CORNERSTONE THERAPEUTICS INC
Form 10-K
March 04, 2010

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

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2009

OR

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

Commission file number: 000-50767

CORNERSTONE THERAPEUTICS INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3523569**
(State or Other Jurisdiction of Incorporation or Organization)	*(IRS Employer Identification No.)*
1255 Crescent Green Drive, Suite 250 **Cary, North Carolina** *(Address of Principal Executive Offices)*	**27518** *(Zip Code)*

Registrant s telephone number, including area code:
(919) 678-6611

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

Title of Each Class	Name of Each Exchange on Which Registered

Common Stock, $0.001 par value per share	**The NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act:
None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

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

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

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

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

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant s proxy statement for the registrant s 2010 annual meeting of stockholders currently expected to be held on May 20, 2010, which is currently expected to be filed pursuant to Regulation 14A within 120 days after the end of the registrant s fiscal year ended December 31, 2009, are incorporated by reference into Part III of this report.

CORNERSTONE THERAPEUTICS INC.

ANNUAL REPORT
ON FORM 10-K

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PART I

Cautionary Statement Regarding Forward-Looking Statements

This annual report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein, other than statements of historical fact, including statements regarding the progress and timing of our product development programs and related trials; our future opportunities; our strategy, future operations, anticipated financial position, future revenues and projected costs; our management s prospects, plans and objectives; and any other statements about management s future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use words such as anticipate, believe, could, estimate, expect, intend, may, plan, project, should, tar other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including our critical accounting estimates ; our ability to develop and maintain the necessary sales, marketing, supply chain, distribution and manufacturing capabilities to commercialize our products; the possibility that the Food and Drug Administration, or FDA, will take enforcement action against us or one or more of our marketed drugs that do not have FDA-approved marketing applications; patient, physician and third-party payor acceptance of our products as safe and effective therapeutic products; our heavy dependence on the commercial success of a relatively small number of currently marketed products; our ability to maintain regulatory approvals to market and sell our products with FDA-approved marketing applications; our ability to obtain FDA approval to market and sell our products under development; our ability to enter into additional strategic licensing, collaboration or co-promotion transactions on favorable terms, if at all; our ability to maintain compliance with NASDAQ listing requirements; adverse side effects experienced by patients taking our products; difficulties relating to clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the results of preclinical studies and clinical trials with respect to our product candidates and whether such results will be indicative of results obtained in later clinical trials; our ability to satisfy FDA and other regulatory requirements; and our ability to obtain, maintain and enforce patent and other intellectual property protection for our products and product candidates. These and other risks are described in greater detail below in Item 1A. Risk Factors. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. In addition, any forward-looking statements in this annual report on Form 10-K represent our views only as of the date of this annual report on Form 10-K and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise. Our forward-looking statements do not reflect the potential impact of any acquisitions, mergers, dispositions, business development transactions, joint ventures or investments we may enter into or make.

ITEM 1. *BUSINESS*

Background

Cornerstone Therapeutics Inc. is a specialty pharmaceutical company focused on acquiring, developing and commercializing significant products primarily for the respiratory and related markets. Prior to our October 31, 2008 merger with Cornerstone BioPharma Holdings, Inc., or Cornerstone BioPharma, we were known as Critical Therapeutics, Inc., or Critical Therapeutics. Following the closing of the merger, former Cornerstone BioPharma

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

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

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

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

Overview

We are a specialty pharmaceutical company that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Growing our lead products;

Acquiring additional products that complement our lead products;

Aggressively advancing our development initiatives; and

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

Our Promoted Products

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

CUROSURF

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

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

Market Opportunity. Approximately one out of every 10, or 50,000, premature infants require surfactant treatment in the United States each year. Surfactants are typically dispensed in over 2,000 hospital neonatal intensive care units annually. The surfactant market generated almost $100 million in sales in 2009 and is relatively stable because the number of premature infants requiring treatment does not vary significantly from year to year.

Benefits of CUROSURF. CUROSURF has a higher concentration of phospholipids, lower volume per dose and lower viscosity as compared to other surfactant products used to treat RDS. These characteristics help reduce the impact on the infant by shortening the drug s administration time, reducing the required manipulation of the infant, and lowering the rate of reflux and endotracheal tube blockage.

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

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

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

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

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

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

FACTIVE

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

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

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

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

FACTIVE targets the infection site with high lung tissue penetration. In a clinical study, FACTIVE produced a concentration in bronchoalveolar tissue which is 3,567 times the MIC90 requirement to eradicate *Streptococcus pneumoniae* in critical lung tissue, cells and fluids (bronchoalveolar macrophages, epithelial lining fluid and bronchial mucosa). In another clinical study of 310 patients with CAP, five-day treatment with FACTIVE produced a 100% eradication of *Streptococcus pneumoniae*, 95.5% eradication of *Haemophilus influenzae*, 94.4% eradication of *Chlamydia pneumoniae* and 88.8% eradication of *Mycoplasma pneumoniae*. In a study of five-day treatment for

ABECB, FACTIVE demonstrated clinical success rate was 94% (247 of 264 patients). In a separate study, five-day treatment with FACTIVE for CAP produced a clinical success rate of 95% (230 of 242 patients). These findings are in line with longer treatment regimens of other fluoroquinolone antibiotics.

Proprietary Rights. We have an exclusive license from LG Life Sciences, Ltd., or LGLS, to market FACTIVE in the United States, under nine issued U.S. patents with claims to the composition of matter of the

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API in FACTIVE, gemifloxacin mesylate, and to the formulation of FACTIVE. The FACTIVE patents extend through September 2019. FACTIVE has composition of matter patent protection that extends into 2017, longer than the composition of matter patent protection for any currently marketed oral fluoroquinolone or other oral antibiotic widely used to treat respiratory tract infections. We have also licensed from LGLS the U.S. trademark rights to FACTIVE.

SPECTRACEF

Overview. SPECTRACEF, an antibiotic administered orally in tablet form, is a third generation cephalosporin with the API cefditoren pivoxil. The SPECTRACEF product line currently includes SPECTRACEF 200 mg and SPECTRACEF 400 mg. We sometimes refer to these products collectively as the SPECTRACEF Dose Packs. SPECTRACEF 200 mg is currently available in a 10 day Dose Pack. SPECTRACEF 200 mg, two tablets twice daily, is indicated for the treatment of the same respiratory tract infections as SPECTRACEF 400 mg. Additionally, SPECTRACEF 200 mg, one tablet twice daily, is indicated for pharyngitis and tonsillitis and uncomplicated skin and skin-structure infections.

SPECTRACEF 400 mg is a single 400 mg tablet, twice-daily dosage of SPECTRACEF, which is indicated for the treatment of mild to moderate infections in adults and adolescents 12 years of age or older that are caused by pathogens associated with particular respiratory tract infections, including CAP and ABECB. SPECTRACEF 400 mg is currently available in a 10-day Dose Pack and a 14-day Dose Pack. We received approval for SPECTRACEF 400 mg in July 2008 and launched it in October 2008. We believe that patients will find taking one 400 mg tablet twice daily to be more convenient than taking two SPECTRACEF 200 mg tablets twice daily. Our net sales of SPECTRACEF were $9.4 million, $7.0 million and $6.9 million in 2009, 2008 and 2007, respectively.

Market Opportunity. Like FACTIVE, SPECTRACEF competes in the fragmented U.S. oral solid antibiotic market and is subject to competition from other branded and generic products. According to Wolters Kluwer Health, there were approximately 7.9 million prescriptions written in the United States for second and third generation oral solid cephalosporins.

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

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

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

ZYFLO CR

Overview. ZYFLO CR and ZYFLO, which contain the API zileuton, are leukotriene synthesis inhibitor drugs. ZYFLO was approved by the FDA in 1996 as an immediate-release, four-times-a-day tablet for the prevention and chronic treatment of asthma in adults and children 12 years of age and older. ZYFLO was first launched in the United

States in 1997; we began selling ZYFLO in the United States in October 2005. The FDA approved our new drug application, or NDA, for ZYFLO CR in May 2007, and we launched ZYFLO CR in October 2007. We believe ZYFLO CR offers a more convenient regimen for patients, which we believe

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

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

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

Market Opportunity. Asthma is a chronic respiratory disease characterized by the narrowing of the lung airways, making breathing difficult. An asthma attack leaves the victim short of breath as the airways become constricted and inflamed. The National Center for Health Statistics estimated that in 2008 in the United States approximately 7.6% of the population, or approximately 23 million people, had asthma and approximately 3.9% of the population, or 12 million people, had asthma attacks.

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

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

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

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

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

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

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Proprietary Rights. We licensed from Abbott exclusive worldwide rights to ZYFLO CR, ZYFLO and other formulations of zileuton for multiple diseases and conditions. The U.S. patent covering the composition of matter of zileuton that we licensed from Abbott expires in December 2010. The U.S. patent for ZYFLO CR will expire in June 2012 and relates only to the controlled-release technology used to control the release of zileuton.

Other Products

We market but do not promote the products described below. We market these products without their having FDA-approved marketing applications. For a more complete discussion regarding FDA drug approval requirements, please see Item 1. Business Regulatory Matters in this annual report on Form 10-K and Item 1A. Risk Factors Some of our specialty pharmaceutical products are now being marketed without approved NDAs or ANDAs in this annual report on Form 10-K.

ALLERX DOSE PACKS

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

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

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

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

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

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

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

HYOMAX

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

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

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

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

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

Product Development Pipeline

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

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

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

During 2009, 2008 and 2007, our research and development expenses were $4.3 million, $3.8 million and $948,000, respectively. Our development priorities may change from time to time, and the actual dates of regulatory submissions may differ from the target dates referenced above.

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

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

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

Benefits of CRTX 067, CRTX 069, CRTX 072 and CRTX 074. Most cough/cold products that are currently marketed are in an immediate-release formulation, meaning they must be dosed every four to six hours, which can be inconvenient. For example, patients may not be able to sleep through the night because their antitussive is not effective for more than four hours. We believe that CRTX 067, CRTX 069, CRTX 072 and CRTX 074 could improve patients compliance and quality of life by providing more convenient twice-daily, longer lasting dosing.

Proprietary Rights. We have licensed the rights to market CRTX 067, CRTX 069 and CRTX 074 utilizing Neos s Dynamic Time Release Suspension®, or DTRS®, technology and Coating Place, Inc. s, or Coating Place, drug resin complex technology. We expect that these licensed technologies will allow us to formulate these product candidates with one or more APIs that require immediate activation followed by a sustained timed release of the remaining APIs over a 12-hour period. Neos s DTRS technology is covered under a pending U.S. patent application that if issued would expire in 2025. Coating Place s drug resin complex technology is covered under a pending U.S. patent application that if issued would expire in 2025. Suitable patented, drug delivery technologies are currently being evaluated for CRTX 072.

Allergy Product Candidates CRTX 058 and CRTX 070

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

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

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

2009.

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

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

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

Anti-Asthma Product Candidate CRTX 073

Overview. ZYFLO CR remains an important asset to us; therefore, we have implemented a life cycle management strategy to improve the dosing regimen for this product. We believe that offering more convenient dosing for ZYFLO CR may improve patient compliance and overall quality of life as it relates to their asthma condition.

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

Anti-Infective Product Candidates CRTX 062 and CRTX 068

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

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

Other Technology Assets

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

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

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

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

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

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

Alpha-7 Program

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

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

HMGB1 Program

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