

The number of shares of common stock eligible to vote as of the record date of September 29, 2008 was 43,332,598 shares.

Table of Contents

EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers, their ages and their positions as of March 15, 2009 are as follows:

Name	Age	Position
Craig A. Collard	43	President and Chief Executive Officer
Chenyqua Baldwin	42	Vice President, Finance, Chief Accounting Officer, Controller, Assistant Treasurer and Assistant Secretary
Brian Dickson, M.D.	58	Chief Medical Officer
Joshua B. Franklin	39	Vice President, Sales and Marketing
Steven M. Lutz	42	Executive Vice President, Manufacturing and Trade
David Price	46	Executive Vice President, Finance, Chief Financial Officer, Treasurer and Assistant Secretary
Scott B. Townsend, Esq.	42	General Counsel, Executive Vice President of Legal Affairs and Secretary

Craig A. Collard has served as our President and Chief Executive Officer and the chairman of our board of directors since our merger with Cornerstone BioPharma in October 2008. In March 2004, Mr. Collard founded Cornerstone BioPharma Holdings, Ltd. (the assets and operations of which were restructured as Cornerstone BioPharma in May 2005), and served as its President and Chief Executive Officer and a director from March 2004 to October 2008. Before founding Cornerstone BioPharma, Mr. Collard s principal occupation was serving as President and Chief Executive Officer of Carolina Pharmaceuticals, Inc., a specialty pharmaceutical company he founded in May 2003. From August 2002 to February 2003, Mr. Collard served as Vice President of Sales for Verum Pharmaceuticals, Inc., or Verum, a specialty pharmaceutical company in Research Triangle Park, North Carolina. From 1998 to 2002, Mr. Collard worked as Director of National Accounts at DJ Pharma, Inc., a specialty pharmaceutical company which was eventually purchased by Biovail Pharmaceuticals, Inc., or Biovail. His pharmaceutical career began in 1992 as a field sales representative at Dura Pharmaceuticals, Inc., or Dura. He was later promoted to several other sales and marketing positions within Dura. Mr. Collard is a member of the board of directors of Hilltop Home Foundation, a Raleigh, North Carolina, non-profit corporation, in addition to our board of directors. Mr. Collard holds a B.S. in Engineering from the Southern College of Technology (now Southern Polytechnic State University) in Marietta, Georgia.

Chenyqua Baldwin has served as our Vice President of Finance, Chief Accounting Officer, Controller, Assistant Treasurer and Assistant Secretary since our merger with Cornerstone BioPharma. Ms. Baldwin was a founding stockholder of Cornerstone BioPharma and served as its Vice President of Finance from March 2004 to October 2008. Before joining Cornerstone BioPharma, Ms. Baldwin s principal occupation was serving as Vice President of Finance for Carolina Pharmaceuticals, Inc. from January 2004 to August 2004. From February 2001 to January 2004, Ms. Baldwin served in the positions of Director of Finance and Director of Accounting with Biovail. Ms. Baldwin holds a Masters of Accounting and B.S. in Business Administration from the University of North Carolina at Chapel Hill.

Brian Dickson, M.D. has served as our Chief Medical Officer since our merger with Cornerstone BioPharma. Dr. Dickson served as the Chief Medical Officer of Cornerstone BioPharma from May 2005 to October 2008. Before joining Cornerstone BioPharma, Dr. Dickson served as the Chief Medical Officer at Inveresk Research Group Inc., or Inveresk, from May 2004 until December 2004. From January 2005 to April 2005, Dr. Dickson served as an

independent consultant to pharmaceutical companies. Prior to Inveresk, he served as Chief Medical Officer at Covalent Group Inc. (now Encorium), a contract research organization, from 2001 to 2003. Dr. Dickson also worked in senior management with Smith, Kline & French Laboratories Ltd. from 1978 to 1987, Searle from 1988 to 1991, and Warner Lambert / Parke Davis from 1991 to 1994. In addition to Dr. Dickson s industry experience, he is a past Editor-in-Chief of the Journal of Pharmaceutical Medicine and is a member of the Faculty of Pharmaceutical Medicine. Dr. Dickson received his Doctor of Medicine from Adelaide University in South Australia.

Table of Contents

Joshua B. Franklin has served as our Vice President of Sales and Marketing since December 2008 and before that as Vice President of Marketing since our merger with Cornerstone BioPharma. Mr. Franklin served as Vice President of Marketing for Cornerstone BioPharma from September 2008 to October 2008. Before joining Cornerstone BioPharma, 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 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.

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

David Price has served as our Executive Vice President, Finance, Chief Financial Officer, Treasurer and Assistant Secretary since our merger with Cornerstone BioPharma. Mr. Price served as Executive Vice President, Finance, and Chief Financial Officer of Cornerstone BioPharma from September 2008 to October 2008. Before joining Cornerstone BioPharma, Mr. Price served as a Managing Director for Jefferies & Company, Inc, an investment banking firm, from April 2006 to September 2008 in the Specialty Pharmaceutical and Pharmaceutical Services investment banking practice. From September 2000 to March 2006, Mr. Price served as a Managing Director for Bear, Stearns & Co. Inc., an investment banking firm, in London and in New York. Mr. Price served as the Director of the Merger Integration Practice of PriceWaterhouseCoopers Consulting from 1997 to 2000. From 1993 to 1997, Mr. Price served as Mergers and Acquisitions Director for Lex Service PLC, an automotive services provider. He worked as an Audit Senior Manager and Corporate Finance Manager for Price Waterhouse, an accounting firm, in London and Los Angeles from 1987 to 1993. He worked for Arthur Andersen & Co., an accounting firm, as an Audit Assistant from 1984 to 1987. Mr. Price qualified as a Chartered Accountant in 1987 with the Institute of Chartered Accountants in England and Wales and holds an Honours degree in Accounting and Financial Management from Lancaster University, Lancaster, United Kingdom.

Scott B. Townsend, Esq. has served as our General Counsel, Executive Vice President of Legal Affairs and Secretary since our merger with Cornerstone BioPharma. Before the merger, Mr. Townsend served as our Senior Vice President of Legal Affairs from March 2007 to October 2008, as our General Counsel from June 2006 to October 2008 and as our Secretary from September 2004 to October 2008. Mr. Townsend served as our Vice President of Legal Affairs from August 2004 to March 2007. From August 2000 to August 2004, Mr. Townsend was employed by the law firm Wilmer Cutler Pickering Hale and Dorr LLP (formerly known as Hale and Dorr LLP) as a junior partner from May 2002 to August 2004 and as an associate from August 2000 to May 2002. Mr. Townsend was an associate with the law firm Kilpatrick Stockton LLP in Charlotte, North Carolina, from July 1999 to July 2000 and an associate with the law firm Goodwin Procter LLP in Boston, Massachusetts, from September 1997 to July 1999. Mr. Townsend holds an A.B. in Economics and Government from Bowdoin College and a J.D. from The University of Virginia School of Law.

Table of Contents

NON-EMPLOYEE DIRECTORS OF THE REGISTRANT

Our non-employee directors, their ages and their positions as of March 15, 2009 are as follows:

Name	Age	Position
Christopher Codeanne	41	Director
Michael Enright	47	Director
Michael Heffernan	44	Director
Alastair McEwan	53	Director

Christopher Codeanne has served on our board of directors since our merger with Cornerstone BioPharma. Since April 2008, Mr. Codeanne has served as Chief Operating Officer and Chief Financial Officer of Oncology Development Partners, LLC (d/b/a Oncopartners), a specialized international oncology contract research organization. From December 2006 through April 2008, Mr. Codeanne served as the Chief Financial Officer of Averion International Corp., or Averion, a publicly traded international contract research organization. Prior to Averion, from 2002 through July 2006, Mr. Codeanne was the Chief Financial Officer of SCIREX Corporation (which was acquired by Premier Research Group plc in 2006), or SCIREX, an international, full-service clinical research organization. From 1999 to 2002, Mr. Codeanne served as Director of Finance of SCIREX. Mr. Codeanne is a member of the American Institute of Certified Public Accountants, the Connecticut Society of Certified Public Accountants and Financial Executives International. Mr. Codeanne holds a B.A. in Accounting from Fairfield University and an MBA from the University of Connecticut.

Michael Enright has served on our board of directors since our merger with Cornerstone BioPharma. Since 1995, Mr. Enright has served as Chief Financial Officer for Atlantic Search Group, Inc., a staff augmentation and functional outsourcing services organization serving pharmaceutical companies and contract research organizations in the United States and India. Prior to 1995, Mr. Enright held positions in employee benefits administration with Hauser Insurance Group and The Prudential Insurance Company, and in financial management with General Electric Company s aerospace business group. Mr. Enright holds a B.A. in Finance from Villanova University and an MBA from the Kenan-Flagler School of Business of the University of North Carolina at Chapel Hill.

Michael Heffernan has served on our board of directors since our merger with Cornerstone BioPharma. Since 2002, Mr. Heffernan has served as President and Chief Executive Officer of Collegium Pharmaceutical, Inc., or Collegium, a specialty pharmaceutical company that develops and commercializes products to treat central nervous system, respiratory and skin-related disorders. From 1999 to 2001, Mr. Heffernan served as President and Chief Executive Officer of PhyMatrix Corp., an integrated health care services company. From 1995 to 1999, Mr. Heffernan served as President and Chief Executive Officer of Clinical Studies Ltd., a pharmaceutical clinical development company. From 1987 to 1994, Mr. Heffernan served in variety of sales and marketing positions with Eli Lilly and Company, a pharmaceutical company. Mr. Heffernan has also served on the board of directors of TyRx Pharma, Inc. since 2002. Mr. Heffernan holds a B.S. in Pharmacy from the University of Connecticut and is a Registered Pharmacist.

Alastair McEwan has served on our board of directors since our merger with Cornerstone BioPharma. Mr. McEwan joined Cornerstone BioPharma s board of directors in August 2005 and became chairman of its board of directors in January 2006. From October 2005 through December 2005, Mr. McEwan served as Cornerstone BioPharma s interim Chief Financial Officer. From June 1996 to December 2004, Mr. McEwan served in a variety of positions at Inveresk, including as Group Executive Vice President, as President of Inveresk Global Clinical Operations and President of

Inveresk Clinical Americas operations. Mr. McEwan served as a member of the Group Executive Board of Inveresk from 1999 to 2004. Mr. McEwan also serves as a member of Averion s board of directors. Mr. McEwan qualified as a Chartered Accountant in 1979 with the Institute of Chartered Accountants of Scotland and holds a Bachelor of Commerce from the University of Edinburgh.

Table of Contents

PART II

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

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

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

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

Year Ended December 31, 2007	**High**	**Low**
First Quarter (from January 1 to March 31)	$ 25.90	$ 15.00
Second Quarter (from April 1 to June 30)	$ 32.30	$ 16.00
Third Quarter (from July 1 to September 30)	$ 25.10	$ 17.10
Fourth Quarter (from October 1 to December 31)	$ 25.20	$ 12.70

On March 20, 2009, the closing price per share of our common stock as reported on the NASDAQ Capital Market was $3.20, and we had approximately 56 stockholders of record. This number does not include beneficial owners for whom shares are held by nominees in street name.

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

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

Not applicable.

Issuer Purchases of Equity Securities

During the fourth quarter of 2008, we purchased 2,265 shares of our common stock as set forth in the following table:

ISSUER PURCHASES OF EQUITY SECURITIES

Period		(a) Total Number of Shares Purchased(1)	(b) Average Price Paid per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
10/1/2008	10/31/2008	2,265(2)	$ 3.90(2)		
11/1/2008	11/30/2008	220	3.60		
12/1/2008	12/31/2008				
Total		2,485	$ 3.87		

(1) Relates to shares employees have elected to have withheld to cover their minimum tax withholding requirements related to the vesting of restricted stock during the fourth quarter of 2008.

(2) As adjusted for the 10-to-1 reverse stock split effected on October 31, 2008.

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

Not required for smaller reporting companies.

Table of Contents

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

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.

Overview

We are a specialty pharmaceutical company focused on acquiring, developing and commercializing significant products primarily for the respiratory market. Our commercial strategy is to in-license or acquire rights to non-promoted or underperforming, patent-protected, branded pharmaceutical products, or late stage product candidates, and then maximize their potential value and competitive position by promoting the products using our sales and marketing capabilities and applying various life cycle management techniques to extend the period we can sell the product and related derivative products. We currently market our products only in the United States.

On October 31, 2008, Critical Therapeutics and Cornerstone BioPharma completed their previously announced merger. Cornerstone BioPharma s reasons for the merger included, among other things, the opportunity to expand Cornerstone BioPharma s respiratory product portfolio, the potential for enhanced future growth and value and the ability to access additional capital. Following the closing of the merger, former Cornerstone BioPharma stockholders owned approximately 70%, and former Critical Therapeutics stockholders owned approximately 30%, of our common stock, after giving effect to shares issuable pursuant to outstanding options and warrants held by Cornerstone BioPharma s stockholders immediately prior to the effective time of the merger, but without giving effect to any shares issuable pursuant to options and warrants held by Critical Therapeutics stockholders immediately prior to the effective time of the merger. Because former Cornerstone BioPharma stockholders owned, immediately following the merger, approximately 70% of the combined company on a fully diluted basis and as a result of certain other factors, Cornerstone BioPharma was deemed to be the acquiring company for accounting purposes and the transaction was treated as a reverse acquisition in accordance with GAAP. Accordingly, for all purposes, our financial statements for periods prior to the merger reflect the historical results of Cornerstone BioPharma, and not Critical Therapeutics, and our financial statements for all subsequent periods reflect the results of the combined company. 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 and ZYFLO) prior to the completion of the merger.

Key Marketed Products

We currently promote SPECTRACEF, ZYFLO CR and the ALLERX Dose Pack family of products. In addition, we have a co-promotion agreement with DEY for the exclusive co-promotion along with us of ZYFLO CR. Under the DEY agreement, we pay DEY a portion of quarterly net sales of ZYFLO CR, after third-party royalties, in excess of $1.95 million.

SPECTRACEF. SPECTRACEF is a third generation cephalosporin with the API cefditoren pivoxil that we are marketing in 200 mg and 400 mg tablet formulations. SPECTRACEF is indicated for the treatment of mild to moderate infections caused by pathogens associated with particular respiratory tract infections. In October 2006, we acquired from Meiji the exclusive U.S. rights to manufacture and sell SPECTRACEF 200 mg and additional

cefditoren pivoxil products and to use the SPECTRACEF trademark from Meiji pursuant to a license and supply agreement, as amended and supplemented. In exchange for these exclusive U.S. rights, we agreed to pay Meiji a $6.0 million non-refundable license fee in installments over five years and quarterly royalties based on the net sales of the cefditoren pivoxil products covered by the agreement. We paid $250,000 of the license fee in 2006, $1.0 million in 2007 and $1.0 million in October 2008. Additional installments of the license fee are due and payable as follows: $1.0 million in October 2009, $1.25 million in

Table of Contents

October 2010 and $1.5 million in October 2011. We are also obligated to make aggregate combined purchases of the API cefditoren pivoxil, SPECTRACEF 200 mg, SPECTRACEF 400 mg and sample packs of SPECTRACEF 400 mg from Meiji exceeding specified dollar amounts annually over a five-year period following the October 2008 launch of SPECTRACEF 400 mg.

ZYFLO CR and ZYFLO. We currently market ZYFLO CR and ZYFLO, which contain the API zileuton and are indicated for the prevention and chronic treatment of asthma in adults and children 12 years of age and older. The FDA approved our NDA for ZYFLO CR, our twice-daily controlled release zileuton product, in May 2007, and we launched ZYFLO CR in October 2007. We began selling ZYFLO in the United States in October 2005.

ALLERX Dose Pack Products. We currently market three ALLERX Dose Pack products, each in 10-day and 30-day regimens:

ALLERX 10 Dose Pack and ALLERX 30 Dose Pack, both of which we began marketing in February 2008;

ALLERX Dose Pack DF and ALLERX Dose Pack DF 30, which we began marketing in August 2006 and July 2007, respectively; and

ALLERX Dose Pack PE and ALLERX Dose Pack PE 30, which we began marketing in September 2006 and October 2007, respectively.

Each of these products is administered orally and is indicated for the temporary relief of symptoms associated with allergic rhinitis. In February 2005, we acquired all of the rights to the ALLERX products held by Adams in exchange for our rights to the Humibid® family of products. We began marketing the first of our ALLERX 10 day Dose Pack products in February 2005. Since adding multiple line extensions as well as a 30 day Dose Pack for patient convenience, we now market ALLERX 10 Dose Pack and ALLERX 30 Dose Pack. We believe that ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX Dose Pack PE and ALLERX Dose Pack PE 30 are protected under claims in the 372 Patent, which we licensed directly from Pharmaceutical Innovations in August 2006. Under our license agreement with Pharmaceutical Innovations, as amended, we pay Pharmaceutical Innovations royalties based on a percentage of annual net sales of each product, subject to specified minimums.

Other Products

We currently generate revenues from product sales and royalties from the sale of other products that we do not actively promote. Of these, HYOMAX, BALACET 325, APAP 500 and DECONSAL have generated the most net revenues to date for us. Of our marketed products that we do not promote, only our BALACET 325 and APAP 325 products are promoted by a third party.

HYOMAX. The HYOMAX line of products consists of generic formulations of four antispasmodic medications containing the API hyoscyamine sulfate, an anticholinergic, which may be prescribed for various gastrointestinal disorders. Aristos launched the first HYOMAX product, HYOMAX SL 0.125 mg tablets, in May 2008, followed by HYOMAX SR 0.375 mg tablets and HYOMAX FT 0.125 mg chewable melt tablets in June 2008 and HYOMAX DT 0.125 mg immediate release/0.25 mg sustained release tablets in July 2008. We pay Sovereign its costs to manufacture the HYOMAX products exclusively for us, as well as a royalty based on a share of the net profits realized from the sale of the products.

BALACET 325, APAP 325 and APAP 500. These products are indicated for the relief of mild to moderate pain. In July 2004, we licensed from Vintage the rights to BALACET 325 and APAP 500 for an upfront payment of $5.0 million, a note payable of $3.0 million and ongoing quarterly royalty payments equal to a percentage of the

products net sales. We paid the note payable in full in February 2006. We began marketing BALACET 325 in April 2005, but ceased all promotional efforts for this product in January 2007 to concentrate our resources on the respiratory market. In December 2006, we licensed the rights to an authorized generic formulation of BALACET 325 from Vintage. In July 2008, we began marketing APAP 325 through our Aristos subsidiary as a generic formulation of BALACET 325.

Table of Contents

In September 2005, we entered into a supply and marketing agreement with Pliva relating to APAP 500. Under this agreement, which we terminated effective December 31, 2008, Pliva sold APAP 500 that was supplied to it by Vintage and paid us royalties based on the quarterly net sales of APAP 500.

In April 2007, we entered into a co-promotion agreement with Atley Pharmaceuticals to co-promote BALACET 325, and APAP 325, which was added pursuant to an amendment to the co-promotion agreement in July 2008. Under this agreement, we pay Atley Pharmaceuticals co-promotion fees based on a percentage of the net profits from our sales of BALACET 325 and APAP 325 above a specified baseline based on prescriptions by all prescribers within assigned sales territories.

DECONSAL. In July 2004, we acquired all rights related to prescription products marketed under the DECONSAL brand name from Carolina Pharmaceuticals Ltd., or Carolina Pharmaceuticals, an entity under common control with us, in exchange for quarterly royalties equal to a percentage of the net sales of DECONSAL products through December 31, 2006. In January 2005, we launched DECONSAL II, an expectorant and nasal decongestant combination tablet for oral administration with the APIs guaifenesin and phenylephrine. In 2006, we launched the DECONSAL CT Tannate Chewable Tablets and DECONSAL DM Tannate Chewable Tablets, which contain an antihistamine, a nasal decongestant and, with respect to DECONSAL DM, an antitussive. In May 2007, the FDA announced that manufacturers must stop making products that contain guaifenesin in a timed release dosage form by August 27, 2007 and stop shipping in interstate commerce by November 25, 2007. As a result, we stopped selling DECONSAL II in November 2007.

Product Candidates

Our product development pipeline includes two SPECTRACEF line extensions, an anticholinergic and antihistamine combination product candidate, and two extended-release antitussive and antihistamine combination product candidates. The SPECTRACEF line extensions include:

SPECTRACEF Once Daily, a single tablet, once-daily dosage of SPECTRACEF, for which we commenced a clinical trial in the fourth quarter of 2008 and expect to commence additional clinical trials in late 2009, with an sNDA submission targeted for 2011; and

SPECTRACEF Suspension, an oral, liquid suspension of SPECTRACEF, for which we expect to rely on previous clinical trials for use of this product candidate by children with pharyngitis or tonsillitis, conduct clinical trials in 2010 for the use of this product candidate by children with acute otitis media and submit an NDA in 2011 for use of this product candidate by children with acute otitis media, pharyngitis or tonsillitis.

We are developing CRTX 058, an anticholinergic and antihistamine combination product candidate for the treatment of the symptoms of allergic rhinitis. We are targeting an NDA submission for CRTX 058 in 2011. We are also developing CRTX 067 and CRTX 069, antitussive and antihistamine combination product candidates, for which we are targeting regulatory submissions in 2009. If approved, we are planning to commercially launch CRTX 067 and CRTX 069 in late 2010 or early 2011.

History of Losses

From inception in 2004 through 2006, we incurred operating losses, including net losses of $305,000 in 2006 and $11.4 million in 2005. Our net income was $9.0 million in 2008 and $570,000 in 2007. As of December 31, 2008, our accumulated deficit was $4.1 million. We expect to continue to incur significant development and commercialization expenses as we seek FDA approval for SPECTRACEF Once Daily and SPECTRACEF Suspension; advance the development of our other product candidates, including our anticholinergic and antihistamine combination product

candidate, CRTX 058, and our antitussive and antihistamine combination product candidates, CRTX 067 and CRTX 069; seek regulatory approvals for our product candidates that successfully complete clinical testing; and expand our sales team and marketing capabilities to prepare for the commercial launch of future products, subject to FDA approval. We also expect to incur additional expenses to add operational, financial and management information systems and personnel, including personnel to support our product development efforts. Accordingly, we will need to increase our

Table of Contents

revenues to be able to sustain and increase our profitability. There is no assurance that we will be able to do so.

Financial Operations Overview

Net Revenues

Our net revenues are comprised of net product sales and royalty agreement revenues. We recognize product sales net of estimated allowances for product returns; estimated rebates in connection with contracts relating to managed care, Medicaid and Medicare; estimated chargebacks; price adjustments; product vouchers; co-pay vouchers; and prompt payment and other discounts. The primary factors that determine our net product sales are the level of demand for our products, unit sales prices and the amount of sales adjustments that we recognize. Royalty agreement revenues consist of royalties we receive under license agreements with third parties that sell products to which we have rights. The primary factors that affect royalty agreement revenues are the demand and sales prices for such products and the royalty rates that we receive on the sales of such products by third parties.

From time to time, we implement price increases on our branded products. Our branded and generic products are subject to rebates, chargebacks and other sales allowances that have the effect of decreasing the net revenues that we ultimately realize from product sales. Our generic products may also be subject to substantial price competition from equivalent generic products introduced by other pharmaceutical companies. Such competition may also decrease our net revenues from the sale of our generic products.

Cost of Product Sales

Our cost of product sales is primarily comprised of the costs of manufacturing and distributing our pharmaceutical products. In particular, cost of product sales includes third-party manufacturing and distribution costs, the cost of API, freight and shipping, reserves for excess or obsolete inventory and labor, benefits and related employee expenses for personnel involved with overseeing the activities of our third-party manufacturers. Cost of product sales excludes amortization of product rights.

We contract with third parties to manufacture all of our products and product candidates. Changes in the price of raw materials and manufacturing costs could adversely affect our gross margins on the sale of our products. Changes in our mix of products sold also will result in variations in our cost of product sales. Accordingly, our management expects gross margins will change as our product mix is altered by changes in demand for our existing products or the launch of new products.

Sales and Marketing Expenses

Our sales and marketing expenses consist of labor, benefits and related employee expenses for personnel in our sales, marketing and sales operations functions; advertising and promotion costs, including the costs of samples; and the fees we pay under our co-promotion agreements to third parties to promote our products, which are based on a percentage of net profits from product sales, determined in accordance with the particular agreement. The most significant component of our sales and marketing expenses is labor, benefits and related employee expenses. We expect that our sales and marketing expenses will increase as we expand our sales and marketing infrastructure to support additional products and product lines and as a result of increased co-promotion fees due to greater product sales.

Royalty Expenses

Royalty expenses include the contractual amounts we are required to pay the licensors from which we have acquired the rights to our marketed products or third-parties to whom we pay royalties under settlement agreements relating to

our products. Royalties are generally based on a percentage of the products net sales. With respect to the HYOMAX line of products, royalties are based on a percentage of the net profits earned by us on the sale of the products. Although product mix affects our royalties, we generally expect that our royalty expenses will increase as total net product sales increase.

Table of Contents

General and Administrative Expenses

General and administrative expenses primarily include labor, benefits and related employee expenses for personnel in executive, finance, accounting, business development, information technology, regulatory/medical affairs and human resource functions. Other costs include facility costs not otherwise included in sales and marketing or research and development expenses and professional fees for legal and accounting services. General and administrative expenses also consist of the costs of maintaining and overseeing our intellectual property portfolio, which include the cost of external legal counsel and the mandatory fees of the U.S. Patent and Trademark Office and foreign patent and trademark offices. General and administrative expense also includes depreciation expense for our property and equipment, which we depreciate over the estimated useful lives of the assets using the straight-line method. We expect that general and administrative expenses will increase as we continue to build the infrastructure necessary to support our commercialization and product development activities and to meet our compliance obligations as a public company. In addition, we have incurred additional legal, accounting and related costs relating to our October 2008 merger.

Research and Development Expenses

Research and development expenses consist of product development expenses incurred in identifying, developing and testing our product candidates and the write-off of in-process research and development expenses related to the alpha-7 program acquired from Critical Therapeutics in connection with our merger. Product development expenses consist primarily of labor, benefits and related employee expenses for personnel directly involved in product development activities; fees paid to professional service providers for monitoring and analyzing clinical trials; expenses incurred under joint development agreements; regulatory costs; costs of contract research and manufacturing; and the cost of facilities used by our product development personnel. We expense product development costs as incurred. We believe that significant investment in product development is important to our competitive position and plan to increase our expenditures for product development to realize the potential of the product candidates that we are developing or may develop.

Our product development expenses reflect costs directly attributable to product candidates in development during the applicable period and to product candidates for which we have discontinued development. Additionally, product development expenses include our costs of qualifying new cGMP third-party manufacturers for our products, including expenses associated with any related technology transfer. We do not allocate indirect costs (such as salaries, benefits or other costs related to our accounting, legal, human resources, purchasing, information technology and other general corporate functions) to the research and development expenses associated with individual product candidates. Rather, we include these costs in general and administrative expenses.

Amortization of Product Rights

We capitalize our costs to license product rights from third parties as such costs are incurred and amortize these amounts on a straight-line basis over the estimated useful life of the product or the remaining trademark or patent life. We re-evaluate the useful life of our products on an annual basis to determine whether the value of our product rights assets have been impaired and appropriately adjust amortization to account for such impairment. Amortization of product rights is expected to increase in the future as we begin amortizing product rights related to new products.

Other Charges

Other charges include expenses related to settlements of litigation and the impairment of fixed assets.

Critical Accounting Estimates

Management s discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of our financial statements requires our management to make estimates and assumptions that affect our reported assets and liabilities, revenues and expenses and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, our reported

Table of Contents

financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

We regard an accounting estimate or assumption underlying our financial statements as a critical accounting estimate where:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

- the impact of the estimates and assumptions on our financial condition or operating performance is material.

Our significant accounting policies are described in the notes to our consolidated financial statements appearing elsewhere in this annual report on Form 10-K. Not all of these significant accounting policies, however, fit the definition of critical accounting estimates. We believe that our estimates relating to revenue recognition, product rights, inventory, accrued expenses and stock-based compensation described below fit the definition of critical accounting estimates.

Revenue Recognition

Net Product Sales

Product Sales. We recognize revenue from our product sales in accordance with SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Statement of Financial Accounting Standards, or SFAS, No. 48, *Revenue Recognition When Right of Return Exists*, or SFAS 48, 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. Under SFAS 48, we are required to reasonably 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.

Product Returns. Consistent with industry practice, we offer contractual return rights that allow our customers to return product within an 18-month period, from six months prior to and up to twelve months subsequent to the expiration date of our products. Our products have a 24 to 36 month expiration period from the date of manufacture. We adjust our estimate of product returns if we become aware of other factors that we believe could significantly impact our expected returns. These factors include our estimate of inventory levels of our products in the distribution channel, the shelf life of the product shipped, review of consumer consumption data as reported by external information management companies, actual and historical return rates for expired lots, the remaining time to expiration of the product, and the forecast of future sales of the product, as well as competitive issues such as new product entrants and other known changes in sales trends. We evaluate this reserve on a quarterly basis, assessing each of the factors described above, and adjust the reserve accordingly.

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

Price Adjustments and Chargebacks. 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. We make these judgments based on the facts and circumstances known to us in accordance with GAAP. In the event that the sales mix to third-party payors is different from our estimates, we may

be required to pay higher or lower total price adjustments and/or chargebacks than we have estimated.

Special Promotional Programs. 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

Table of Contents

stocking allowances. We account for these programs in accordance with Emerging Issues Task Force, or EITF, Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products)*. We have initiated three voucher programs for SPECTRACEF whereby we offer a point-of-sale subsidy to retail consumers. 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. The first program expired on December 31, 2008. The second and third programs are still ongoing, and we have no present intention to cancel these programs. We account for the costs of these special promotional programs as price adjustments.

Prompt Payment Discounts. We typically require customers of branded and generic products to remit payments within 31 days and 61 days, respectively. In addition, we offer wholesale distributors a prompt payment discount as an incentive to remit payment within the first 30 days after the date of our invoice for branded products and 60 days after the date of our invoice for generic products. 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.

The following table provides a summary of activity with respect to our sales allowances (in thousands):

	Product Returns	Rebates	Price Adjustments and Chargebacks	Prompt Payment Discounts
Balance at December 31, 2006	$ 5,781	$ 140	$ 687	$ 43
Current provision related to sales in current period	2,879	228	1,259	645
Payments and credits	(3,747)	(65)	(1,118)	(607)
Balance at December 31, 2007	4,913	303	828	81
Current provision related to sales in current period	5,523	1,610	9,106	1,887
Current provision related to sales made in prior periods	1,401		(185)	
Acquired in the merger	353	51	133	
Payments and credits	(7,147)	(1,080)	(5,575)	(1,666)
Balance at December 31, 2008	$ 5,043	$ 884	$ 4,307	$ 302

Expense recognized for product returns was $6.9 million and $2.9 million in 2008 and 2007, respectively, representing 8% and 9% of gross product sales in 2008 and 2007, respectively. Expense recognized for product returns related to current year provisions were $5.5 million in 2008, or 7% of gross product sales. Expense recognized for product returns related to changes in prior year estimates in 2008 were $1.4 million and related primarily to product returns of DECONSAL, BALACET and SPECTRACEF, offset by lower than originally anticipated returns for ALLERX.

Expense recognized for rebates was $1.6 million and $228,000 in 2008 and 2007, respectively, representing approximately 2% and 1% of gross product sales in 2008 and 2007, respectively. The increase in rebates is primarily due to the overall increase in sales and our entry into additional supplemental Medicaid rebate programs during 2008.

Expense recognized for price adjustments and chargebacks was $8.9 million and $1.3 million in 2008 and 2007, respectively, representing approximately 11% and 4% of gross product sales in 2008 and 2007, respectively. This increase was primarily due to $3.3 million and $3.1 million of increases in price adjustments and chargebacks, respectively, related to the launch of the generic products, which typically have higher levels of price adjustments and chargebacks than branded products. Price adjustments were also increased by

Table of Contents

$1.0 million due to the costs of the SPECTRACEF point-of-sale voucher programs for retail customers that we launched in 2008 and by $300,000 due to increases in price adjustments and chargebacks related to our branded products.

Expense recognized for prompt payment discounts was $1.9 million and $645,000 in 2008 and 2007, respectively, representing approximately 2% of gross product sales in each year.

Royalty Agreement Revenues

We receive royalties under license agreements with a number of third parties that sell products to which we have rights. The license agreements provide for the payment of royalties based on sales of the licensed product. These revenues are recorded based on estimates of the sales that occurred in the relevant period. The relevant period estimates of sales are based on interim data provided by the licensees and analysis of historical royalties paid, adjusted for any changes in facts and circumstances, as appropriate. We maintain regular communication with our licensees to gauge the reasonableness of our estimates. Differences between actual royalty agreement revenues and estimated royalty agreement revenues are reconciled and adjusted for in the period in which they become known, typically the following quarter.

Product Rights

Product rights are capitalized as incurred and are amortized over the estimated useful life of the product or the remaining trademark or patent life on a straight-line or other basis to match the economic benefit received. Amortization begins once FDA approval has been obtained and commercialization of the product begins. We evaluate our product rights annually to determine whether a revision to their useful lives should be made. This evaluation is based on our management s projection of the future cash flows associated with the products. At December 31, 2008, we had an aggregate of $17.7 million in capitalized product rights, which we expect to amortize over a period of seven to fourteen years.

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 write down inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product revenues. As of December 31, 2008, we had $11.2 million in inventory and an inventory reserve of $677,000. The inventory reserve includes provisions for inventory that management believes will become short-dated before being sold. Short-dated inventory is inventory that has not expired yet, but which wholesalers or pharmacies refuse to purchase because of its near-term expiration date.

Accrued Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate certain expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such services as of each balance sheet date in our consolidated financial statements. Examples of estimated expenses for which we accrue include product development expenses; reserves for product returns; rebates to third parties, including private insurers and government programs such as Medicaid; royalties owed to third-parties on sales of products; interest owed on debt instruments; and compensation and benefits for employees.

Table of Contents

Stock-Based Compensation

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS 123(R), using the prospective application method, which requires us to recognize compensation cost for all awards granted or modified after January 1, 2006. Awards outstanding at January 1, 2006 continue to be accounted for using the accounting principles originally applied to the award. The expense associated with stock-based compensation is recognized on a straight-line basis over the service period of each award.

Prior to the adoption of SFAS 123(R), we recognized employee stock-based compensation expense using the intrinsic value method, which measures stock-based compensation expense as the amount at which the market price of the stock at the date of grant exceeds the exercise price. Because the exercise price for options awarded to employees is equal to the fair value at the grant date, we did not recognize compensation expense for stock options granted to employees prior to 2006.

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, in accordance with SFAS 123(R). We use the Black-Scholes-Merton option-pricing model to calculate the fair value of stock-based compensation under SFAS 123(R). There are a number of assumptions used to calculate the fair value of stock options or restricted stock issued to employees under this pricing model.

Accounting for equity instruments granted by us under SFAS 123(R) and EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, requires us to estimate the fair value of the equity instruments granted. If our estimates of the fair value of these equity instruments are too high or too low, stock-based compensation expense will be overstated or understated, respectively. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services can be readily estimated, we use the value of such goods or services to determine the fair value of the equity instruments. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services cannot be readily estimated, as is true in connection with most compensatory stock options and warrants granted to employees and non-employees, our board of directors determines fair value contemporaneously with the issuance or grant.

The two factors that most affect stock-based compensation are the estimate of the underlying fair value of our common stock and the estimate of the stock price volatility. Prior to the completion of the merger on October 31, 2008, 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.

For example, in addition to the factors enumerated above, Cornerstone BioPharma s board of directors specifically considered the following in making its determination of fair value. With respect to the grants on March 16, 2007, May 24, 2007, September 14, 2007 and December 5, 2007, Cornerstone BioPharma s financial performance was improving due to growing product sales, relatively strong gross margins, and leveraging of its sales force and fixed overhead. 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.

Table of Contents

Results of Operations

Comparison of the Years Ended December 31, 2008 and 2007

Net Revenues

The following table sets forth a summary of our net revenues for 2008 and 2007, including ZYFLO CR and ZYFLO net product sales completed after the closing of our merger on October 31, 2008:

	Year Ended December 31,			
	2008	2007	Change ($)	Change (%)
	(In thousands, except percentages)			
Net Product Sales				
ALLERX 10 Dose Pack/ALLERX 30 Dose Pack	$ 12,335	$ 11,103	$ 1,232	11%
ALLERX Dose Pack DF/ALLERX Dose Pack DF 30	6,244	967	5,277	546%
ALLERX Dose Pack PE/ALLERX Dose Pack PE 30	7,816	1,439	6,377	443%
SPECTRACEF	6,981	6,886	95	1%
BALACET 325	4,388	4,403	(15)	
HYOMAX	22,962		22,962	N/A
DECONSAL CT and DECONSAL DM	(59)	99	(158)	(160%)
ZYFLO CR and ZYFLO(1)	888		888	N/A
Other currently marketed products	1,911	671	1,240	185%
Discontinued products	(261)	679	(940)	(138%)
Total Net Product Sales	63,205	26,247	36,958	141%
Royalty Agreement Revenues	1,662	1,824	(162)	(9%)
Net Revenues	$ 64,867	$ 28,071	$ 36,796	131%

(1) Does not include the historical sales of ZYFLO CR and ZYFLO made by Critical Therapeutics prior to the completion of the merger on October 31, 2008.

Net Product Sales. Net product sales were $63.2 million in 2008, compared to $26.2 million in 2007, an increase of approximately $37.0 million, or 141%. This increase was primarily due to:

$23.0 million in net product sales of the HYOMAX line of products, the first of which was launched in May 2008;

a $12.9 million increase in net product sales of the ALLERX Dose Pack family of products, primarily due to increased sales volume, price increases on all ALLERX Dose Pack products and packaging issues in 2007 that delayed product shipments until 2008; and

$888,000 in net product sales of ZYFLO CR and ZYFLO during the last two months of 2008.

Royalty Agreement Revenues. Royalty agreement revenues were $1.7 million in 2008, compared to $1.8 million in 2007, a decrease of approximately $162,000, or 9%. This decrease was primarily due to a net decrease in royalty agreement revenues based on the underlying volume of sales pursuant to our license agreements with third parties.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $1.3 million and $3.2 million in 2008 and 2007, respectively) was $6.0 million in 2008, compared to $3.3 million in 2007, an increase of approximately $2.7 million, or 80%. Gross margin (exclusive of amortization of product rights of $1.3 million and $3.2 million in 2008 and 2007, respectively) was 91% in 2008 and 87% in 2007. Cost of product sales in 2008 and 2007 consisted primarily of the expenses associated with manufacturing and distributing products and reserves established for excess or obsolete inventory. The increase in our gross

Table of Contents

margin was primarily due to higher gross margins associated with our HYOMAX line of products, which we launched in 2008. We recorded inventory write-offs of $599,000 and $169,000 in 2008 and 2007, respectively. The write-offs in 2008 and 2007 resulted from excess or obsolete inventory that, due to its expiration dating, would not be sold.

Sales and Marketing Expenses. Sales and marketing expenses were $17.0 million in 2008, compared to $10.4 million in 2007, an increase of approximately $6.6 million, or 64%. This increase was primarily due to the following:

a $1.7 million increase in labor, benefits, related employee expenses and travel-related expenses, primarily due to the reorganization of our commission-based sales force in May 2008, whereby we consolidated all of our sales functions under one national sales director, reduced the size of our sales team from 93 sales professionals to 59 sales professionals and began compensating all of our sales professionals with salaries, bonuses and related benefits. Although this reorganization resulted in a reduction in the total number of employees on our sales force, our labor, benefits, other employee expenses and travel-related expenses increased due to the more generous pay, benefits and travel-reimbursement packages given to the former commission-based sales professionals who were retained following the reorganization;

a $1.7 million increase in co-promotion expenses that was primarily due to renegotiated contract terms with our co-promotion partners; and

a $1.4 million increase in advertising and promotion expenses, primarily due to product launches and increased promotional efforts.

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

Royalty Expenses. Royalty expenses were $16.2 million in 2008, compared to $3.4 million in 2007, an increase of approximately $12.8 million, or 375%. This increase was primarily due to the launch of the HYOMAX line of products in 2008 and increased net product sales of the ALLERX family of products.

General and Administrative Expenses. General and administrative expenses were $9.8 million in 2008, compared to $4.2 million in 2007, an increase of approximately $5.6 million, or 134%. This increase was primarily due to the following:

$2.7 million increase in labor, benefits, related employee expenses and travel-related expenses due to our growth during 2008;

$1.4 million in merger-related legal and accounting expenses that were not capitalized as direct costs of the merger;

$648,000 increase in FDA regulatory related fees;

$266,000 increase in product liability and other insurance related costs;

$170,000 increase in facility lease related costs; and

$160,000 increase in corporate advertising and promotional costs.

Research and Development Expenses. Research and development expenses were $3.8 million in 2008, compared to $948,000 in 2007, an increase of approximately $2.9 million, or 305%. Our product development expenses for particular product candidates 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.

Table of Contents

The following table summarizes our research and development expenses for 2008 and 2007:

	Year Ended December 31,	
	2008	2007
	(In thousands)	
Product candidate:		
SPECTRACEF 400 mg	$ 93	$ 383
SPECTRACEF Once Daily	521	
SPECTRACEF Qualification of Backup Manufacturer		90
SPECTRACEF Suspension	257	
ALLERX	272	402
Anticholinergic and Antihistamine Product Candidate (CRTX 058)	13	
Antitussive and Antihistamine Combination Product Candidates (CRTX 067 and CRTX 069)	661	
Alpha-7 Product Candidate (CRTX 803)	1,909	
ZYFLO CR	66	
Generic Product Development	44	73
Consulting	2	
Total	$ 3,838	$ 948

Research and development expenses for SPECTRACEF 400 mg of $93,000 in 2008 and of $383,000 in 2007 were incurred for a bioequivalence study, the sNDA submission for SPECTRACEF 400 mg and related consulting costs.

Research and development expenses for SPECTRACEF Once Daily of $521,000 were incurred for the formulation and manufacturing of batches that were used for a Phase II pharmacokinetic clinical study.

Research and development expenses for SPECTRACEF Suspension of $257,000 included manufacturing costs for clinical trial batches of the previous suspension formulation developed by TAP.

Research and development expenses for ALLERX of $272,000 in 2008 were incurred for ALLERX NDA studies and validation studies for the qualification of new facilities to manufacture bulk tablets for the ALLERX product line. Research and development expenses for ALLERX of $402,000 in 2007 were incurred for validation studies and manufacturing methodology and technology transfer in connection with a change in our third-party manufacturing site used to produce bulk tablets for the ALLERX product line.

Research and development expenses for the antitussive and antihistamine combination product candidates (CRTX 067 and CRTX 069) of $661,000 were incurred for the formulation and manufacturing of non-GMP and GMP batches that will be used as clinical trial material for clinical studies.

Research and development expenses for an alpha-7 product candidate of $1.9 million relate to the write-off of in-process research and development expenses acquired from Critical Therapeutics in connection with our merger.

Amortization of Product Rights. Amortization of product rights was $1.3 million in 2008, compared to $3.2 million in 2007, a decrease of approximately $1.9 million, or 58%. This decrease was primarily due to the BALACET product rights becoming fully amortized as of March 31, 2008.

Other Charges. Other charges were $173,000 in 2008, compared to $245,000 in 2007, a decrease of approximately $72,000, or 29%. This decrease was primarily due to lower litigation expenses, offset, in part, by charges related to the impairment of fixed assets.

Other Expenses

Interest Expense, Net. Net interest expense was $1.2 million in 2008, compared to $1.4 million in 2007, a decrease of approximately $199,000, or 14%. This decrease was primarily due to the conversion of our

Table of Contents

promissory note with Carolina Pharmaceuticals, or the Carolina Note, into common stock on October 31, 2008 in connection with our merger.

Loss on Marketable Security. Other expenses also included losses of $8,000 and $323,000 in 2008 and 2007, respectively, on our investment in Auriga Laboratories, Inc., or Auriga. We recorded these losses because our management determined that the decline in the value of this marketable security was other than temporary.

Provision for Income Taxes

The provision for income taxes was $414,000 in 2008, compared to $130,000 in 2007. The increase in the provision for income taxes was due to an $8.7 million increase in income before income taxes, offset, in part, by the elimination of our prior year deferred income tax valuation allowance of $4.2 million. Our effective tax rate was 4% in 2008 and 19% in 2007.

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 principal and interest payments on our debt. To date, we have funded our operations primarily from product sales, royalty agreement revenues and borrowings under the Carolina Note and the Paragon line of credit. We borrowed $13.0 million under the Carolina Note in April 2004. In connection with the closing of our merger, all of 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). As of December 31, 2008, we had $9.3 million in cash and cash equivalents and $3.9 million in borrowing availability under the Paragon line of credit.

Cash Flows

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

	Year Ended December 31,	
	2008	**2007**
Cash provided by (used in):		
Operating activities	$ 12,629	$ 1,563
Investing activities	(346)	(718)
Financing activities	(3,238)	(720)
Net increase in cash and cash equivalents	$ 9,045	$ 125

Net Cash Provided By Operating Activities

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

Net cash provided by operating activities in 2008 reflected our net income of $9.0 million, adjusted by non-cash expenses totaling $1.5 million and changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling $2.1 million. Non-cash items primarily included amortization and depreciation of $1.4 million, write-off of research and development costs acquired in the merger relating to the alpha-7 program of $1.9 million and stock-based compensation of $749,000. Accounts receivable (exclusive of accounts receivable acquired in our merger) increased by $5.1 million from December 31, 2007 to December 31, 2008, primarily due to increased net product sales, including increased sales of generic products, which have longer payment terms. Inventories (exclusive of inventories acquired in our merger) increased by $2.4 million from December 31, 2007 to December 31, 2008, primarily due to the purchase of ZYFLO CR inventory in December 2008. Prepaid expenses (exclusive of prepaid expenses

Table of Contents

acquired in our merger) increased by $602,000, primarily due to voucher programs and increased insurance. Accounts payable (exclusive of accounts payable assumed in our merger) increased by $2.6 million from December 31, 2007 to December 31, 2008, primarily due to increased payables for manufacturing, product development and marketing expenses. Accrued expenses (exclusive of accrued expenses assumed in our merger) increased by $4.5 million, primarily due to increased royalties, rebates and chargebacks resulting from increased product sales, offset, in part, by a decrease in accrued interest due to the conversion of the Carolina Note and payment of accrued interest in connection with our merger. Income taxes 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 provided by operating activities in 2007 reflected our net income of $570,000, adjusted by non-cash expenses totaling $4.5 million and changes in accounts receivable, inventories, accrued expenses and other operating assets and liabilities. Non-cash items included amortization and depreciation of $3.2 million, stock-based compensation of $801,000 and loss on our investment in Auriga common stock of $323,000. Accounts receivable increased $4.3 million from December 31, 2006, primarily due to increased sales at the end of 2007. Inventories increased $1.3 million from December 31, 2006, primarily due to stocking and lead time requirements related to the manufacturing of SPECTRACEF. Accrued expenses increased $1.0 million from December 31, 2006, primarily due to increased accruals for royalty expenses of $1.5 million and interest expense of $941,000, offset, in part, by a decrease in sales allowances of $475,000 and accrued settlement expenses of $1.1 million.

Net Cash Used in Investing Activities

Our primary source of cash flows from investing activities is cash acquired in connection with our merger, net of costs paid. 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 2008 primarily reflected the purchase of product rights for $2.5 million and the purchase of property and equipment for $638,000, offset, in part 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 investing activities in 2007 primarily reflected net advances to related parties of $614,000, the purchase of product rights for $75,000 and the purchase of property and equipment of $64,000, offset, in part, by net proceeds received from the net collection of deposits of $35,000.

Net Cash Used in Financing Activities

Our primary source of cash flows from financing activities is the Paragon line of credit. Our primary uses of cash in financing activities are the SPECTRACEF license agreement liability and principal payments on the Paragon line of credit and the Carolina Note. In connection with the closing of our merger on October 31, 2008, 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).

Net cash used in financing activities in 2008 reflected net payments on the Paragon 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.

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

Funding Requirements

We expect to continue to incur significant development and commercialization expenses as we seek FDA approval for the SPECTRACEF line extensions; advance the development of our other product candidates, including our anticholinergic and antihistamine combination product candidate and our two antitussive and antihistamine combination product candidates; seek regulatory approvals for our product candidates that

Table of Contents

successfully complete clinical testing; and expand our sales team and marketing capabilities to prepare for the commercial launch of future products, subject to FDA approval. We also expect to incur additional expenses to add operational, financial and management information systems and personnel, including personnel to support our product development efforts. Accordingly, we will need to increase our revenues to be able to sustain and increase our profitability on an annual and quarterly basis. There is no assurance that we will be able to do so. Our failure to achieve consistent profitability could impair our ability to raise capital, expand our business, diversify our product offerings and continue our operations.

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

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

To the extent that our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. Our only committed external source of funds is borrowing availability under the Paragon line of credit, which is described in more detail below under Paragon Line of Credit. Our ability to borrow under the Paragon line of credit is subject to our satisfaction of specified conditions. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

As of December 31, 2008, we had approximately $9.3 million of cash and cash equivalents on hand and borrowing availability of $3.9 million under the Paragon line of credit. Based on our current operating plans, we believe that our existing cash and cash equivalents, revenues from product sales and borrowing availability under the Paragon line of credit are sufficient to continue to fund our existing level of operating expenses and capital expenditure requirements for the foreseeable future.

Paragon Line of Credit

In April 2005, we obtained financing under a bank line of credit for up to $4.0 million with Paragon Commercial Bank. We have used the Paragon line of credit to fund our general operations and product acquisitions. As amended

and renewed in June 2008, the Paragon line of credit is subject to a monthly borrowing base equal to 75% of our accounts receivable balances outstanding 90 days or less and 100% of the $500,000 assignment of deposits to us by our President and Chief Executive Officer. Because our borrowing base under the Paragon line of credit exceeded $4.0 million as of December 31, 2008, the full amount of the line of credit was available for borrowings and the issuance of letters of credit. Of this amount, we had no borrowings outstanding and had issued letters of credit totaling $68,000, resulting in $3.9 million of available borrowing capacity. We are currently considering financing alternatives to fund capital expenditures in the future.

Table of Contents

Amounts outstanding under the Paragon line of credit bear interest at a variable rate equal to the Wall Street Journal prime rate, which was 3.25% as of December 31, 2008. The Paragon line of credit is collateralized by our accounts receivable, inventories, intangible assets, other personal property, a $2.0 million deed of trust on the personal residence of our President and Chief Executive Officer and an assignment of deposits in the amount of $500,000 to us by our President and Chief Executive Officer. Our President and Chief Executive Officer and Carolina Pharmaceuticals, Inc., a company under common control with us, have jointly guaranteed the Paragon line of credit. The Paragon line of credit requires, among other requirements, that we not incur any additional debt without Paragon s consent and that our President and Chief Executive Officer maintains a certain level of liquid assets and remains primarily employed as one of our executive officers. Interest is due monthly with all outstanding principal due on maturity in June 2009. The maximum amount outstanding under the Paragon line of credit during 2008 was $3.5 million.

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.

Recent Accounting Pronouncements

See Note 2: Summary of Significant Accounting Policies in Item 8. Financial Statements and Supplementary Data in this annual report on Form 10-K for a description of recent accounting pronouncements, including the expected dates of adoption and estimated effects, if any, on our consolidated financial statements.

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

Not required for smaller reporting companies.

Table of Contents

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

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Cornerstone Therapeutics Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Cornerstone Therapeutics Inc. (a Delaware corporation) and Subsidiaries as of December 31, 2008 and 2007, and the related consolidated statements of income, stockholders equity (deficit) and comprehensive income, and cash flows for each of the two years in the period ended December 31, 2008. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cornerstone Therapeutics Inc. as of December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America.

/s/ GRANT THORNTON LLP

Raleigh, North Carolina
March 26, 2009

Table of Contents

CORNERSTONE THERAPEUTICS INC.

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

	December 31, 2008	2007
Assets		
Current assets:		
Cash and cash equivalents	$ 9,286	$ 241
Marketable securities	300	8
Accounts receivable, net	13,660	6,529
Amounts due from related parties		648
Inventories, net	11,222	2,998
Prepaid expenses	1,081	278
Deferred income tax asset	2,428	
Total current assets	37,977	10,702
Property and equipment, net	895	209
Product rights, net	17,702	4,936
Goodwill	13,231	
Amounts due from related parties	38	29
Deposits	46	33
Total assets	$ 69,889	$ 15,909
Liabilities and Stockholders Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 10,288	$ 2,214
Accrued expenses	19,052	11,092
Current portion of license agreement liability	2,543	647
Line of credit		1,750
Income taxes payable	2,937	130
Total current liabilities	34,820	15,833
Long-term liabilities:		
License agreement liability, less current portion	2,313	2,959
Note payable, related party		9,412
Deferred income tax liability	3,330	
Total long-term liabilities	5,643	12,371
Total liabilities	40,463	28,204
Commitments and contingencies, Note 16		

Stockholders equity (deficit)		
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; 12,023,747 and 5,934,496 shares issued and outstanding as of December 31, 2008 and December 31, 2007, respectively	12	6
Additional paid-in capital	33,519	797
Accumulated deficit	(4,105)	(13,098)
Total stockholders equity (deficit)	29,426	(12,295)
Total liabilities and stockholders equity (deficit)	$ 69,889	$ 15,909

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

Table of Contents

CORNERSTONE THERAPEUTICS INC.

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

	Year Ended December 31, 2008	2007
Net revenues	$ 64,867	$ 28,071
Costs and expenses:		
Cost of product sales (exclusive of amortization of product rights)	5,951	3,300
Sales and marketing	16,993	10,391
Royalties	16,193	3,409
General and administrative	9,757	4,177
Research and development	3,838	948
Amortization of product rights	1,334	3,160
Other charges	173	245
Total costs and expenses	54,239	25,630
Income from operations	10,628	2,441
Other expenses:		
Interest expense, net	(1,211)	(1,410)
Loss on marketable security	(8)	(323)
Other expenses	(2)	(8)
Total other expenses	(1,221)	(1,741)
Income before income taxes	9,407	700
Provision for income taxes	(414)	(130)
Net income	$ 8,993	$ 570
Net income per share, basic	$ 1.29	$ .10
Net income per share, diluted	$ 1.14	$ .08
Weighted-average common shares, basic	6,951,896	5,934,496
Weighted-average common shares, diluted	7,861,119	6,751,127

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

Table of Contents

CORNERSTONE THERAPEUTICS INC.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity (Deficit)	Total Comprehensive Income
	Shares	Amount					
Balance as of December 31, 2006	5,934,496	6	(4)	(178)	(13,668)	(13,844)	
Stock-based compensation			801			801	
Unrealized loss on investment				(145)		(145)	$ (145)
Reclassification adjustment for losses on investments included in net income (net of tax)				323		323	323
Net income					570	570	570
Total comprehensive income							$ 748
Balance as of December 31, 2007	5,934,496	6	797		(13,098)	(12,295)	
Issuance of shares in connection with the Merger (net of issuance costs of $504)	4,325,498	4	22,971			22,975	
Exercise of common stock warrants	316,101		52			52	
Stock-based compensation			749			749	
Conversion of related party note payable to common stock	1,443,913	1	8,951			8,952	
Issuance of common stock to employees under stock incentive plan	3,959						
Restricted stock buyback	(220)						
Net income					8,993	8,993	8,993
Total comprehensive income							$ 8,993

Balance as of December 31, 2008	12,023,747	$ 12	$ 33,519	$	$	(4,105)	$ 29,426

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

Table of Contents

CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2008	**2007**
Cash flows from operating activities		
Net income	8,993	570
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization and depreciation	1,425	3,231
Change in allowance for prompt payment discounts	221	38
Change in allowance for inventory obsolescence	476	101
Stock-based compensation	749	801
Loss on marketable security	8	323
Write-off of acquired in-process research and development	1,900	
Impairment of property and equipment	56	
Benefit for deferred income taxes	(3,310)	
Changes in operating assets and liabilities:		
Accounts receivable	(5,050)	(4,287)
Amounts due from related parties		117
Inventories	(2,400)	(1,252)
Prepaid expenses	(602)	(12)
Accounts payable	2,573	783
Accrued expenses	4,505	1,020
Income taxes payable	3,085	130
Net cash provided by operating activities	12,629	1,563
Cash flows from investing activities		
Advances to related parties	(19)	(876)
Proceeds from collection of advances to related parties	657	262
Purchase of property and equipment	(638)	(64)
Purchase of product rights	(2,450)	(75)
Collection of deposits	223	50
Payment of deposits	(237)	(15)
Cash acquired in connection with the Merger, net of costs paid	2,118	
Net cash used in investing activities	(346)	(718)
Cash flows from financing activities		
Principal payments on license agreement liability	$ (576)	$ (720)
Proceeds from line of credit	7,250	9,000
Principal payments on line of credit	(9,000)	(9,000)
Principal payments on related party note payable	(460)	
Exercise of common stock warrants	52	

Payment of stock issuance costs in connection with the Merger	(504)	
Net cash used in financing activities	(3,238)	(720)
Net increase in cash and cash equivalents	9,045	125
Cash and cash equivalents as of beginning of year	241	116
Cash and cash equivalents as of end of year	$ 9,286	$ 241
Supplemental disclosure of cash flow information		
Cash paid during the year for interest	$ 2,734	$ 433
Cash paid during the year for income taxes	$ 644	$
Supplemental schedule of non-cash investing and financing activities		
Product rights acquired through issuance of a license agreement	$	$ 2,565
Related party note payable converted to common stock in connection with the Merger	$ 8,952	$
Common stock issued in connection with the Merger	$ 23,479	$

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

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: ORGANIZATION AND BASIS OF PRESENTATION

Nature of Operations

Cornerstone Therapeutics Inc., together with its subsidiaries (collectively, the Company), is a specialty pharmaceutical company focused on acquiring, developing and commercializing significant products for the respiratory market. Key elements of the Company s strategy are to in-license or acquire rights to under-promoted, patent-protected, branded respiratory pharmaceutical products, or late-stage product candidates; implement life cycle management strategies to maximize the potential value and competitive position of the Company s currently marketed products, newly acquired products and product candidates that are currently in development; grow product revenue through the Company s specialty sales force which is focused on the respiratory market; and maintain and strengthen the intellectual property position of the Company s currently marketed products, newly acquired products and product candidates.

Principles of Consolidation

The Company s consolidated financial statements include the accounts of Cornerstone Therapeutics Inc., a Delaware corporation, and its wholly owned subsidiaries: Cornerstone BioPharma Holdings, Inc. (Cornerstone BioPharma), a Delaware corporation; Cornerstone BioPharma, Inc., a Nevada corporation; Cornerstone Biopharma, Ltd., an Anguilla international business company; Aristos Pharmaceuticals, Inc., a Delaware corporation; and CTI Securities Corporation, a Massachusetts corporation.

Cornerstone Biopharma, Ltd. was dissolved in September 2007, and CTI Securities Corporation was dissolved effective December 31, 2008. All significant intercompany accounts and transactions have been eliminated in consolidation.

Merger

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

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

the Company.

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

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

Segment and Geographic Information

The Company follows the provisions of Statement of Financial Accounting Standards (SFAS) No. 131, *Disclosures about Segments of an Enterprise and Related Information* (SFAS 131). SFAS 131 establishes standards for reporting financial and descriptive information regarding operating segments. SFAS 131 also establishes standards for related disclosures about products and services and geographic areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions as to how to allocate resources and assess performance. The Company s chief operating decision makers, as defined under SFAS 131, are the chief executive officer and the chief financial officer. All of the Company s revenues are generated in the United States and 96% of its total assets are located in the United States as of December 31, 2008. The remaining 4% of the Company s assets consisted of inventory on hand at international locations.

The Company operates in two segments a prescription branded pharmaceuticals segment and a prescription generic pharmaceuticals segment. The prescription branded pharmaceuticals segment is engaged in the development, licensing, manufacture, marketing and distribution of prescription branded pharmaceutical products. The prescription generic pharmaceuticals segment is engaged in the development, licensing, manufacture, marketing and distribution of prescription generic pharmaceutical products. For segment reporting purposes, the two segments are aggregated as permitted by SFAS 131 and reported as a single segment called prescription pharmaceutical sales. The financial information disclosed herein represents all of the material financial information related to the Company s two operating segments as so aggregated.

Concentrations of Credit Risk and Limited Suppliers

The financial instruments that potentially subject the Company to concentrations of credit risk are cash, cash equivalents and accounts receivable. The Company s cash and cash equivalents are maintained with various financial institutions and are monitored against the Company s investment policy, which limits concentrations of investments in individual securities and issuers.

The Company relies on certain materials used in its development and manufacturing processes, some of which are procured from a single source. The Company purchases its pharmaceutical ingredients pursuant to long-term supply agreements with a limited number of suppliers. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt the development or commercialization process and thereby adversely affect the

Company s operating results. In addition, a disruption in the commercial supply of or a significant increase in the cost of the active pharmaceutical ingredient (API) from these sources could have a material adverse effect on the Company s business, financial position and results of operations.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company sells primarily to large national wholesalers, which in turn, may resell the product to smaller or regional wholesalers, retail pharmacies or chain drug stores. The following tables list all of the Company s customers that individually comprise greater than 10% of total gross product sales and their aggregate percentage of the Company s total gross product sales for the years ended December 31, 2008 and 2007, and all customers that comprise more than 10% of total accounts receivable and such customers aggregate percentage of the Company s total accounts receivable as of December 31, 2008 and 2007:

	Year Ended December 31,	
	2008 Gross Product Sales	2007 Gross Product Sales
Cardinal Health	40%	43%
McKesson Drug	31%	34%
Amerisouce-Bergen Drug Corp	15%	14%
Total	86%	91%

	December 31,	
	2008 Accounts Receivable	2007 Accounts Receivable
Cardinal Health	35%	
McKesson Drug	32%	75%
Amerisouce-Bergen Drug Corp	16%	17%
Total	83%	92%

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

The Company maintains cash deposits with federally insured banks that may at times exceed federally insured limits. As of December 31, 2008 and 2007, the Company had balances of $1.3 million and $130,000, respectively, in excess of federally insured limits.

Marketable Securities

Marketable securities consist primarily of auction rate securities and an investment in the common stock of a U.S. publicly traded company. The auction rate securities are of investment-grade quality and have an original maturity date greater than 90 days and can be sold within one year. The Company recorded its investments in marketable securities in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (SFAS 115). The classification of marketable securities is generally determined at the date of purchase. The Company s marketable securities are classified as available-for-sale and reported at fair value with unrealized losses recognized net of tax in other comprehensive income (loss). Gains and losses on sales of investments in marketable securities, which are computed based on specific identification of the adjusted cost of each security, are included in investment income at the time of the sale.

During the years ended December 31, 2008 and 2007, the Company recorded losses of $8,000 and $323,000, respectively, for the other-than-temporary impairment of the investment in the common stock of the U.S. publicly traded company in accordance with SFAS 115, as management does not believe the value of this security will be recovered. The investment was still held by the Company as of December 31, 2008.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Accounts Receivable

The Company typically requires customers of branded and generic products to remit payments within 31 days and 61 days, respectively. In addition, the Company offers wholesale distributors a prompt payment discount as an incentive to remit payment within the first 30 days after the invoice date for branded products and 60 days after the invoice date for generic products. This discount is generally 2%, but may be higher in some instances due to product launches or customer and/or industry expectations. Because the Company s wholesale distributors typically take the prompt payment discount, the Company accrues 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of sale, and the Company applies earned discounts at the time of payment. The Company adjusts the accrual periodically to reflect actual experience. Historically, these adjustments have not been material.

The Company performs ongoing credit evaluations and does not require collateral. As appropriate, the Company establishes provisions for potential credit losses. In the opinion of management, no allowance for doubtful accounts was necessary as of December 31, 2008 or 2007. The Company writes off accounts receivable when management determines they are uncollectible and credits payments subsequently received on such receivables to bad debt expense in the period received.

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

	2008	2007
Trade accounts receivable	$ 13,289	$ 3,585
Royalties receivable	427	998
Other receivables	246	2,027
Total accounts receivable	13,962	6,610
Less allowance for prompt payment discounts	(302)	(81)
Accounts receivable, net	$ 13,660	$ 6,529

Inventories

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

On a quarterly basis, the Company analyzes its inventory levels and writes down inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product revenues.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	2008	2007
Raw materials	$ 6,393	$ 1,564
Work in process	1,832	287
Finished goods:		
Pharmaceutical products trade	3,182	625
Pharmaceutical products samples	492	723
Total	11,899	3,199
Inventory allowances	(677)	(201)
Inventories, net	$ 11,222	$ 2,998

Property and Equipment

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

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

	Useful Life (Years)	2008	2007
Computers and software	3-5	$ 365	$ 244
Machinery and equipment	3-7	113	6
Furniture and fixtures	5-7	523	114
Leasehold improvements	Lesser of lease term or 7	82	15
Total		1,083	379
Less accumulated depreciation		(188)	(170)
Property and equipment, net		$ 895	$ 209

Depreciation expense for the years ended December 31, 2008 and 2007 was $91,000 and $71,000, respectively, and is included in general and administrative expenses in the accompanying consolidated statements of income.

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

Intangible Assets

Product rights are capitalized as incurred and are amortized over the estimated useful life of the product or the remaining trademark or patent life on a straight-line or other basis to match the economic benefit received. Amortization begins once Food and Drug Administration (FDA) approval has been obtained and commercialization of the product begins. The Company evaluates its product rights annually to determine

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

whether a revision to their useful lives should be made. This evaluation is based on management s projection of the future cash flows associated with the products.

Impairment of Long-Lived Assets

The Company evaluates the recoverability of its long-lived assets, including property and equipment and identifiable intangible assets, in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144). SFAS 144 requires companies to perform impairment testing on an exception basis whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets is not recoverable. The Company measures the recoverability of assets to be held and used by comparing the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment equals the amount by which the carrying amount of the assets exceeds the fair value of the assets. Any write-downs are recorded as permanent reductions in the carrying amount of the assets.

The Company also follows the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, (SFAS 142). Under SFAS 142, goodwill and purchased intangible assets with indefinite lives are not amortized but are reviewed periodically for impairment. The Company performs an annual evaluation of goodwill as of October 1 of each fiscal year to test for impairment and more frequently if events or circumstances indicate that goodwill may be impaired. Because the Company has a single operating segment, which is its sole reporting unit, the Company performs this test by comparing the fair value of the entity to its book value, including goodwill. If the fair value exceeds the book value, goodwill is not impaired. If the book value exceeds the fair value, then the Company would calculate the potential impairment loss by comparing the implied fair value of goodwill with the book value. If the implied fair value of goodwill is less than the book value, then an impairment charge would be recorded. There was no impairment of goodwill or other intangible assets as of December 31, 2008.

Revenue Recognition

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

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

Net Product Sales

Product Sales. The Company recognizes revenue from its product sales in accordance with Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*, and SFAS No. 48, *Revenue Recognition When Right of Return Exists* (SFAS 48), upon transfer of title, which occurs when product is received by its customers. The Company sells its products primarily to large national wholesalers, which have the right to return the products they purchase. Under SFAS 48, the Company is required to reasonably estimate the amount of future returns at the time of revenue recognition. The Company

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

recognizes product sales net of estimated allowances for product returns, rebates, price adjustments, chargebacks, and prompt payment and other discounts.

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

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

Price Adjustments and Chargebacks. The Company s estimates of price adjustments and chargebacks are based on its estimated mix of sales to various third-party payors, which are entitled either contractually or statutorily to discounts from the Company s listed prices of its products. In the event that the sales mix to third-party payors is different from its estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it has estimated.

Special Promotional Programs. The Company, from time to time, offers certain promotional incentives to its customers for its products. These programs include sample cards to retail consumers, certain product incentives to pharmacy customers and other sales stocking allowances. The Company accounts for these programs in accordance with Emerging Issues Task Force (EITF) No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products)*. The Company has initiated three voucher programs for SPECTRACEF® whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these voucher programs based on the historical redemption rates for similar completed programs used by other pharmaceutical companies as reported to the Company by a third-party claims processing organization and actual redemption rates for the Company s completed programs. The first program expired on December 31, 2008, and the second and third programs are still ongoing. The Company accounts for the costs of these special promotional programs as price adjustments.

Prompt Payment Discounts. The Company typically offers its wholesale customers a prompt payment discount of 2% as an incentive to remit payment within the first 30 days after the invoice date for branded products and 60 days after the invoice date for generic products (see Accounts Receivable above).

Royalty Agreement Revenues

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

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Advertising

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

Shipping and Handling Costs

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

Stock-Based Compensation

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), using the prospective application method, which requires the Company to recognize compensation cost for new awards and awards modified, repurchased or cancelled on or after January 1, 2006. The expense associated with stock-based compensation is recognized on a straight-line basis over the service period of each award.

Stock-based compensation granted to non-employees is accounted for in accordance with SFAS 123(R) and EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, which requires that compensation be recorded 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.

Other Charges

Other charges were $173,000 and $245,000 for the years ended December 31, 2008 and 2007, respectively, and include miscellaneous expenses related to settlements of litigation and charges related to the impairment of fixed assets.

Income Taxes

Deferred income tax assets and liabilities are computed annually for differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. Income tax expense is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

Fair Value of Financial Instruments

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

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value. It also

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company s choice to use fair value on its earnings. It also requires companies to display the fair value of those assets and liabilities for which they have chosen to use fair value on the face of the balance sheet. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company was required to adopt SFAS 159 on January 1, 2008. The adoption of SFAS 159 did not have a material impact on the Company s consolidated financial statements as the company did not elect the fair value option for any instruments.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. In February 2008, the FASB issued FASB Staff Position Financial Accounting Standard (FSP FAS) 157-2, *Effective Date of FASB Statement No. 157* (FSP FAS 157-2), which defers the effective date of applying the provisions of SFAS 157 to the fair value measurement of nonfinancial assets and nonfinancial liabilities until fiscal years beginning after November 15, 2008. The Company adopted the provisions of SFAS 157 that pertain to financial assets and liabilities on January 1, 2008. The adoption of SFAS 157 did not have a material impact on the Company s consolidated financial statements. The Company is currently evaluating the effect that FSP FAS 157-2 will have on its consolidated financial statements.

Reclassifications

Depreciation expense, which was previously included in amortization and depreciation, is included in general and administrative expenses in the accompanying consolidated statements of income. Accrued interest on the license agreement liability, which was previously included in accrued expenses, is included in the current portion of the license agreement liability in the accompanying consolidated balance sheets. These reclassifications had no effect on stockholders equity (deficit) or net income (loss) as previously reported.

New Accounting Pronouncements

In April 2008, the FASB issued FSP FAS 142-3, *Determination of the Useful Life of Intangible Assets* (FSP FAS 142-3). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142. In developing assumptions about renewal or extension, FSP FAS 142-3 requires an entity to consider its own historical experience or, if it has no experience, market participant assumptions, adjusted for entity-specific factors. FSP FAS 142-3 expands the disclosure requirements of SFAS 142 and is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, with early adoption prohibited. The guidance for determining the useful life of a recognized intangible asset must be applied prospectively to intangible assets acquired after the effective date. The disclosure requirements must be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. The Company does not expect the adoption of FSP FAS 142-3 to have a material impact on its consolidated financial statements.

In November 2007, the EITF issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis

and report any payments received from or made to other collaborators based on other applicable generally accepted accounting principles or, in the absence of other applicable generally accepted accounting principles, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of EITF 07-1 to have a material impact on its consolidated financial statements.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS 141(R)). SFAS 141(R) requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values and changes other practices under SFAS No. 141, *Business Combinations* (SFAS 141), some of which could have a material impact on how an entity accounts for its business combinations. SFAS 141(R) also requires additional disclosure of information surrounding a business combination so that users of the entity s financial statements can fully understand the nature and financial impact of the business combination. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008. The provisions of SFAS 141(R) will impact the Company s financial statements if the Company is a party to a business combination on or after January 1, 2009. In addition, for periods beginning on or after January 1, 2009, SFAS 141(R) requires the Company to report the impact of certain adjustments to valuation allowances on deferred tax assets acquired in business combinations occurring prior to January 1, 2009 as adjustments to income tax expense rather than as adjustments to goodwill.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51* (SFAS 160). SFAS 160 requires entities to report non-controlling minority interests in subsidiaries as equity in consolidated financial statements. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. SFAS 160 is applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for presentation and disclosure requirements, which are applied retrospectively for all periods presented. The Company does not expect the adoption of SFAS 160 to have a material impact on its consolidated financial statements.

NOTE 3: MERGER

As previously discussed in Note 1, on October 31, 2008, the Company completed the Merger whereby the Company, which was then known as Critical Therapeutics, merged (through a transitory subsidiary) with Cornerstone BioPharma, which was accounted for in accordance with SFAS 141. The Company s reasons for the Merger included, among other things, the following considerations: the opportunity to expand the Company s respiratory product portfolio, the potential for enhanced future growth and value and the ability to access additional capital. Because former Cornerstone BioPharma stockholders owned, immediately following the Merger, approximately 70% of the combined company on a fully diluted basis and as a result of certain other factors, Cornerstone BioPharma was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition in accordance with GAAP. Accordingly, Critical Therapeutics assets and liabilities were recorded as of the Merger closing date at their estimated fair values.

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

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

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

Purchase price	$ 25,232

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

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

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

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

In accordance with SFAS 141, the estimated fair value of raw materials was determined based on their replacement cost. The estimated fair values of work in process and finished goods were determined by estimating the selling prices of those goods less the costs of disposal, a reasonable profit allowance and, with respect to work in process, the costs of completion.

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

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

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

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

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

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Pro Forma Results of Operations (Unaudited)

The results of operations of Critical Therapeutics are included in the Company s consolidated financial statements from the closing date of the Merger on October 31, 2008. The following table presents pro forma results of operations and gives effect to the Merger transaction as if the Merger had been consummated at the beginning of the period presented. The unaudited pro forma results of operations are not necessarily indicative of what would have occurred had the business combination been completed at the beginning of the period or of the results that may occur in the future. Furthermore, the pro forma financial information does not reflect the impact of any reorganization or restructuring expenses or operating efficiencies resulting from combining the two companies.

	Year Ended December 31,	
	2008	2007
	(Unaudited)	
Net revenues	$ 78,972	$ 40,940
Net loss	$ (17,073)	$ (38,383)
Basic and diluted net loss per common share	$ (2.46)	$ (6.47)

NOTE 4: GOODWILL AND INTANGIBLE ASSETS

Goodwill

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

Intangible Assets

The following table represents intangible assets as of December 31 (in thousands):

	2008	2007
Product rights	26,730	12,630
Less accumulated amortization	(9,028)	(7,694)

Product rights net	$ 17,702	$ 4,936

The Company amortizes the product rights related to its currently marketed products over their estimated useful lives, which, as of December 31, 2008, ranged from seven to nine years. As of December 31, 2008, the Company had $3.1 million of product rights related to products it expects to launch in the future. The Company expects to begin amortizing these rights upon the commercial launch of the first product using these rights (which, if approved, is targeted to be in late 2010 or early 2011) over an estimated useful life of approximately 14 years. The weighted-average amortization period for the Company s product rights related to its currently marketed products is approximately six years. Amortization expense for the years ended December 31, 2008 and 2007 was $1.3 million and $3.2 million, respectively.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Future estimated amortization expense (excluding the rights related to products expected to be launched) subsequent to December 31, 2008 is as follows (in thousands):

2009	$ 2,042
2010	2,042
2011	2,031
2012	2,025
2013	2,025
Thereafter	4,437
	$ 14,602

NOTE 5: LINE OF CREDIT

In April 2005, the Company obtained financing under a bank line of credit for up to $4.0 million. Interest is due monthly with all outstanding principal and interest due on maturity. The initial maturity of the line of credit was April 2006 and thereafter has been successively renewed on an annual basis on each maturity date. The line of credit s current maturity date is June 2009, and the line of credit is currently subject to a monthly borrowing base calculated based upon up to 75% of the Company s accounts receivable balances outstanding 90 days or less and a $500,000 assignment of deposits from the Company s President and Chief Executive Officer. The line of credit requires that the Company s President and Chief Executive Officer remain primarily employed by the Company in an executive management level position. Amounts outstanding under the line of credit bear interest at a variable rate equal to the Wall Street Journal prime rate, which was 3.25% as of December 31, 2008.

Because the Company s borrowing base under the line of credit exceeded $4.0 million as of December 31, 2008 and 2007, the full amount of the line of credit was available for borrowings and the issuance of letters of credit on each of these dates. As of December 31, 2008, the Company had no borrowings outstanding and had issued letters of credit totaling $68,000, resulting in $3.9 million of available borrowing capacity. As of December 31, 2007, the Company had $1.7 million in borrowings outstanding and had issued letters of credit totaling $68,000, resulting in $2.2 million of available borrowing capacity.

NOTE 6: RELATED PARTY NOTE PAYABLE

In April 2004, the Company executed a promissory note with Carolina Pharmaceuticals Ltd. (Carolina Pharmaceuticals), an entity under common control with the Company, to borrow up to $15.0 million for five years with an annual interest rate of 10% (Carolina Note). The Company borrowed $13.0 million under the Carolina Note in April 2004. As of December 31, 2007, $9.4 million in principal and $1.5 million of accrued interest were outstanding under the Carolina Note. The fair value of the Carolina Note was $8.2 million as of December 31, 2007.

In connection with the Merger, the Company entered into a noteholder agreement, as amended (the Noteholder Agreement), with Carolina Pharmaceuticals. The Noteholder Agreement required Carolina Pharmaceuticals to surrender the Carolina Note to the Company prior to the effective time of the Merger and required the Company to,

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

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As required by the Noteholder Agreement, Carolina Pharmaceuticals surrendered the Carolina Note prior to the closing of the Merger with instructions that the principal amount outstanding be converted into common stock of the Company. Immediately prior to the effective time of the Merger, the Company issued Carolina Pharmaceuticals 1,443,913 shares of common stock in satisfaction of the principal amount outstanding under the Carolina Note and paid Carolina Pharmaceuticals $2.2 million in full satisfaction of the accrued interest outstanding thereunder. The fair value of the shares issued in extinguishment of the Carolina Note on the date of exchange was $3.90 per share, or $5.6 million, which was $3.3 million less than the Carolina Note s outstanding principal balance on the date of exchange. Under APB Opinion No. 26, *Early Extinguishment of Debt*, the forgiveness of debt between related parties may, in essence, be capital transactions. The Company has concluded that Carolina Pharmaceuticals forgiveness of the $3.3 million of principal under the Carolina Note was, in essence, a capital contribution by Carolina Pharmaceuticals to the Company. Accordingly, the Company has included the entire $9.0 million principal balance that was extinguished in common stock and additional paid-in capital in the accompanying consolidated financial statements.

NOTE 7: STOCKHOLDERS EQUITY (DEFICIT)

Authorized Capital

As of December 31, 2008, the authorized capital stock of the Company consisted of 90,000,000 shares of voting common stock with a par value of $0.001 per share and 5,000,000 shares of undesignated preferred stock with a par value of $0.001 per share. The common stock holders are entitled to one vote per share. The rights and preferences of the preferred stock may be established from time to time by the Company s board of directors.

Warrants to Purchase Common Stock

In February 2006, the Company issued a warrant to purchase 3,571 shares of common stock at $0.42 per share in exchange for services. The warrant was valued at $2,000 and was exercisable for a ten-year period from the date of grant. The fair value of the warrant granted was estimated on the date of grant using the Black-Scholes-Merton pricing model with the following assumptions: dividend yield of 0%, expected volatility of 157%, risk-free interest rate of 4.51% and expected life of ten years. The warrantholder exercised the warrant in October 2008 prior to the completion of the Merger.

In July 2004, Cornerstone Biopharma Holdings, Ltd., an entity affiliated with the Company, issued an option to purchase 5% of its common shares to a company owned by a former stockholder of an affiliated company in connection with a license agreement. The option had an exercise price of $100,000, had an exercise period that extended through December 31, 2009 and was exercisable for such number of shares that would give the optionholder a 5% ownership interest in Cornerstone Biopharma Holdings, Ltd. s issued and outstanding shares following the exercise. The fair value of the option was approximately $48,000.

In connection with the May 2005 corporate restructuring of the Company, in July 2006, the option was cancelled and replaced with a warrant exercisable on the same terms but for shares in the Company. The Company did not record any additional compensation expense in 2006 when it issued the warrant because the fair value of the warrant was the same as the fair value of the option that it replaced. In April 2007, the Company amended the warrant to, among other things, decrease its exercise price to $50,000 and extend its exercise period through December 31, 2010. In the year ended December 31, 2007, the Company recorded $508,000 of compensation expense due to the amendment of the

warrant, which is included in general and administrative expenses in the accompanying consolidated statements of income. The warrant was exercised on October 30, 2008 prior to the Merger. In connection with the exercise, the Company issued the warrantholder 312,530 shares of common stock.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In June 2005, the Company issued two warrants to purchase 2,380 shares each of common stock at $0.42 per share in exchange for services. The warrants were valued at $2,000 and are exercisable for a ten-year period from the date of grant. The fair value of the warrants granted was estimated on the date of grant using the Black-Scholes-Merton pricing model with the following assumptions: dividend yield of 0%, expected volatility of 75%, risk-free interest rate of 3.91% and expected life of ten years. These warrants remain outstanding as of December 31, 2008.

In connection with the Merger, the Company assumed, for financial reporting purposes, warrants to purchase the Company s common stock from Critical Therapeutics. These warrants were originally issued by Critical Therapeutics in June 2005 and October 2006, and were fully vested prior to the closing of the Merger. The warrants issued in June 2005 are exercisable for up to 348,084 shares of the Company s common stock, have an exercise price of $65.80 per share, expire in June 2010 and contain a cashless exercise feature. The warrants issued in October 2006 are exercisable for up to 372,787 shares of the Company s common stock, have an exercise price of $26.20 per share and expire in October 2011. As of December 31, 2008, none of these warrants have been exercised.

NOTE 8: STOCK-BASED COMPENSATION

Overview of Stock-Based Compensation Plans

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

In connection with the Merger, the Company assumed, for financial reporting purposes, the Critical Therapeutics, Inc. 2000 Equity Incentive Plan (the 2000 Equity Plan) and the Critical Therapeutics, Inc. 2003 Stock Incentive Plan (the 2003 Stock Incentive Plan). As of December 31, 2008, there were 106,666 and 159,066 shares of common stock authorized under the 2000 Equity Plan and the 2003 Stock Incentive Plan, respectively. There were no shares of common stock available for award under either of these plans as of December 31, 2008.

2004 Stock Incentive Plan Assumed from Critical Therapeutics in the Merger

In connection with the Merger, the Company also assumed, for financial reporting purposes, the Critical Therapeutics, Inc. 2004 Stock Incentive Plan, as amended (the 2004 Stock Incentive Plan). The 2004 Stock Incentive Plan provides for the award to the Company s employees, directors and consultants of shares of common stock to be granted through incentive and nonstatutory stock options, restricted stock and other stock-based awards.

The exercise price of stock options granted under the 2004 Stock Incentive Plan is determined by the compensation committee of the Company s board of directors and may be equal to or greater than the fair market value of the Company s common stock on the date the option is granted. Equity awards granted under the 2004 Stock Incentive Plan generally become exercisable over a period of four years from the date of grant and expire 10 years after the grant date. As of December 31, 2008, there were 587,333 shares of common stock authorized, and 153,083 shares available for award, under the 2004 Stock Incentive Plan.

The 2004 Stock Incentive Plan provides for an annual increase in the number of shares authorized for award under the plan, if approved by the Company s board of directors. This increase, if approved, is effective on January 1 of each year and may not exceed the lesser of 4% of the Company s outstanding shares on the effective date of the increase or 133,333 shares. Pursuant to this provision, on December 18, 2008, the Company s board of directors authorized an

additional 133,333 shares of common stock for award under the plan, effective January 1, 2009.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2005 Stock Option Plan and 2005 Stock Incentive Plan

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

Cornerstone BioPharma s board of directors determined the terms and grant dates of all equity awards issued under the 2005 Plans and the underlying fair market value of Cornerstone BioPharma s common stock covered by such awards. Under the 2005 Plans, equity awards generally become exercisable over a period of four years from the date of grant and expire 10 years after the grant date. Certain option and share awards provide for accelerated vesting if there is a change in control as defined by the 2005 Stock Incentive Plan.

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

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

Stock Option Activity

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

	Number of Shares		Weighted Average Exercise Price
Outstanding at January 1, 2007	682,876	$	0.46
Granted	1,135,064	$	1.81
Forfeited	(7,352)	$	0.63
Outstanding at January 1, 2008	1,810,588	$	12.80
Granted	432,004	$	3.72

Assumed in Merger	245,813	$	40.39
Forfeited	(39,008)	$	1.93
Expired	(11,825)	$	41.29
Outstanding at December 31, 2008	2,437,572	$	5.45
Vested or expected to vest at December 31, 2008	2,400,901	$	5.50
Exercisable December 31, 2008	1,071,371	$	9.32
Exercisable December 31, 2007	406,501	$	0.46

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Using the Black-Scholes-Merton option pricing model, the weighted-average grant date fair values of options granted during the years ended December 31, 2008 and 2007 were $2.50 and $1.15 per share, respectively. There were no options exercised during the years ended December 31, 2008 and 2007.

The following table further discloses by grant date the stock option grants that the Company made during the years ended December 31, 2007 and 2008 prior to the completion of the Merger:

Grant Date	Number of Stock Options Granted	Exercise Price	Fair Value of Common Stock at Grant Date	Intrinsic Value of Stock Options at Grant Date
3/16/2007	1,065,414	$ 1.76	$ 1.76	$
5/24/2007	15,829	1.76	1.76	
9/14/2007	29,996	2.02	2.02	
12/5/2007	23,804	2.02	2.02	
10/31/2008	351,275	3.90	3.90	
	1,486,318			$

Stock option grants made in the years ended December 31, 2008 and 2007 prior to the Merger were made under the 2005 Stock Incentive Plan. Stock option grants made after the Merger were made under the 2004 Stock Incentive Plan.

As of December 31, 2008, the aggregate intrinsic value of options outstanding and exercisable was $2.4 million and $1.5 million, respectively. As of December 31, 2007, the aggregate intrinsic value of options outstanding and exercisable was $1.3 million and $628,000, respectively.

The following table summarizes information about the Company s stock options outstanding as of December 31, 2008:

	Outstanding			Exercisable	
Exercise Price	Number of Options Outstanding	Weighted-Average Contractual Life Outstanding (In Years)	Weighted-Average Exercise Price	Options Exercisable	Weighted-Average Exercise Price

$0.42	633,271	7.06	$	0.42	522,076	$ 0.42
$1.05	39,283	6.50	$	1.05	36,308	$ 1.05
$1.76	1,077,451	8.21	$	1.76	269,463	$ 1.76
$2.02-$2.93	99,996	9.73	$	2.75	7,321	$ 2.33
$3.90	351,292	9.83	$	3.90	7,827	$ 3.90
$7.40-$16.50	27,674	2.02	$	10.56	26,750	$ 10.53
$16.51-$28.50	81,225	1.41	$	20.37	76,629	$ 20.34
$28.51-$55.20	42,300	2.04	$	43.38	41,198	$ 43.49
$55.21-$74.70	75,780	1.12	$	65.07	74,515	$ 64.98
$74.71-$85.80	9,300	3.74	$	78.39	9,284	$ 78.39
	2,437,572	7.54	$	5.45	1,071,371	$ 9.32

As of December 31, 2008 and 2007, there was approximately $1.7 million and $1.1 million, respectively, of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.41 and 3.06 years, respectively.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Restricted Stock Issuances

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

The Company also entered into restricted stock agreements with certain employees under the 2004 Stock Incentive Plan and the 2005 Stock Incentive plan during the year ended December 31, 2008 and assumed restricted stock in connection with the Merger.

The following table summarizes the Company s restricted stock activity:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested January 1, 2008	51,039	$ 0.00
Granted	473,855	3.96
Assumed in the Merger (unvested)	5,460	17.20
Vested	(54,999)	1.32
Unvested December 31, 2008	475,355	$ 4.01

Included in the above table is a grant of 325,133 shares of restricted stock made by the Company on October 31, 2008 immediately prior to the completion of the Merger. In connection with the grant, the Company s board of directors determined that the fair value of the stock granted was $3.90 per share, the closing price of Critical Therapeutics stock on the date of grant. Following the Merger, the Company determines the fair value of restricted stock issuances based on the closing price of the Company s stock on the date of grant. As of December 31, 2008 the intrinsic value of the restricted stock outstanding was $1.3 million.

As of December 31, 2008, there was approximately $1.7 million of total unrecognized compensation cost related to unvested restricted stock issued under the Company s equity compensation plans, which is expected to be recognized over a weighted-average period of 3.57 years. The Company did not grant restricted stock under its equity compensation plans during the year ended December 31, 2007.

Stock-Based Compensation Expense

During 2008 and 2007, the Company recorded approximately $728,000 and $290,000 in employee stock-based compensation expense and $21,000 and $3,000 in non-employee stock-based compensation expense (exclusive of

compensation expense related to a warrant amendment), respectively, based on the total fair value of shares vested. During the year ended December 31, 2008, $593,000 and $135,000 of the employee stock-based compensation expense was charged against general and administrative and sales and marketing costs, respectively. During the year ended December 31, 2007, $222,000 and $68,000 of the employee stock-based compensation expense was charged against general and administrative and sales and marketing costs, respectively.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Determining the appropriate fair value model and the related assumptions requires judgment. The fair value of each stock option is estimated using the Black-Scholes-Merton option-pricing model on the date of grant, as follows:

	Year Ended December 31,	
	2008	2007
Estimated dividend yield	0.00%	0.00%
Expected stock price volatility	75.00%	68.00%
Risk-free interest rate	1.43% - 3.05%	3.52% - 4.79%
Expected life of option (in years)	6	6.04
Weighted-average fair value per share	$2.50	$1.15

The Company has not paid and does not anticipate paying cash dividends; therefore the expected dividend rate is assumed to be 0%.

The expected stock price volatility for stock options awarded prior to October 31, 2008 (the date the Merger was completed) was based on the historical volatility of a representative peer group of three comparable companies selected using publicly available industry and market capitalization data. These companies were Aspreva Pharmaceuticals, Inc, Critical Therapeutics and Oscient Pharmaceuticals Corporation. The expected stock price volatility for the stock options awarded on and after October 31, 2008 is based on Critical Therapeutics (now the Company s) historical volatility from July 1, 2004 through the month of grant, and on the historical volatility of a representative peer group of three comparable companies selected using publicly available industry and market capitalization data. These companies were Oscient Pharmaceuticals Corporation, Inspire Pharmaceuticals, Inc. and Atherogenics, Inc.

The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption.

The expected life of the stock options granted during the year ended December 31, 2008 was estimated based on the historical exercise patterns over the option lives while considering employee exercise strategy and cancellation behavior. The expected life of employee stock options granted during the year ended December 31, 2007 was based on the mid-point between the vesting date and the contractual term in accordance with the simplified method prescribed in SAB No. 107, *Share-Based Payment*. The expected life for stock-based compensation granted to non-employees is the contractual life.

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

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

NOTE 9: NET INCOME PER SHARE

The Company computes net income per share in accordance with SFAS No. 128, *Earnings per Share* (SFAS 128). Under the provisions of SFAS 128, basic net income per share is computed by dividing net income by the weighted-average number of common shares outstanding. Diluted net income per share is computed by dividing net income by the sum of the weighted-average number of common shares and dilutive

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

common share equivalents then outstanding. Common share equivalents consist of the incremental common shares issuable upon the exercise of stock options and warrants and the impact of non-vested restricted stock grants.

The following table reconciles the numerator and denominator used to calculate diluted net income per share (in thousands):

	Year Ended December 31,	
	2008	**2007**
Numerator:		
Net income	$ 8,993	$ 570
Denominator:		
Weighted-average common shares, basic	6,951,896	5,934,496
Dilutive effect of stock options, warrants and restricted stock	909,223	816,631
Weighted-average common shares, diluted	7,861,119	6,751,127

For the years ended December 31, 2008 and 2007, there were 94,244 and zero, respectively, potential common shares outstanding that were excluded from the diluted net income per share calculation because their effect would have been anti-dilutive.

NOTE 10: LEASES

Lease Obligations

The Company leases its facilities, certain equipment and automobiles under non-cancelable operating leases expiring at various dates through 2016. Rent expense was $719,000 and $466,000 for the years ended December 31, 2008 and 2007, respectively.

The Company s headquarters occupies approximately 15,000 square feet of office space in Cary, North Carolina. The lease expires on March 16, 2016, and the Company has an option to extend the term of the lease for an additional five years through March 2021. Initial annual base rent under the lease is approximately $350,000 with annual rent increases of approximately 3%. In addition to rent, the Company is obligated to pay certain operating expenses and taxes.

Future minimum aggregate payments under non-cancelable lease obligations as of December 31, 2008 are as follows (in thousands):

Year Ending	**Operating Leases**

2009	$	698
2010		402
2011		376
2012		371
2013		383
Thereafter		976
Total minimum lease payments	$	3,206

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 11: ACCRUED EXPENSES

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

	2008	2007
Accrued product returns	$ 5,043	$ 4,913
Accrued rebates	884	303
Accrued price adjustments and chargebacks	4,307	828
Accrued compensation and benefits	2,507	1,596
Accrued royalties	6,259	1,940
Accrued interest, affiliate		1,490
Accrued expenses, other	52	22
Total accrued expenses	$ 19,052	$ 11,092

NOTE 12: EMPLOYEE BENEFIT PLANS

In 2004, the Company implemented a profit-sharing plan that was subject to the provisions of the Employee Retirement Income Security Act of 1974. Participants of the defined benefit pension plan (which the Company terminated in 2006) were not eligible to participate in the profit-sharing plan. The Company was required to fund the plan in an amount equal to 7.5% of the participant s compensation for the plan year. The Company terminated the profit-sharing plan in 2006 and outstanding liabilities related to the plan were accrued as of December 31, 2006. The Company paid $138,000 in 2007 to settle the liability.

The Company established a qualified 401(k) plan (the Cornerstone Plan), effective January 1, 2005, covering all employees who are least 21 years of age. The Company s employees may elect to make contributions to the plan within statutory and plan limits, and the Company may elect to make matching or voluntary contributions. As of December 31, 2008, the Company had not made any contributions to the 401(k) plan. The Company incurred $2,000 and $4,000 of expenses related to the plan for the years ended December 31, 2008 and 2007, respectively.

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

NOTE 13: INCOME TAXES

As discussed in Note 1, the Company s consolidated financial statements include the accounts of Cornerstone Therapeutics Inc., Cornerstone BioPharma, Cornerstone BioPharma, Inc., Cornerstone BioPharma, Ltd. and Aristos

Pharmaceuticals, Inc. During 2006 and until Cornerstone BioPharma, Ltd. was dissolved in 2007, Cornerstone BioPharma, Ltd. was an Anguilla international business company and was taxed as a foreign corporation for U.S. tax purposes. Because Cornerstone BioPharma, Ltd. is not subject to income tax in Anguilla, the Company s consolidated financial statements do not include a provision for income taxes from this entity. Cornerstone BioPharma, Ltd. s income would have been taxed to the owner of Cornerstone BioPharma if Cornerstone BioPharma, Ltd. had issued dividends to Cornerstone BioPharma, or if Cornerstone BioPharma had sold the stock of this subsidiary. The entity was dissolved in 2007.

The Company adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109* (FIN 48), effective January 1, 2007. The Company determined

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

that the adoption of FIN 48 did not have a material effect on the Company s consolidated financial position; therefore, no liability for unrecognized income tax benefits was recognized as of the date of adoption. As of December 31, 2008 and 2007, the Company continues to have no unrecognized tax benefits. Additionally, there are no unrecognized tax benefits that would affect the effective tax rate. The Company does not reasonably expect any change to the amount of unrecognized tax benefits within the next twelve months.

The Company recognizes annual interest and penalties related to uncertain tax positions as general and administrative expenses in its statement of operations. As of the date of adoption and as of December 31, 2008 and 2007, the Company had no interest or penalties related to uncertain tax positions.

The Company had no tax-related interest expense in the statement of operations or accrued in the statement of financial position as of December 31, 2008 or 2007. The Company had approximately $48,000 and $0 in penalties related to the underpayment of required taxes included in the statement of operations and accrued in the statement of financial position as of December 31, 2008 and 2007, respectively.

The 2005 through 2008 tax years of the Company are open to examination by federal and state tax authorities. The Company has not been informed by any tax authorities for any jurisdiction that any of its tax years is under examination as of December 31, 2008.

The provision for income taxes includes the following (in thousands):

	Year Ended, December 31	
	2008	2007
Current:		
Federal	$ 3,161	$ 62
State	563	68
Total	3,724	130
Deferred:		
Federal	(2,930)	
State	(380)	
Total	(3,310)	
Total tax provision	$ 414	$ 130

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company s deferred tax assets as of December 31 are as follows (in thousands):

	2008	2007
Current:		
Deferred tax assets:		
Accounts receivable, net	$ 116	$ 31
Inventories, net	400	177
Accrued expenses	2,542	2,881
Valuation allowance		(3,089)
Total current deferred tax assets	3,058	
Deferred tax liabilities:		
Acquired intellectual property	(630)	
Net current deferred tax assets	$ 2,428	$

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	2008	2007
Noncurrent:		
Deferred tax assets:		
Tax loss carryforwards	$ 61,888	$ 656
Deferred compensation	293	203
Product license rights, net	315	244
Organizational costs, net		2
Tax credits	1,900	62
Valuation allowance	(63,788)	(1,143)
Total noncurrent deferred tax assets	608	24
Deferred tax liabilities:		
Acquired intellectual property	(3,783)	
Property and equipment, net	(155)	(24)
Total noncurrent deferred tax liabilities	(3,938)	(24)
Net deferred tax liability noncurrent	(3,330)	
Total net deferred tax liability	$ (902)	$

Income taxes computed at the statutory federal income tax rate of 34% are reconciled to the provision (benefit) for income taxes as follows:

	2008	2007
United States federal tax at statutory rate	$ 3,198	$ 238
State taxes (net of federal benefit)	412	30
Nondeductible expenses	403	237
Acquired in-process research and development	729	
Other	(96)	(32)
Decrease in valuation allowance	(4,232)	(343)
Provision for income taxes	$ 414	$ 130

The Company had net deferred tax assets totaling approximately $4.2 million as of December 31, 2007, all of which were offset by a valuation allowance. SFAS No. 109, *Accounting for Income Taxes* (SFAS 109), requires the Company to record a valuation allowance when it is more likely than not that some portion or all of the deferred tax

assets will not be realized. The Company maintained a 100% valuation allowance equal to the net deferred tax assets throughout the year ended December 31, 2007.

As of December 31, 2008, the Company is in a three-year cumulative positive income before income taxes position. Based on its three-year cumulative pre-tax income, its trend of increasing profits and its expected profitability in the year ending December 31, 2009 and future years, the Company has now concluded that it is more likely than not that substantially all of its deferred tax assets, except most of those acquired in the Merger, will be realized. As a result, in accordance with SFAS 109, as of December 31, 2008 the Company reversed all of the valuation allowance previously applied to such deferred tax assets. The reversal of the valuation allowance resulted in a significant non-cash income tax benefit in the fourth quarter of 2008 equal to the Company s estimated realizable deferred tax assets, excluding those deferred tax assets resulting from the Merger, most of which maintain a full valuation allowance, including some whose adjustment will be made either to goodwill or to income tax expense in future periods.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of the effective date of the Merger, the Company determined that it was more likely than not that only $200,000 of the $64.3 million of deferred tax assets acquired from Critical Therapeutics would be realized, including assets from federal net operating loss carryforwards (NOLs), state net economic loss carryforwards (NELs) and federal tax credits. This determination was based on current projections of future taxable income when taking into consideration limitations on the utilization of NOLs and tax credits imposed by Section 382 and 383, respectively, of the Internal Revenue Code (the Code). Sections 382 and 383 of the Code impose limitations on a corporation s ability to utilize its NOLs and tax credits, respectively, if it experiences an ownership change. In general terms, an ownership change results from transactions increasing the ownership of certain stockholders in the stock of a corporation by more than 50 percentage points over a three-year period. As a result of the Merger, Critical Therapeutics experienced an ownership change that significantly limits the Company s ability to utilize Critical Therapeutics NOLs and tax credits to offset the Company s future income or taxes, respectively. Therefore, the $64.1 million of deferred tax assets resulting from these NOLs and tax credits are offset by a full valuation allowance. The reversal of the valuation allowance that relates to the Company s use of these deferred tax assets in the year ended December 31, 2008 of $277,000 was recorded as a reduction of goodwill.

As of December 31, 2008, the Company has federal NOLs of approximately $162.2 million that begin to expire in the year 2021, state NELs of approximately $154.0 million that begin to expire in 2009 and federal tax credits of approximately $1.9 million that begin to expire in 2021. Because of the limitations discussed above, the Company has concluded that it is not more likely than not that it will be able to utilize any of these federal or state loss carryforwards or federal tax credit carryforwards. Accordingly, the Company has established a valuation allowance with respect to the entire amount of these loss carryforwards and tax credit carryforwards. The Company recognized approximately $816,000 in tax benefits in 2008 related to NOL carryforwards, including $277,000 that was recorded as a reduction of goodwill.

Separate from the impact of the Merger, the Company also recognized approximately $45,000 and $60,000 of tax benefits related to the utilization of contribution carryforwards and tax credits, respectively, in the year ended December 31, 2008.

As a result of the Merger, the following deferred tax assets and liabilities were acquired:

	2008	2007
Current:		
Deferred tax assets (liabilities):		
Accrued expenses	$ 201	$
Acquired intellectual property	(630)	
Net current deferred tax liabilities	(429)	
Noncurrent:		
Deferred tax assets (liabilities):		
Tax loss carryforwards	$ 62,165	$
Tax credits	1,900	

Acquired intellectual property	(3,783)
Valuation allowance	(64,065)
Net noncurrent deferred tax liabilities	(3,783)
Total net deferred tax liability	(4,212)

As discussed above, the net deferred tax liabilities resulting from the Merger have been recorded as an adjustment to goodwill and were included in the assumed liabilities in Note 3.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 14: RELATED PARTY TRANSACTIONS

Stockholders

During the years ended December 31, 2008 and 2007, the Company made advances of $19,000, $615,000, respectively, to its President and Chief Executive Officer, who, prior to the closing of the Merger, was Cornerstone BioPharma s majority stockholder. Unpaid advances of $648,000 are included in amounts due from related parties as of December 31, 2007. There were no unpaid advances as of December 31, 2008, as the Company s President and Chief Executive Officer repaid all advances prior to the closing of the Merger.

The Company has certain agreements with its President and Chief Executive Officer, who is the Company s largest stockholder, that provide certain benefits related to a qualified termination or change of control, as defined by the agreements.

Other Related Parties

As of December 31, 2007, the Company owed Carolina Pharmaceuticals $260,000 in accrued royalties related to the sale of Humibid® and DECONSAL®. This amount is included in accrued royalties as disclosed in Note 2. The Company paid $260,000 to Carolina Pharmaceuticals for royalties during the year ended December 31, 2008. The Company did not pay any royalties to Carolina Pharmaceuticals in the year ended December 31, 2007. The Company s President and Chief Executive Officer is the Chief Executive Officer and Chairman of the board of directors of Carolina Pharmaceuticals and certain other executive officers of the Company are directors of Carolina Pharmaceuticals.

In May 2005, the Company licensed certain product rights to Auriga Laboratories, Inc. (Auriga), which is also owned in part and at that time was directed by some of the Company s stockholders. The effective date of the agreement is August 1, 2005. The Company received a royalty ranging from 8% to 30% of net sales, depending on the level of net sales. The Company s royalty is not to exceed $1.7 million on an annual basis. Auriga assumed responsibility for royalty payments to the previous owner of the product rights as of the effective date. In 2006, the royalty agreement with Auriga was amended to reduce the royalty rates from 30% to 5% of net sales in a specific calendar quarter. The amendment also provided for Auriga to issue the Company 200,000 shares of its common stock. The fair value of the stock, determined as the trading price on date of grant discounted 15% for lack of marketability due to a one-year lock up period, was $332,000. The Company included this amount in royalty agreement revenues.

In connection with Auriga s August 2005 assumption of responsibility for royalty payments to the previous owner of the product rights, the Company guaranteed Auriga s payment of royalties to the previous owner of the product rights. On July 23, 2008, the previous owner of the product rights agreed to an amendment whereby the Company s guarantee is capped at $100,000 and extends only to royalty obligations incurred by Auriga prior to such date. Because Auriga did not pay any of these royalty obligations to the previous owner of the product rights by August 29, 2008 as it had agreed, as of September 30, 2008, the Company recorded an accrual for the entire amount of the capped guarantee, or $100,000, in accrued expenses. The Company paid the previous owner the amount owed under the guarantee in November 2008.

The Company recognized royalty agreement revenues under the agreements with Auriga of $56,000 and $58,000 for the years ended December 31, 2008 and 2007, respectively. The Company recorded $56,000 in accounts payable as of December 31, 2007 due to returns related to 2006 sales that were processed against royalties in 2007. The Company had no outstanding accounts payable to Auriga as of December 31, 2008.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 15: LICENSE AGREEMENT LIABILITY

Abbott

On December 18, 2003, the Company entered into a license agreement with Abbott Laboratories (Abbott) granting the Company an exclusive worldwide license, under patent rights and know-how controlled by Abbott, to develop, make, use and sell certain controlled-release and injectable formulations of zileuton. This license included an exclusive sublicense of Abbott s rights in proprietary controlled-release technology originally licensed to Abbott by Jagotec AG (Jagotec). In March 2004, the Company acquired from Abbott the U.S. trademark ZYFLO and an exclusive worldwide license, under patent rights and know-how controlled by Abbott, to develop, make, use and sell the immediate-release formulation of zileuton for all clinical indications. As partial consideration for the December 2003 license, the Company agreed to make aggregate milestone payments of up to $13.0 million to Abbott upon the achievement of various development and commercialization milestones, including specified minimum net sales of licensed products. As of December 31, 2008, aggregate milestone payments of up to $6.5 million remain under the December 2003 license. In connection with an obligation that the Company assumed in connection with the Merger to make a $1.5 million milestone payment to Abbott on the second anniversary of FDA approval of the ZYFLO CR new drug application (NDA) in May 2009, the Company has accrued $1.5 million as of December 31, 2008. The amount due was accrued at the present value of the total $1.5 million owed, and the accretion of the discount is included in interest expense based upon imputed interest at 5% per annum. Except for a termination right provided to a party in connection with a breach by the other party, the term of the December 2003 license agreement is perpetual although the Company has 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

On December 3, 2003, the Company entered into an agreement with Jagotec under which Jagotec consented to Abbott s sublicense to the Company of rights to make, use and sell a controlled-released zileuton formulation covered by Jagotec s patent rights and know-how that the Company markets as ZYFLO CR. In addition to an upfront fee, the Company agreed to make aggregate milestone payments to Jagotec of up to $6.6 million upon the achievement of various development and commercialization milestones. As of December 31, 2008, aggregate milestone payments of up to $1.6 million remain under this agreement. In connection with an obligation that the Company assumed in connection with the Merger to make a $375,000 milestone payment to Jagotec on the second anniversary of FDA approval of the ZYFLO CR NDA in May 2009, the Company has accrued $368,000 as of December 31, 2008. The amount due was accrued at the present value of the total $375,000 owed, and the accretion of the discount is included in interest expense based upon imputed interest at 5% per annum. Except for a termination right provided to a party in connection with a breach by the other party, the term of this agreement is perpetual.

Meiji

On October 12, 2006, the Company entered into a license and supply agreement with Meiji Seika Kaisha, Ltd. (Meiji) granting the Company an exclusive, nonassignable U.S. license to manufacture and sell a 200 mg dosage of SPECTRACEF, using cefditoren pivoxil supplied by Meiji. In consideration for the license, the Company agreed to

pay Meiji a nonrefundable license fee of $6.0 million in six installments over a period of five years from the date of the agreement. The agreement provided that if a generic cefditoren product was launched in the United States prior to October 12, 2011, the Company would be released from its obligation to make any further license fee payments due after the date of launch. In the year ended December 31, 2006, the

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Company estimated that a generic cefditoren product would be available in two and a half years, which would limit the total installment payments to $2.25 million.

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

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

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

	2008	2007
License agreement liability to Abbott; imputed interest at 5% per annum; principal and interest payable in May 2009	$ 1,471	$
License agreement liability to Jagotec; imputed interest at 5% per annum; principal and interest payable in May 2009	368	
License agreement liability to Meiji; imputed interest at 12% per annum; principal and interest payable for the remaining three and four years, respectively	3,017	3,606
Less current portion	(2,543)	(647)
Long-term	$ 2,313	$ 2,959

Principal maturities of the license agreement liability subsequent to December 31, 2008 are as follows (in thousands):

2009	$ 2,543
2010	972
2011	1,341
Total	$ 4,856

NOTE 16: COMMITMENTS AND CONTINGENCIES

Royalties

The Company has contractual obligations to pay royalties to the former owners of certain product rights that have been acquired by or licensed to the Company, some of which are described above in Note 15. These royalties are based on a percentage of net sales of the particular licensed product.

In August 2006, the Company entered into an agreement with Pharmaceutical Innovations, LLC (Pharmaceutical Innovations) for an exclusive license to a U.S. patent and know-how to manufacture, package, market and distribute various day-night products. In exchange for these rights, the Company was

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

required to pay Pharmaceutical Innovations a special royalty of 8.5% of initial net sales of day-night products up to a total of $250,000. The Company paid this special royalty in the years ended December 31, 2006 and 2007. In addition, the Company is obligated to pay royalties based on a percentage of the products annual net sales. The royalty rate increases as the annual net sales increase. Minimum annual royalties are $300,000 per year under this agreement during the life of the licensed patent based on the products currently marketed by the Company. The Company exceeded the minimum annual royalty during the years ended December 31, 2007 and 2008 and expects to do so in the year ending December 31, 2009.

On July 1, 2001, the Company acquired from The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute) (The Feinstein Institute), an exclusive worldwide license, under patent rights and know-how controlled by The Feinstein Institute relating to a cytokine called HMGB1, to make, use and sell products covered by the licensed patent rights and know-how. As partial consideration for the license, among other things, the Company agreed to make payments to The Feinstein Institute ranging from $50,000 to $275,000 for each additional distinguishable product depending on whether it was covered by the licensed patent rights or by the licensed know-how, in each case upon the achievement of specified development and regulatory milestones for the applicable licensed product. As of December 31, 2008, none of these milestones had been achieved. In addition, the Company is obligated to pay royalties to The Feinstein Institute based on product sales. In the event of no product sales, the Company will be required to pay minimum annual royalties of $15,000 in years 2009 through 2011 and $75,000 in years 2012 through the expiration of the patent in 2023.

The Company also has entered into two sponsored research and license agreements with The Feinstein Institute, one agreement in July 2001 related to identifying identify inhibitors and antagonists of HMGB1 and related proteins and a second agreement in January 2003 in the field of cholinergic anti-inflammatory technology, including alpha-7. Under the terms of these agreements, the Company acquired an exclusive worldwide license to make, use and sell products covered by the patent rights and know-how arising from the sponsored research. In connection with the July 2001 sponsored research and license agreement, the Company agreed to make payments to The Feinstein Institute ranging from $50,000 to $200,000 for each additional distinguishable product depending on whether it was covered by the licensed patent rights or by the licensed know-how. In connection with the January 2003 sponsored research and license agreement, the Company agreed to pay additional amounts in connection with the filing of any U.S. patent application or issuance of a U.S. patent relating to the field of cholinergic anti-inflammatory technology. The Company also agreed to make aggregate milestone payments to The Feinstein Institute of up to $1.5 million in both cash and shares of the Company s common stock upon the achievement of specified development and regulatory approval milestones with respect to any licensed product. As of December 31, 2008, none of these milestones had been achieved. In addition, the Company is obligated to pay royalties to The Feinstein Institute based on product sales. Under the January 2003 sponsored research and license agreement, the Company agreed to pay minimum annual royalties beginning in 2008 to The Feinstein Institute, regardless of whether the Company sells any licensed products, of $100,000 in 2008, which minimum annual royalties amount will increase by $50,000 annually to a maximum of $400,000 in 2014, with a minimum annual royalty payment of $400,000 thereafter payable through the expiration of the patent in 2023. The required minimum annual royalty for the year ended December 31, 2008 was paid by Critical Therapeutics prior to the completion of the merger.

Supply Agreements

Concentrations

The Company purchases inventory from pharmaceutical manufacturers. During the year ended December 31, 2008, two vendors accounted for 14% of the Company s inventory purchases. During the year ended December 31, 2007, one vendor accounted for 23% of the Company s inventory purchases. Three vendors accounted for 25% of the Company s accounts payable as of December 31, 2008. Three vendors

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

accounted for 37% of the Company s accounts payable as of December 31, 2007. As of December 31, 2008 and 2007, the Company had outstanding purchase orders related to inventory totaling approximately $4.3 million and $2.8 million, respectively.

Vintage

The Company has entered into an agreement with Vintage Pharmaceuticals, LLC (Vintage) to exclusively manufacture BALACET 325, APAP 325 and APAP 500 for prices established by the agreement, subject to renegotiation at each anniversary date. The agreement expires in July 2010 and may be renewed for subsequent one-year terms.

Meiji

In connection with the license agreement with Meiji as described in Note 15, Meiji is the Company s exclusive supplier of cefditoren pivoxil and, through October 2018, of SPECTRACEF 400 mg so long as Meiji is able to supply 100% of the Company s requirements for SPECTRACEF 400 mg. Additionally, Meiji will be a non-exclusive supplier of SPECTRACEF 200 mg through October 2018. The Company is 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 the Company does not meet its minimum purchase requirement in a given year, the Company must pay Meiji an amount equal to 50% of the shortfall in that year. The Company expects to exceed the minimum purchase requirements. These minimum purchase requirements cease to apply if a generic cefditoren product is launched in the United States prior to October 12, 2011.

Shasun

Shasun Pharma Solutions (Shasun) manufactures all of the Company s commercial supplies of the zileuton API pursuant to an agreement dated February 8, 2005. The Company has committed to purchase zileuton API from Shasun in the amounts of $5.8 million in 2009 and $1.6 million in 2010, respectively, which are in excess of the Company s minimum purchase requirements. The agreement will expire on the earlier of the date on which the Company has purchased a specified amount of the API for zileuton or December 31, 2010. The agreement will automatically extend for successive one-year periods after December 31, 2010, unless Shasun provides the Company with 18-months prior written notice of cancellation.

Jagotec

Jagotec manufactures all of the Company s bulk, uncoated tablets of ZYFLO CR pursuant to a manufacture and supply agreement dated August 20, 2007. The Company has agreed to purchase from Jagotec a minimum of 20.0 million ZYFLO CR tablet cores in each of the four 12-month periods starting May 30, 2008. The Company expects to exceed the minimum purchase requirements. The agreement s initial term extends to May 22, 2012, and will automatically continue thereafter, unless the Company provides Jagotec with 24-months prior written notice of termination or Jagotec provides the Company with 36-months prior written notice of termination.

Patheon

Patheon Pharmaceuticals, Inc. (Patheon) coats, conducts quality control and quality assurance and stability testing and packages commercial supplies of ZYFLO CR for the Company using uncoated ZYFLO CR tablets the Company supplies to Patheon. The Company has agreed to purchase from Patheon at least 50% of the Company s requirements for such manufacturing services for ZYFLO CR for sale in the United States

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

each year during the term of this agreement. The agreement s initial term extends to May 9, 2010, and will automatically continue for successive one-year periods thereafter, unless the Company provides Patheon with 12-months prior written notice of termination or Patheon provides the Company with 18-months prior written notice of termination.

Patheon also manufactures all of the Company s ZYFLO immediate release tablets pursuant to a commercial manufacturing agreement. The Company has agreed to purchase from Patheon at least 50% of the Company s commercial supplies of ZYFLO immediate-release tablets for sale in the United States each year for the term of the agreement. The agreement s current term extends to September 15, 2009, and will automatically continue for successive one-year periods thereafter, unless the Company provides Patheon with 12-months prior written notice of termination or Patheon provides the Company with 18-months prior written notice of termination.

Sovereign

Sovereign Pharmaceuticals, Ltd. (Sovereign) manufactures all of the Company s requirements of three HYOMAX® products pursuant to an exclusive supply and marketing agreement that the Company entered into in May 2008. Additionally, the Company purchases all of its requirements for HYOMAX DT tablets pursuant to purchase orders it places from time to time with Sovereign, which manufactures and supplies the HYOMAX DT tablets to the Company pursuant to an agreement between Sovereign and Capellon Pharmaceuticals, Ltd. to which the Company is not a party. The Company pays Sovereign its costs to manufacture the HYOMAX products exclusively for the Company, as well as a royalty based on a share of the net profits realized from the sale of the products. The term of the agreement expires in April 2011 and will be automatically renewed for successive one-year terms unless either party provides written notice of termination at least 90 days prior to the end of the then current term.

DEY Co-Promotion and Marketing Services Agreements

On March 13, 2007, the Company entered into an agreement with Dey, L.P. (DEY), a wholly owned subsidiary of Mylan Inc., under which the Company and DEY agreed to jointly promote ZYFLO and ZYFLO CR. Under the co-promotion and marketing services agreement, the Company granted DEY an exclusive right to promote and detail ZYFLO and ZYFLO CR in the United States, together with the Company.

Under the co-promotion agreement, DEY paid the Company $12.0 million in non-refundable aggregate payments in 2007 and the Company committed to perform a ZYFLO CR clinical trial expected to cost at least $6 million and to fund at least $12 million in promotional expenses, comprised of at least $3.0 million per year from 2007 to 2010. Under the co-promotion agreement, the Company will pay DEY a commission on quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties, in excess of $1.95 million. Following the commercial launch of ZYFLO CR in October 2007 through December 31, 2010, the commission rate is 35% and from January 1, 2011 through December 31, 2013, the commission rate is 20%. The co-promotion agreement expires on December 31, 2013 and may be extended upon mutual agreement by the parties.

Other Co-promotion Agreements

In February 2006, the Company signed a co-promotion agreement with Ascend Therapeutics, Inc. (Ascend) to provide detailing of a product to a specific physician population. As compensation, the Company paid a fee for detailing the

product equal to 50% of net sales. This agreement was terminated in March 2008 at no additional cost to the Company.

In March 2007 and June 2007, the Company entered into co-promotion agreements, as amended, with SJ Pharmaceuticals, LLC (SJ Pharmaceuticals) to co-promote the Company s ALLERX Dose Pack products

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

and SPECTRACEF products, respectively. Under these agreements, the Company pays SJ Pharmaceuticals fees based on a percentage of the net profits of the products sold above a specified baseline based upon prescriptions by assigned, targeted prescribers within assigned sales territories. The Company terminated its ALLERX Dose Pack co-promotion agreement with SJ Pharmaceuticals effective December 31, 2008. In connection with that termination, the Company is obligated to pay SJ Pharmaceuticals a termination fee on a quarterly basis for six months following termination equal to the average amount paid per month during the final six months preceding the termination date. The Company recorded the entire amount of the termination fee in accrued expenses in the accompanying consolidated balance sheet as of December 31, 2008. On February 25, 2009, SJ Pharmaceuticals terminated the SPECTRACEF co-promotion agreement effective April 24, 2009. Neither SJ Pharmaceuticals nor the Company is required to pay the other party any termination fee in connection with the termination.

In April 2007, the Company entered into a co-promotion agreement, as amended, with Atley Pharmaceuticals, Inc. (Atley Pharmaceuticals) to co-promote a prescription pain product beginning July 1, 2007. Under the agreement, the Company pays Atley Pharmaceuticals fees based on a percentage of the net profits from sales of the product (as well as an authorized generic equivalent of the product marketed by the Company) above a specified baseline within assigned sales territories.

Like the ALLERX Dose Packs co-promotion agreement with SJ Pharmaceuticals that the Company terminated, each of the Company s co-promotion agreements (other than the DEY co-promotion and marketing services agreement) is subject to sunset fees that require the Company to pay additional fees for up to one year in the event of certain defined terminations of the agreements.

Settlements

Adams Respiratory Therapeutics, Inc.

In October 2004, the Company and a related party, Carolina Pharmaceuticals, Inc., were named as co-defendants in litigation brought by Adams Respiratory Therapeutics, Inc. (Adams) that alleged trademark infringement, false advertising and unfair competition claims and sought damages and injunctive relief. The Company vigorously defended these allegations and filed various counterclaims. In January 2005, Adams and the Company entered into an agreement under which in February 2005 the Company received all of the rights to the ALLERX products held by Adams and Adams received all of the rights to the Humibid family of products held by the Company. Additionally, the parties released each other from all claims and damages in the above mentioned lawsuit. The agreement required the Company to assume the financial responsibility for the first $1.0 million of returned Humibid product that was sold by the Company prior to February 15, 2005 and returned to Adams during the 18-month period beginning February 15, 2005. The Company had recorded $1.0 million in accrued expenses in the accompanying consolidated balance sheet as of December 31, 2007 for this Humibid liability. The Company also had $746,000 in accrued royalty expenses related to ALLERX sales as of December 31, 2007. Conversely, Adams was financially responsible for the first $1.0 million of ALLERX product returns for the same 18-month period. The Company had recorded approximately $355,000 in accounts receivable in the accompanying consolidated balance sheet as of December 31, 2007. After the 18-month period or the $1.0 million threshold is met, the agreement provided that Adams would have the responsibility for all Humibid product returns whether sold by the Company or Adams. In connection with this agreement, Adams is obligated to pay the Company a royalty ranging from 1% to 2% of net Humibid sales for a period of three years after February 15, 2005 with a minimum annual royalty of $50,000. The Company had recorded

$100,000 in accounts receivable in the accompanying consolidated balance sheet as of December 31, 2007, related to the minimum royalty.

In 2006, a major wholesaler indicated that it was in possession of a significant amount of Humibid prescription inventory. Adams filed a complaint alleging that the Company and Carolina Pharmaceuticals, Inc. did not disclose the outstanding inventory in accordance with the prior agreement and are therefore financially

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

responsible for the returns. The Company and Carolina Pharmaceuticals, Inc. believed they were not liable for these returns under the agreement and filed a counterclaim. Since all Humibid prescription products were sold by Carolina Pharmaceuticals, Inc., the Company did not accrue any amounts related to this claim.

In May 2008, the Company settled the dispute with Adams. The agreement provides that all parties to the settlement are to be released from all legal claims made prior to January 2008 and that the Company and Carolina Pharmaceuticals, Inc. shall pay to Reckitt Benckiser Inc., the parent of Adams, $1.5 million in three installments to be paid as follows: $500,000 by June 20, 2008; $500,000 by June 30, 2008; and $500,000 by September 30, 2008. In exchange, the Company is released from all liabilities. All amounts were paid by September 30, 2008 as required. The Company paid $290,000 of the final $500,000 installment and the balance of $210,000 was paid by Carolina Pharmaceuticals, Inc.

Others

In November 2006, the Company filed a legal complaint against a pharmaceutical company, certain affiliates of the pharmaceutical company and the manufacturer of a product launched by the pharmaceutical company that the Company believed infringed upon the patent of one of its products. By January 2007, the disputes with all involved parties were settled. The terms of the settlements required the parties to admit and acknowledge that the claims of the patent are valid and enforceable and covenant that the parties will not infringe on the claims of the patent by making, using, selling or offering for sale any product that would infringe on the patent. The settlements provided that the Company pay the parties for the value of certain inventory on hand, which was destroyed. The total actual inventory payments made related to the settlement in the year ended December 31, 2007 amounted to $236,000, and the excess accrual of $20,000 was reversed as of December 31, 2007. In addition, as part of the settlement, the Company also committed to pay $75,000 for trademark rights. The Company also made this payment in the year ended December 31, 2007.

Legal Proceedings

In 2007, the U.S. Patent and Trademark Office ordered a re-examination of a patent licensed to the Company that covers one or more of the Company s day-night products. Subsequently, in October 2007, the Company filed suit against a pharmaceutical company in the U.S. District Court for the Eastern District of North Carolina alleging infringement of the patent. In November 2007, before a response to the Company s claims was due, the defendant moved to stay the litigation pending the re-examination of the Company s patent. The court granted defendants motion and stayed the litigation pending the re-examination of the patent in February 2008. In cooperation with its licensor, the Company intends to vigorously pursue its claims and to vigorously defend against any counterclaims that might be asserted. Additionally, in June 2008, the defendant requested that the U.S. Patent and Trademark Office re-examine a related second patent licensed to the Company by an affiliate of the licensor of the first patent. The U.S. Patent and Trademark Office granted this request and ordered a re-examination of the second patent in August 2008. The Company s intellectual property counsel has concluded that valid arguments exist for distinguishing the claims of the Company s patents over the references cited in the requests for re-examination.

In an unrelated action, another pharmaceutical company filed suit in November 2008 against the Company in the U.S. District Court for the District of Maryland seeking, among other things, a declaratory judgment that the second patent is invalid. Because no monetary relief has been requested in this action, no amount has been accrued in these

consolidated financial statements. In cooperation with the licensor, the Company intends to vigorously defend against the declaratory judgment claim and to vigorously pursue appropriate counterclaims.

On September 17, 2008, a purported shareholder class action lawsuit was filed by a single plaintiff against Critical Therapeutics and each of its then current directors in the Court of Chancery of the State of Delaware. The action is captioned *Jeffrey Benison IRA v. Critical Therapeutics, Inc., Trevor Phillips, Richard W. Dugan, Christopher Mirabelli, and Jean George*, Case No. 4039, Court of Chancery, State of Delaware.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The plaintiff, which claimed to be one of Critical Therapeutics stockholders, brought the lawsuit on its own behalf, and sought certification of the lawsuit as a class action on behalf of all of Critical Therapeutics then current stockholders, except the defendants and their affiliates. The complaint alleged, among other things, that the defendants breached fiduciary duties of loyalty and good faith, including a fiduciary duty of candor, by failing to provide Critical Therapeutics stockholders with a proxy statement/prospectus adequate to enable them to cast an informed vote on the proposed merger, and by possibly failing to maximize stockholder value by entering into an agreement that effectively discourages competing offers. The complaint sought, among other things, an order (i) enjoining the defendants from proceeding with or implementing the proposed merger on the terms and under the circumstances as they then existed, (ii) invalidating the provisions of the proposed merger that purportedly improperly limited the effective exercise of the defendants continuing fiduciary duties, (iii) ordering defendants to explore alternatives and to negotiate in good faith with all bona fide interested parties, (iv) in the event the proposed merger was consummated, rescinding it and setting it aside or awarding rescissory damages, (v) awarding compensatory damages against defendants, jointly and severally, and (vi) awarding the plaintiff and the purported class their costs and fees.

On October 17, 2008, Critical Therapeutics and the other defendants entered into a memorandum of understanding with the plaintiff regarding the settlement of the lawsuit. In connection with the settlement, the parties agreed that Critical Therapeutics would make certain additional disclosures to Critical Therapeutics stockholders, which are contained in a supplement to the proxy statement/prospectus that was mailed to Critical Therapeutics stockholders. After the completion of certain confirmatory discovery by counsel to the plaintiff, as contemplated by the memorandum of understanding, the parties entered into a stipulation and agreement of compromise, settlement and release on November 24, 2008. On December 3, 2008, the court entered a scheduling order preliminarily approving class treatment of the case and setting a briefing and hearing schedule to consider the proposed settlement of the case. On December 23, 2008, the Company caused a court-approved notice of pendency of class action, proposed class action determination, proposed settlement of class action, settlement hearing and right to appear to be mailed to all persons that held Critical Therapeutics stock during the period May 1, 2008 through October 31, 2008, other than the defendants and their affiliates. On February 26, 2009, the court approved the settlement resolving all of the claims that were or could have been brought in the action being settled, including all claims relating to the Merger, the merger agreement and any disclosure made in connection therewith. In addition, in connection with the settlement, the court awarded plaintiff s counsel $175,000 for attorneys fees and expenses to be paid by the Company, which was accrued as of December 31, 2008.

Product Agreements

In August 2006, the Company loaned Neos Therapeutics, L.P. (Neos) $500,000 under a secured subordinated promissory note agreement. In December 2006, the Company entered into a product development agreement with Neos providing the Company with an exclusive license to certain products under development utilizing Neos s patent-pending time release suspension technology. Under the terms of the agreement, the note with Neos was forgiven. The Company has recorded the $500,000 consideration as product rights related to the time release suspension technology. The agreement, as amended and restated in August 2008, requires Neos to develop the first product at its own expense up to a defined milestone. After that milestone is achieved, the Company is required to reimburse Neos 110% of all direct costs incurred and pay $150 per hour for personnel time incurred in the development of the products. The Company will also make milestone payments up to $1.0 million for each product based on specific events. As of December 31, 2008, Cornerstone had accrued $57,000 in development costs and had not made any milestone payments. Upon commercialization, the Company would also pay Neos royalties based on a

percentage of net sales.

In December 2008, the Company entered into an additional development, license and services agreement with Neos to license certain Neos patent-pending technology. Under the agreement, Neos will perform

Table of Contents

CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

development work on a new product candidate. The Company is required to pay hourly fees for the development work in addition to up to an aggregate of $400,000 in fees.

During the year ended December 31, 2008, the Company entered various research and development agreements. As of December 31, 2008, the Company had outstanding commitments related to ongoing research and development contracts totaling approximately $523,000.

Severance

Selected executive employees of the Company have employment agreements which provide for severance payments ranging from three to 24 months of salary, benefits and, with respect to certain executives, bonuses, upon termination, depending on the reasons for the termination. The executive would also be required to execute a release and settlement agreement. No amount has been accrued for severance as of December 31, 2008 or 2007.

Table of Contents

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

Not applicable.

ITEM 9A. ***CONTROLS AND PROCEDURES***

Not applicable.

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

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2008. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2008, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level as a result of the material weakness in our internal control over financial reporting described below.

Management s Report on Internal Control Over Financial Reporting

On October 31, 2008, Critical Therapeutics completed the merger with Cornerstone BioPharma. Cornerstone BioPharma was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition in accordance with GAAP. Accordingly, for all purposes, including reporting with the 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. In addition, as a result of the merger, Critical Therapeutics accounting and finance personnel, management team (other than Mr. Townsend), accounting systems, accounting policies and internal control over financial reporting were replaced by Cornerstone BioPharma s accounting and finance personnel, management team, accounting systems, accounting policies and internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Prior to the completion of the merger, Cornerstone BioPharma was a private company that had not assessed its internal control over financial reporting using a recognized framework, and due to the limited time between the date of the merger and our December 31, 2008 year end and our management s focus on post-merger integration activities, our management was unable to conduct such an assessment as of December 31, 2008. In addition, because of the significance of Cornerstone BioPharma s operations and financial condition to the post-merger combined company and the replacement of Critical Therapeutics accounting and finance personnel, management team, accounting systems, accounting policies and internal control

over financial reporting prior to December 31, 2008, our management concluded that a report limited to Critical Therapeutics historical internal control over financial reporting would not be meaningful (and could be misleading) to investors with respect to the effectiveness of our internal control over financial reporting as of December 31, 2008.

Table of Contents

Accordingly, this annual report on Form 10-K does not contain a management s report on internal control over financial reporting.

Our management is currently assessing our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework*. We expect to complete this assessment during 2009. As part of this assessment, our management intends to remediate any identified material weaknesses in our internal control over financial reporting prior to December 31, 2009. Our annual report on Form 10-K for the year ended December 31, 2009 will include a management s report on internal control over financial reporting.

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

Because we are classified as a non-accelerated filer under SEC rules, we are not required to include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting in this annual report on Form 10-K for the year ended December 31, 2008 pursuant to temporary rules of the SEC. Under those temporary rules, we will be required to include such an attestation report of our independent registered public accounting firm in our next annual report on Form 10-K for the year ending December 31, 2009.

Changes in Internal Control Over Financial Reporting

As discussed above, following the consummation of the merger, Critical Therapeutics accounting and finance personnel, management team (other than Mr. Townsend), accounting systems, accounting policies and internal control over financial reporting were replaced by Cornerstone BioPharma s accounting and finance personnel, management team, accounting systems, accounting policies and internal control over financial reporting. Because of the magnitude of this change and Cornerstone BioPharma s becoming part of a public company, our management initiated a top-down review of Cornerstone BioPharma s (now our) internal control over financial reporting. Among other things, our management is assessing the impact of the merger and public company status on our existing internal control structure and considering whether additional controls are appropriate to address new or increased risks that may affect the reliability of our financial reporting and the preparation of our financial statements for our stockholders and other external users. As part of the process, our management is also considering whether any changes to our control environment, including our information systems and our internal control monitoring systems, are appropriate. Management expects to complete this assessment during 2009.

Although our management has not completed its assessment of our internal control over financial reporting, based on the portion of its assessment completed as of March 17, 2009, our management has determined that our accounting and finance department lacks a sufficient number of personnel with appropriate accounting knowledge and experience to record our financial results in conformity with GAAP, which prevents us from being able to timely and effectively close our books at the end of each interim and annual period. Our management has determined that this understaffing constitutes a material weakness in our internal control over financial reporting because it results in a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

As discussed above, our management is currently assessing our internal control over financial reporting and expects to complete this assessment during 2009. In light of the material weakness described above and as part of our management s ongoing assessment, our Audit Committee and our president and chief executive officer has directed our management to particularly review the expertise, training and sufficiency of our finance and accounting personnel,

especially with respect to the financial statement close process. Based on the results of this review, our management will take appropriate steps to remediate the presently identified material weakness, which may include, as appropriate, hiring additional personnel, providing additional training to our existing personnel and outsourcing certain functions to third-party consultants. As part of its overall assessment of our internal control over financial reporting, our management also intends to take any

Table of Contents

further steps necessary to remediate any identified material weaknesses in our internal control over financial reporting prior to December 31, 2009.

As noted above, our management s assessment of our internal control over financial reporting is not complete, and, accordingly, our management may identify additional material weaknesses as part of its assessment. Based on the foregoing, our management, with the participation of our chief executive officer and chief financial officer, concluded that, during the fiscal quarter ended December 31, 2008, there were changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. ***OTHER INFORMATION***

Not applicable.

Table of Contents

PART III

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

Directors and Executive Officers

Information regarding our directors may be found under the captions Proposal One Election of Directors and Corporate Governance Board Committees in the Proxy Statement for our 2009 Annual Meeting of Stockholders. Information regarding our executive officers may be found under the caption Executive Officers of the Registrant in Part I of this annual report on Form 10-K. Such information is incorporated herein by reference.

Compliance With Section 16(a) of the Exchange Act

Information regarding compliance with Section 16(a) of the Exchange Act by our directors, officers and beneficial owners of more than 10% of our common stock may be found under the caption Stock Ownership Information Section 16(a) Beneficial Ownership Reporting Compliance in the Proxy Statement for our 2009 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Code of Ethics

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

Director Nominees

Information regarding procedures for recommending nominees to the board of directors may be found under the caption Corporate Governance Director Nomination Process in the Proxy Statement for our 2009 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Audit Committee

We have a separately designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Additional information regarding the Audit Committee may be found under the captions Corporate Governance Board Committees Audit Committee and Corporate Governance Audit Committee Report in the Proxy Statement for our 2009 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Audit Committee Financial Expert

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

ITEM 11. *EXECUTIVE COMPENSATION*

Information with respect to this item may be found under the caption Information About Executive and Director Compensation in the Proxy Statement for our 2009 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Table of Contents

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

Information with respect to this item may be found under the captions Stock Ownership Information and Information About Executive and Director Compensation Securities Authorized for Issuance Under Equity Compensation Plans in the Proxy Statement for our 2009 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

Information with respect to this item may be found under the captions Corporate Governance Transactions with Related Persons and Corporate Governance Board Determination of Independence in the Proxy Statement for our 2009 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

Information with respect to this item may be found under the captions Corporate Governance Independent Registered Public Accounting Firm s Fees and Corporate Governance Pre-Approval Policy and Procedures in the Proxy Statement for our 2009 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

PART IV

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

(a) (1) *Financial Statements.*

For a list of the financial information included herein, see Index to Consolidated Financial Statements on page 94 of this annual report on Form 10-K.

(a) (2) *Financial Statement Schedules.*

We have omitted financial statement schedules because they are not applicable or the required information is included in the consolidated financial statements or notes thereto.

(a) (3) *Exhibits.*

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

ZYFLO CR, ZYFLO, ALLERX, CRTX, CT2, DECONSAL, RESPIVENT, HYOMAX and BALACET are registered trademarks of Cornerstone Therapeutics Inc. or its subsidiaries. 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.

Table of Contents

SIGNATURES

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

CORNERSTONE THERAPEUTICS INC.

By: /s/ CRAIG A. COLLARD

Craig A. Collard
President and Chief Executive Officer
March 26, 2009

Date: March 26, 2009

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

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

Signature	Title	Date
/s/ CRAIG A. COLLARD Craig A. Collard	President, Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2009
/s/ DAVID PRICE David Price	Executive Vice President, Finance, and Chief Financial Officer (Principal Financial Officer)	March 26, 2009
/s/ CHENYQUA BALDWIN Chenyqua Baldwin	Vice President, Finance, Chief Accounting Officer and Controller (Principal Accounting Officer)	March 26, 2009
/s/ CHRISTOPHER CODEANNE Christopher Codeanne	Director	March 26, 2009
/s/ MICHAEL ENRIGHT	Director	March 26, 2009

Michael Enright		
/s/ MICHAEL HEFFERNAN	Director	March 26, 2009
Michael Heffernan		
/s/ ALASTAIR MCEWAN	Director	March 26, 2009
Alastair McEwan		

Table of Contents

Exhibit Index

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of May 1, 2008, by and among the Registrant, Neptune Acquisition Corp. and Cornerstone BioPharma Holdings, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K dated May 1, 2008 (SEC File No. 000-50767)).
2.2	Amendment No. 1, dated as of August 7, 2008, to Agreement and Plan of Merger, dated as of May 1, 2008, among the Registrant, Neptune Acquisition Corp. and Cornerstone BioPharma Holdings, Inc. (incorporated by reference to Exhibit 2.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008 (SEC File No. 000-50767)).
2.3	Form of Merger Partner Stockholder Agreement among the Registrant, Cornerstone BioPharma Holdings, Inc. and certain stockholders of Cornerstone BioPharma Holdings, Inc. (incorporated by reference to Exhibit 2.2 to the Registrant s Registration Statement on Form S-4/A dated September 29, 2008 (SEC File No. 333-152442)).
2.4	Merger Partner Noteholder Agreement, dated as of May 1, 2008, among the Registrant, Cornerstone BioPharma Holdings, Inc., Cornerstone BioPharma, Inc. and Carolina Pharmaceuticals Ltd. (incorporated by reference to Exhibit 2.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008 (SEC File No. 000-50767)).
2.5	Amendment No. 1, dated as of August 7, 2008, to Merger Partner Noteholder Agreement, dated as of May 1, 2008, among the Registrant, Cornerstone BioPharma Holdings, Inc., Cornerstone BioPharma, Inc. and Carolina Pharmaceuticals Ltd. (incorporated by reference to Exhibit 2.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008 (SEC File No. 000-50767)).
2.6	Form of Public Company Stockholder Agreement among Cornerstone BioPharma Holdings, Inc., the Registrant and certain stockholders of the Registrant (incorporated by reference to Exhibit 2.5 to the Registrant s Registration Statement on Form S-4/A dated September 29, 2008 (SEC File No. 333-152442)).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004 (SEC File No. 000-50767)).
3.2	Amendment to the Registrant s Certificate of Incorporation, effecting a 10-to-1 reverse stock split of the Registrant s common stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
3.3	Amendment to the Registrant s Certificate of Incorporation, changing the name of the corporation from Critical Therapeutics, Inc. to Cornerstone Therapeutics Inc. (incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
3.4	Third Amended and Restated Bylaws of the Registrant dated October 4, 2007 (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K dated October 4, 2007 (SEC File No. 000-50767)).
4.1	Form of the Registrant s Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.1+	Co-Promotion and Marketing Services Agreement between the Registrant and Dey, L.P. dated March 13, 2007 (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007 (SEC File No. 000-50767)).
10.2+	Amendment No. 1, dated June 25, 2007, to Co-Promotion and Marketing Services Agreement between the Registrant and Dey, L.P. dated March 13, 2007 (incorporated by reference to Exhibit 10.5 to the

	Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (SEC File No. 000-50767)).
10.3+	Copromotion Agreement between Atley Pharmaceuticals, Inc. and Cornerstone BioPharma, Inc. dated April 2, 2007 (incorporated by reference to Exhibit 10.3 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).

Table of Contents

Exhibit No.	Description
10.4+	First Amendment, dated July 1, 2008, to Copromotion Agreement between Atley Pharmaceuticals, Inc. and Cornerstone BioPharma, Inc. dated April 2, 2007 (incorporated by reference to Exhibit 10.4 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.5+	License and Supply Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated October 12, 2006 (incorporated by reference to Exhibit 10.6 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.6	Amendment No. 1, dated July 27, 2007, to License and Supply Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated October 12, 2006 (incorporated by reference to Exhibit 10.7 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.7+	Letter Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated July 27, 2007 (incorporated by reference to Exhibit 10.8 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.8+	Formulation Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated January 11, 2008 (incorporated by reference to Exhibit 10.9 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.9+	Addendum, dated August 14, 2008, to License and Supply Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated October 12, 2006 (incorporated by reference to Exhibit 10.10 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.10+	Joint Development Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated February 11, 2008 (incorporated by reference to Exhibit 10.11 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.11+	Agreement for Manufacturing and Supply of Zileuton between Rhodia Pharma Solutions Ltd. and the Registrant dated February 8, 2005 (incorporated by reference to Exhibit 10.41 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2004 (SEC File No. 000-50767)).
10.12+	Amendment No. 1, dated May 9, 2007, to Agreement for Manufacturing and Supply of Zileuton, between Shasun Pharma Solutions Limited and the Registrant dated February 8, 2005 (incorporated by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2007 (SEC File No. 000-50767)).
10.13+	Manufacturing and Supply Agreement by and among the Registrant, Jagotec AG and SkyePharma PLC dated August 20, 2007 (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 (SEC File No. 000-50767)).
10.14+	Manufacturing Services Agreement between Patheon Pharmaceuticals Inc. and the Registrant dated May 9, 2007 (incorporated by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2007 (SEC File No. 000-50767)).
10.15+	First Amendment, dated November 5, 2007, to Manufacturing Services Agreement between Patheon Pharmaceuticals Inc. and the Registrant dated May 9, 2007 (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 (SEC File No. 000-50767)).
10.16+	Agreement between Patheon, Inc. (formerly known as MOVA Pharmaceutical Corporation) and Cornerstone BioPharma, Inc. dated August 8, 2007 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.17+	Change of Scope Agreement between Patheon, Inc. (formerly known as MOVA Pharmaceutical Corporation) and Cornerstone BioPharma, Inc. dated November 20, 2007 (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File

No. 000-50767)).

10.18+ Master Manufacturing Agreement between Vintage Pharmaceuticals, LLC and Cornerstone BioPharma, Inc. (formerly known as Cornerstone Pharmaceuticals, Inc.) dated July 20, 2004 (incorporated by reference to Exhibit 10.5 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).

Table of Contents

Exhibit No.	Description
10.19+	License Agreement between the Registrant and Abbott Laboratories dated December 18, 2003 (incorporated by reference to Exhibit 10.10 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.20	Amendment No. 1, dated April 13, 2005, to License Agreement between the Registrant and Abbott Laboratories dated December 18, 2003 (incorporated by reference to Exhibit 10.14 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2006 (SEC File No. 000-50767)).
10.21+	License Agreement between the Registrant and Abbott Laboratories dated March 17, 2004 (incorporated by reference to Exhibit 10.11 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.22	Amendment No. 1, dated September 15, 2004, to License Agreement between the Registrant and Abbott Laboratories dated March 19, 2004 (incorporated by reference to Exhibit 10.16 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2006 (SEC File No. 000-50767)).
10.23+	Agreement between the Registrant and Jagotec AG dated December 3, 2003 (incorporated by reference to Exhibit 10.13 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.24+	Development and Scale-Up Agreement between the Registrant and Jagotec AG dated May 5, 2004 (incorporated by reference to Exhibit 10.25 to Amendment No. 2 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.25+	Patent License Agreement between Pharmaceutical Innovations, LLC and Cornerstone BioPharma, Inc. effective as of August 31, 2006 (incorporated by reference to Exhibit 10.12 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.26+	Amendment No. 1, dated August 10, 2007, to Patent License Agreement between Pharmaceutical Innovations, LLC and Cornerstone BioPharma, Inc. effective as of August 31, 2006 (incorporated by reference to Exhibit 10.13 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.27	Amendment No. 2, dated February 15, 2008, to Patent License Agreement between Pharmaceutical Innovations, LLC and Cornerstone BioPharma, Inc. effective as of August 31, 2006 (incorporated by reference to Exhibit 10.14 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.28+	Development, License and Services Agreement between Neos Therapeutics, L.P. and Cornerstone BioPharma, Inc. dated March 19, 2008 (incorporated by reference to Exhibit 10.15 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.29+	Development and Manufacturing Agreement by and among Neos Therapeutics, L.P., Coating Place, Inc. and Cornerstone BioPharma, Inc. dated February 27, 2008 (incorporated by reference to Exhibit 10.16 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.30+	Amended and Restated Products Development Agreement between Neos Therapeutics, L.P. and Cornerstone BioPharma, Inc. dated August 27, 2008 (incorporated by reference to Exhibit 10.17 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.31+	Supply and Marketing Agreement between Sovereign Pharmaceuticals, Ltd. and Aristos Pharmaceuticals, Inc. dated May 1, 2008 (incorporated by reference to Exhibit 10.18 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.32+	Asset Purchase Agreement between Vintage Pharmaceuticals, LLC and Cornerstone BioPharma, Inc. (as assignee of Cornerstone Biopharma, Ltd. (formerly known as Cornerstone Pharmaceuticals Ltd.)) dated July 20, 2004 (incorporated by reference to Exhibit 10.19 to the Registrant s Current Report on

	Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.33	Amendment No. 1, dated May 20, 2005, to Asset Purchase Agreement between Vintage Pharmaceuticals, LLC and Cornerstone BioPharma, Inc. (as assignee of Cornerstone Biopharma Ltd. (formerly known as Cornerstone Pharmaceuticals Ltd.)) dated July 20, 2004 (incorporated by reference to Exhibit 10.20 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).

Table of Contents

Exhibit No.	Description
10.34	Amendment No. 2, dated November 16, 2005, to Asset Purchase Agreement between Vintage Pharmaceuticals, LLC and Cornerstone BioPharma, Inc. (as assignee of Cornerstone Biopharma Ltd. (formerly known as Cornerstone Pharmaceuticals Ltd.)) dated July 20, 2004 (incorporated by reference to Exhibit 10.21 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.35	Amendment No. 2, dated November 13, 2006, to Asset Purchase Agreement between Vintage Pharmaceuticals, LLC and Cornerstone BioPharma, Inc. (as assignee of Cornerstone Biopharma Ltd. (formerly known as Cornerstone Pharmaceuticals Ltd.)) dated July 20, 2004 (incorporated by reference to Exhibit 10.22 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.36	Amendment No. 3, dated December 7, 2006, to Asset Purchase Agreement between Vintage Pharmaceuticals, LLC and Cornerstone BioPharma, Inc. (as assignee of Cornerstone Biopharma Ltd. (formerly known as Cornerstone Pharmaceuticals Ltd.)) dated July 20, 2004 (incorporated by reference to Exhibit 10.23 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.37+	License Agreement between the Registrant and The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute) dated July 1, 2001, as amended by the First Amendment Agreement dated May 15, 2003 (incorporated by reference to Exhibit 10.5 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.38+	Sponsored Research and License Agreement between the Registrant and The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute) dated July 1, 2001, as amended by the First Amendment Agreement dated July 1, 2003 (incorporated by reference to Exhibit 10.6 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.39+	Sponsored Research and License Agreement between the Registrant and The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute) effective as of January 1, 2003 (incorporated by reference to Exhibit 10.7 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.40+	Amendment No. 2, dated January 8, 2007, to Sponsored Research and License Agreement between the Registrant and The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute) effective as of January 1, 2003 (incorporated by reference to Exhibit 10.8 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2006 (SEC File No. 000-50767)).
10.41+	Amendment No. 3, dated June 29, 2007, to Sponsored Research and License Agreement effective as of January 1, 2003, between the Registrant and The Feinstein Institute for Medical Research. (incorporated by reference to Exhibit 10.7 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (SEC File No. 000-50767)).
10.42+	Exclusive License and Collaboration Agreement between the Registrant and MedImmune, Inc. dated July 30, 2003 (incorporated by reference to Exhibit 10.8 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.43	Amendment No. 1, dated December 7, 2005, to Exclusive License and Collaboration Agreement between MedImmune, Inc. and the Registrant dated July 30, 2003 (incorporated by reference to Exhibit 10.50 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2005 (SEC File No. 000-50767)).
10.44+	License Agreement between the Registrant and Beckman Coulter, Inc. dated January 10, 2005 (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the

quarter ended March 31, 2005 (SEC File No. 000-50767)).

10.45+ License and Supply Agreement between CyDex, Inc. and the Registrant dated May 16, 2007 (incorporated by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (SEC File No. 000-50767)).

10.46+ Exclusive License Agreement between the Registrant and Innovative Metabolics, Inc. dated January 29, 2007 (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K dated January 29, 2007 (SEC File No. 000-50767)).

Table of Contents

Exhibit No.	Description
10.47+	First Amendment, dated June 29, 2007, to Exclusive License Agreement between the Registrant and Innovative Metabolics, Inc. dated January 29, 2007 (incorporated by reference to Exhibit 10.6 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (SEC File No. 000-50767)).
10.48	Feasibility Study Agreement between Baxter Healthcare Corporation and the Registrant effective as of June 9, 2004 (incorporated by reference to Exhibit 10.25 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2004 (SEC File No. 000-50767)).
10.49	Commercial Note issued by Cornerstone BioPharma Holdings, Inc. to Paragon Commercial Bank dated April 21, 2005 (incorporated by reference to Exhibit 10.41 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.50	Security Agreement by Cornerstone BioPharma Holdings, Inc. in favor of Paragon Commercial Bank dated April 21, 2005 (incorporated by reference to Exhibit 10.42 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.51	Modification Agreement among Paragon Commercial Bank, Cornerstone BioPharma Holdings, Inc., Charles W. Cleary (as trustee), Carolina Pharmaceuticals, Inc. (as guarantor) and Craig A. Collard (as guarantor) dated April 10, 2006 (incorporated by reference to Exhibit 10.43 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.52	Modification Agreement among Paragon Commercial Bank, Cornerstone BioPharma Holdings, Inc., Charles W. Cleary (as trustee), Carolina Pharmaceuticals, Inc. (as guarantor) and Craig A. Collard (as guarantor) dated July 31, 2007 (incorporated by reference to Exhibit 10.44 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.53	Letter Agreement among Paragon Commercial Bank, Cornerstone BioPharma Holdings, Inc., Craig A. Collard (as guarantor), Aristos Pharmaceuticals, Inc. (as guarantor) and Cornerstone BioPharma, Inc. (as guarantor) dated June 23, 2008 (incorporated by reference to Exhibit 10.45 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.54	Modification Agreement among Paragon Commercial Bank, Cornerstone BioPharma Holdings, Inc., John S. Towles (as trustee), Craig A. Collard (as guarantor), Aristos Pharmaceuticals, Inc. (as guarantor) and Cornerstone BioPharma, Inc. (as guarantor) dated June 25, 2008 (incorporated by reference to Exhibit 10.46 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.55	Unconditional Guaranty by Cornerstone BioPharma, Inc. in favor Paragon Commercial Bank dated June 25, 2008 (incorporated by reference to Exhibit 10.47 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.56	Security Agreement by Cornerstone BioPharma, Inc. and Cornerstone BioPharma Holdings, Inc. in favor of Paragon Commercial Bank dated June 25, 2008 (incorporated by reference to Exhibit 10.48 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.57	Unconditional Guaranty by Aristos Pharmaceuticals, Inc. in favor of Paragon Commercial Bank dated June 25, 2008 (incorporated by reference to Exhibit 10.49 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.58	Security Agreement by Aristos Pharmaceuticals, Inc. and Cornerstone BioPharma Holdings, Inc. in favor of Paragon Commercial Bank dated June 25, 2008 (incorporated by reference to Exhibit 10.50 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.59	Letter from Paragon Commercial Bank to Cornerstone BioPharma Holdings, Inc. dated October 29, 2008 (incorporated by reference to Exhibit 10.51 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.60	

	Warrant Agreement between the Registrant and Mellon Investor Services LLC as Warrant Agent, dated June 20, 2005 (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K dated June 20, 2005 (SEC File No. 000-50767)).
10.61	Form of Warrant (Included in Exhibit 10.60 hereto).
10.62	Warrant Agreement dated October 31, 2006 by and between the Registrant and Mellon Investor Services (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the period ended September 30, 2006 (SEC File No. 000-50767)).

Table of Contents

Exhibit No.	Description
10.63	Lease Agreement between Regency Park Corporation and Cornerstone BioPharma, Inc. dated August 11, 2004 (incorporated by reference to Exhibit 10.24 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.64	Addendum No. 1, dated January 18, 2005, to Lease Agreement between Regency Park Corporation and Cornerstone BioPharma, Inc. dated August 11, 2004 (incorporated by reference to Exhibit 10.25 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.65	Lease Agreement between Crescent Lakeside, LLC and Cornerstone BioPharma Holdings, Inc. dated May 1, 2008 (incorporated by reference to Exhibit 10.26 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.66#	2004 Stock Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.3 to Amendment No. 2 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.67#	Amendment No. 1 to the 2004 Stock Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.4 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2005 (SEC File No. 000-50767)).
10.68#	Form of Incentive Stock Option Agreement granted under 2004 Stock Incentive Plan applicable to awards made after October 31, 2008.
10.69#	Form of Incentive Stock Option Agreement granted under 2004 Stock Incentive Plan applicable to awards made on or before October 31, 2008 (incorporated by reference to Exhibit 10.26 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2004 (SEC File No. 000-50767)).
10.70#	Form of Nonstatutory Stock Option Agreement granted under 2004 Stock Incentive Plan applicable to awards made after October 31, 2008.
10.71#	Form of Nonstatutory Stock Option Agreement granted under 2004 Stock Incentive Plan applicable to awards made on or before October 31, 2008 (incorporated by reference to Exhibit 10.27 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2004 (SEC File No. 000-50767)).
10.72#	Form of Nonstatutory Stock Option Agreement for a Non-Employee Director granted under the 2004 Stock Incentive Plan applicable to awards made after October 31, 2008.
10.73#	Form of Nonstatutory Stock Option Agreement for a Non-Employee Director granted under the 2004 Stock Incentive Plan applicable to awards made on or before October 31, 2008 (incorporated by reference to Exhibit 10.29 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2004 (SEC File No. 000-50767)).
10.74#	Form of Restricted Stock Agreement granted under 2004 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K dated December 19, 2006 (SEC File No. 000-50767)).
10.75#	Cornerstone BioPharma Holdings, Inc. 2005 Stock Incentive Plan (as Amended and Restated effective October 31, 2008) (incorporated by reference to Exhibit 10.37 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.76#	Form of Nonstatutory Stock Option Agreement Granted Under the Cornerstone BioPharma Holdings, Inc. 2005 Stock Incentive Plan (incorporated by reference to Exhibit 10.39 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.77#	Cornerstone BioPharma Holdings, Inc. 2005 Stock Option Plan (as Amended and Restated effective October 31, 2008) (incorporated by reference to Exhibit 10.38 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.78#	Form of Nonstatutory Employee Stock Option Agreement Granted Under the Cornerstone BioPharma Holdings, Inc. 2005 Stock Option Plan (incorporated by reference to Exhibit 10.40 to the Registrant s

	Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.79#	Non-Employee Director Compensation and Reimbursement Policy of the Registrant applicable prior to October 31, 2008 (incorporated by reference to Exhibit 10.38 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2006 (SEC File No. 000-50767)).
10.80#	Amended and Restated Non-Employee Director Compensation and Reimbursement Policy of the Registrant effective October 31, 2008.

Table of Contents

Exhibit No.	Description
10.81#	Agreement Regarding Employment, Employee Duties, Ownership of Employee Developments, and Confidentiality between Cornerstone BioPharma, Inc. and Joshua B. Franklin dated September 29, 2008
10.82#	Form of Letter Agreement for the Registrant s Change of Control Cash Bonus Program, dated as of July 17, 2008, including a Schedule of Material Terms (incorporated by reference to Exhibit 10.54 to the Registrant s Registration Statement on Form S-4/A dated August 28, 2008 (SEC File No. 333-152442)).
10.83#	Executive Employment Agreement between Cornerstone BioPharma, Inc. and Craig A. Collard dated March 1, 2006 (incorporated by reference to Exhibit 10.27 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.84#	Executive Retention Agreement between Cornerstone BioPharma, Inc. and Craig A. Collard dated February 8, 2006 (incorporated by reference to Exhibit 10.28 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.85#	Executive Employment Agreement between Cornerstone BioPharma, Inc. and Chenyqua Baldwin dated March 1, 2006 (incorporated by reference to Exhibit 10.29 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.86#	Executive Employment Agreement between Cornerstone BioPharma, Inc. and Brian Dickson dated March 1, 2006 (incorporated by reference to Exhibit 10.30 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.87#	Letter Agreement between Cornerstone BioPharma, Inc. and Joshua B. Franklin dated September 12, 2008
10.88#	Executive Employment Agreement between Cornerstone BioPharma, Inc. and Steven Lutz dated March 1, 2006 (incorporated by reference to Exhibit 10.32 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.89#	Executive Employment Agreement between Cornerstone BioPharma Holdings, Inc. and David Price dated August 20, 2008 (incorporated by reference to Exhibit 10.33 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.90#	Amended and Restated Restricted Stock Agreement between Cornerstone BioPharma Holdings, Inc. and David Price dated October 31, 2008 (incorporated by reference to Exhibit 10.34 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.91#	Amended and Restated Employment Agreement dated November 6, 2007 by and between the Registrant and Scott B. Townsend (incorporated by reference to Exhibit 10.6 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 (SEC File No. 000-50767)).
10.92#	First Amendment to Amended and Restated Employment Agreement, dated as of September 16, 2008, by and between the Registrant and Scott B. Townsend (incorporated by reference to Exhibit 10.55 to the Registrant s Registration Statement on Form S-4/A dated September 18, 2008 (SEC File No. 333-152442)).
10.93#	Restricted Stock Agreement dated as of September 16, 2008 between the Registrant and Scott B. Townsend.
10.94#	Amended and Restated Employment Agreement dated April 1, 2008 by and between the Registrant and Trevor Phillips, Ph.D. (incorporated by reference to Exhibit 99.1 to the Registrant s Amendment No. 1 on Form 8-K/A to Current Report on Form 8-K dated March 2, 2008 (SEC File No. 000-50767)).
10.95#	Amended and Restated Employment Agreement dated November 5, 2007 by and between the Registrant and Frank E. Thomas (incorporated by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 (SEC File No. 000-50767)).

10.96#	Employment Agreement, dated August 21, 2007 by and between the Registrant and Thomas P. Kelly (incorporated by reference to Exhibit 99.1 to the Registrant s Current Report on Form 8-K dated August 20, 2007 (SEC File No. 000-50767)).

Table of Contents

Exhibit No.	Description
10.97#	Amended and Restated Employment Agreement dated November 5, 2007 by and between the Registrant and Jeffrey E. Young (incorporated by reference to Exhibit 10.7 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 (SEC File No. 000-50767)).
10.98#	Form of Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement, entered into between Cornerstone BioPharma, Inc. and each of Craig A. Collard, Chenyqua Baldwin, Brian Dickson, Steven Lutz and Alastair McEwan (incorporated by reference to Exhibit 10.35 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.99#	Agreement Regarding Employment, Employee Duties, Ownership of Employee Developments, and Confidentially between Cornerstone BioPharma, Inc. and George Esgro dated March 3, 2008 (incorporated by reference to Exhibit 10.31 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
10.100#	Severance Agreement and General Release between George Esgro and the Registrant dated December 22, 2008 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated December 22, 2008 (SEC File No. 000-50767))
10.101#	Form of Indemnification Agreement, entered into between Cornerstone BioPharma Holdings, Inc. and each of Craig Collard and Alastair McEwan (incorporated by reference to Exhibit 10.36 to the Registrant s Current Report on Form 8-K dated October 30, 2008 (SEC File No. 000-50767)).
21.1	Subsidiaries of the Registrant.
23.1	Consent of Grant Thornton LLP.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Management contract or compensation plan or arrangement.

+ Confidential treatment granted as to certain portions, which portions have been omitted and separately filed with the Securities and Exchange Commission.