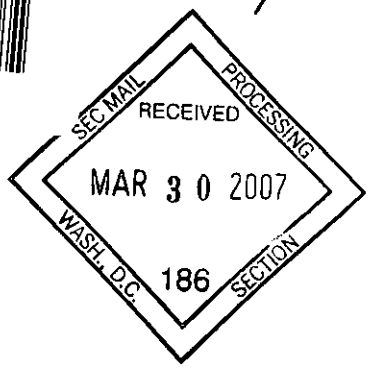

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2006 Annual Report

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CRITICAL Therapeutics

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THOMSON
FINANCIAL

product pipeline

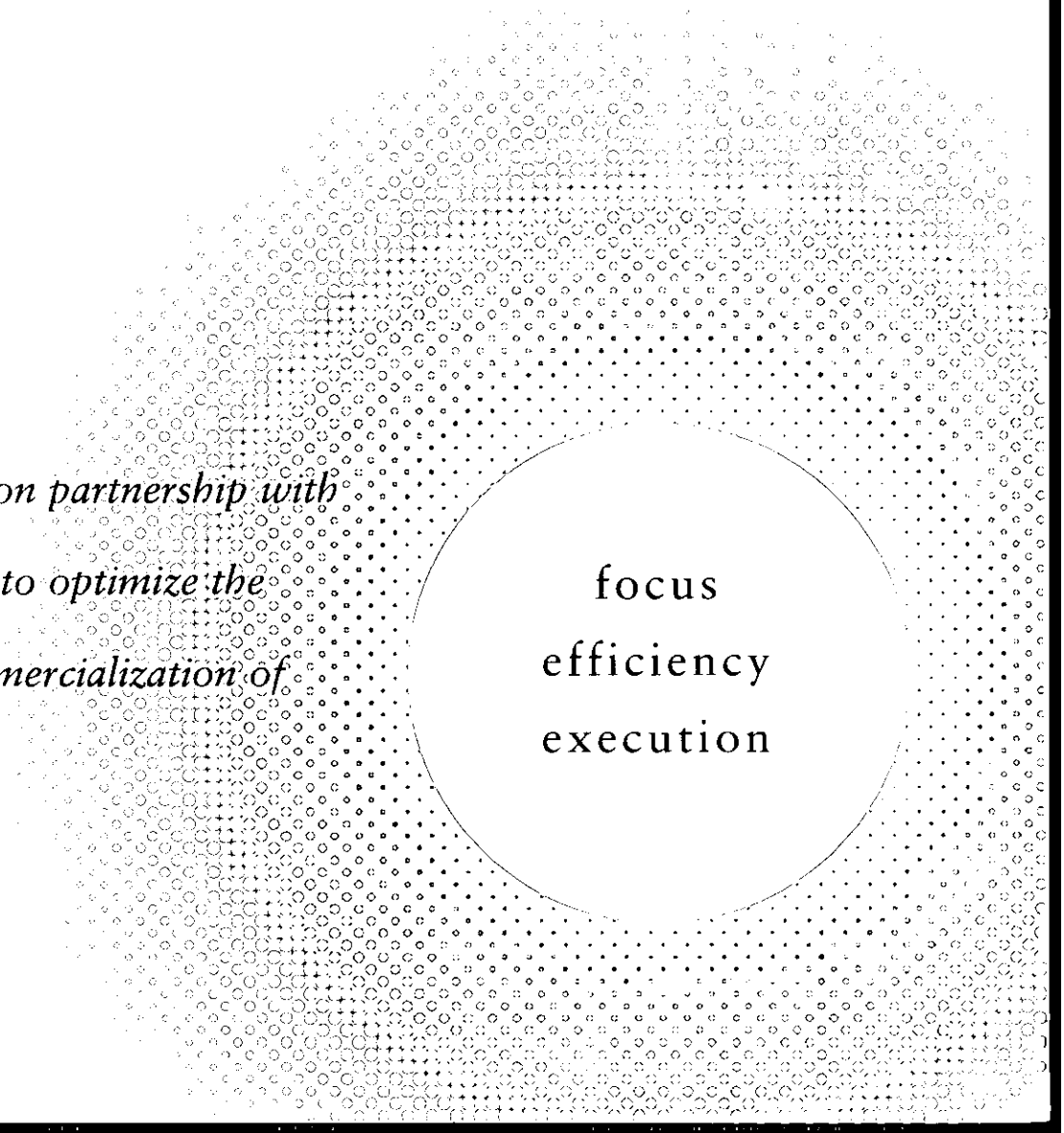
Program	Preclinical	Phase I	Phase II	Phase III	NDA	Marketed
Zileuton						
Asthma (ZYFLO®)						
Asthma (Controlled-Release)						
Zileuton Injection						
Acute Asthma						
Zileuton Life Cycle Management						
R Isomer						
Alpha-7						
Asthma						
Rheumatoid Arthritis						
Acute Lung Injury						
HMGB1 *Partnered with MedImmune, Inc.*						
Rheumatoid Arthritis						
Sepsis						
Lupus						

In 2007, our focus is on enhancing the commercial value of our zileuton franchise, advancing our clinical and pre-clinical programs and building a strong financial position that creates sustainable value.

corporate profile

Critical Therapeutics specializes in developing and commercializing proprietary medicines that improve the health and quality of life of patients with respiratory, inflammatory and critical care diseases. Our first FDA-approved product, ZYFLO® (zileuton tablets) is marketed in the U.S. for the prevention and chronic treatment of asthma in patients 12 and older. Asthma is a chronic respiratory disease without social, economic or political boundaries. It affects an estimated 20.5 million Americans. Our strategy is to more effectively manage this disease through the introduction of a twice-daily, controlled-release formulation of zileuton for asthma patients whose symptoms are not adequately controlled by currently available therapies. We also are developing an injectable formulation of zileuton for the estimated 1.8 million U.S. patients each year who suffer acute asthma attacks that require emergency room care. To maintain the strength of our zileuton programs, we are pursuing life cycle extension opportunities and strategic alliances.

Our zileuton franchise is enhanced by a pre-clinical pipeline. One area of focus is the development of drug candidates that can control the body's inflammatory response through chemical interaction with the Alpha-7 nicotinic receptor agonist. Our second program is in collaboration with MedImmune, Inc. and revolves around the development of antibody therapies to treat acute and chronic diseases associated with the cytokine HMGB1. Founded in 2000, Critical Therapeutics is based in Lexington, Massachusetts and trades under the symbol "CRTX" on the Nasdaq Global Market.



Our co-promotion partnership with DEY enables us to optimize the launch and commercialization of zileuton CR.

executive officers

Frank E. Thomas
President and Chief Executive Officer

Dana Hilt, M.D.
Senior Vice President of Clinical Development
and Chief Medical Officer

Trevor Phillips, Ph.D.
Senior Vice President of Operations
and Chief Operating Officer

Scott B. Townsend, Esq.
Senior Vice President of Legal Affairs, General Counsel
and Secretary

Jeffrey E. Young
Vice President of Finance, Chief Accounting Officer and Treasurer

board of directors

Frank E. Thomas
President and Chief Executive Officer,
Critical Therapeutics, Inc.

Richard W. Dugan
Lead Independant Director,
Retired Partner, Ernst & Young, LLP

Nicholas Galakatos, Ph.D.
General Partner, MPM Asset Management II, LP

Jean George
General Partner, Advanced Technology Ventures

Christopher Mirabelli, Ph.D.
Managing Director, HealthCare Ventures, LLC

James B. Tananbaum, M.D.
Managing Director, Prospect Venture Partners

Christopher Walsh, Ph.D.
Hamilton Kuhn Professor of Biological Chemistry
and Molecular Pharmacology, Harvard Medical School

Robert H. Zeiger
Former Chief Executive Officer of Viragen, Inc.;
marketing consultant for a number of privately-held
pharmaceutical companies

M. Cory Zwerling
Former President of Bristol-Myers Squibb Medical Imaging;
consultant to pharmaceutical companies

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-K

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

(Mark One)

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

For the fiscal year ended December 31, 2006

OR

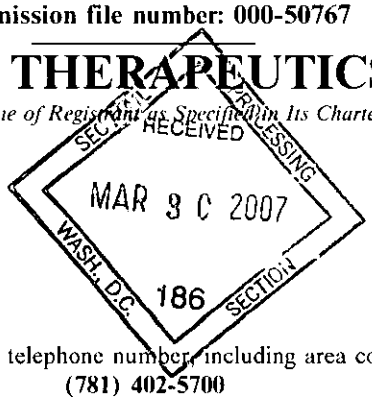
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 000-50767

CRITICAL 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.)*
60 Westview Street, Lexington, Massachusetts *(Address of Principal Executive Offices)*	**02421** *(Zip Code)*

Registrant's telephone number, including area code:
(781) 402-5700

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

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

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

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

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

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 ☑ No ☐

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

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

Large accelerated filer ☐ Accelerated filer ☑ Non-Accelerated filer ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2006 was approximately $65,991,000, based on a price per share of $3.60, the last reported sale price of the registrant's common stock on the NASDAQ Stock Market on that date.

As of February 28, 2007, the registrant had 43,066,165 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's proxy statement for the registrant's 2007 annual meeting of stockholders currently expected to be held on May 2, 2007, which is expected to be filed pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2006, are incorporated by reference into Part III of this report.

CRITICAL THERAPEUTICS, INC.

ANNUAL REPORT
ON FORM 10-K

INDEX

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 expected timing and outcome of the New Drug Application, or NDA, submission for the controlled-release formulation of zileuton, or zileuton CR, possible therapeutic benefits and market acceptance of ZYFLO® (zileuton tablets) and, if approved, zileuton CR, the progress and timing of our drug development programs and related trials, the efficacy of our drug candidates, our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, may be forward-looking statements under the provisions 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," "will," "would" or 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" and risks relating to: the expected timing and outcome of the NDA for zileuton CR and related discussions with the U.S. Food and Drug Administration, or FDA; our ability to transition our management team effectively; our ability to rely on historical data in seeking marketing approval for zileuton CR, including the sufficiency and acceptability of the results of the pharmacokinetic studies of zileuton CR for FDA purposes; our ability to successfully market and sell ZYFLO and, if approved, zileuton CR, including the success of our co-promotion arrangement with DEY, L.P.; our ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize ZYFLO and, if approved, zileuton CR; patient, physician and third-party payor acceptance of ZYFLO and, if approved, zileuton CR, as a safe and effective therapeutic product; adverse side effects experienced by patients taking ZYFLO and, if approved, zileuton CR; our ability to successfully enter into additional strategic co-promotion, collaboration or licensing transactions on favorable terms, if at all; conducting 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 heavy dependence on the commercial success of ZYFLO and, if approved, zileuton CR; our ability to obtain the substantial additional funding required to conduct our research, development and commercialization activities; our dependence on our strategic collaboration with MedImmune, Inc; and our ability to obtain, maintain and enforce patent and other intellectual property protection for ZYFLO, our discoveries and drug candidates. These and other risks are described in greater detail below under the caption "Risk Factors" in Part I, Item 1A. 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 represent our views only as of the date of this annual report 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*

Overview

Critical Therapeutics, Inc. is a biopharmaceutical company focused on the development and commercialization of products designed to treat respiratory, inflammatory and critical care diseases linked to the body's inflammatory response. Our marketed product is ZYFLO, an immediate-release tablet

formulation of zileuton, which the FDA approved in 1996 for the prevention and chronic treatment of asthma in adults and children 12 years of age or older. We licensed from Abbott Laboratories exclusive worldwide rights to ZYFLO and other formulations of zileuton for multiple diseases and conditions. We began selling ZYFLO in the United States in October 2005, and are developing a controlled-release formulation of zileuton, or zileuton CR, and an injectable formulation of zileuton, or zileuton injection. In connection with the restructuring that we announced in October 2006, we decided to focus our resources on these formulations.

We are currently developing zileuton CR, a tablet designed to be taken twice daily, two tablets per dose. We have submitted a New Drug Application, or NDA, for zileuton CR that was accepted for filing by the FDA as of September 29, 2006. Under the Prescription Drug User Fee Act, or PDUFA, guidelines, the PDUFA date for our NDA is May 31, 2007, which is the date by which we expect to receive an action letter from the FDA on this filing. If we receive regulatory approval on a timely basis, we expect to launch zileuton CR in the second half of 2007. On March 13, 2007, we entered into a co-promotion agreement with DEY, L.P., an affiliate of Merck KGaA, under which we and DEY have agreed to jointly promote ZYFLO and, if approved by the FDA, zileuton CR.

In addition, we are developing zileuton injection initially for use in emergency room or urgent care centers for patients who suffer acute exacerbations of asthma. In August 2006, we announced results from our Phase I/II clinical trial designed to evaluate safety, tolerability and pharmacokinetics of zileuton injection in patients with asthma. We plan to initiate a Phase II clinical trial in the second half of 2007 with zileuton injection in asthma patients.

We plan to continue to evaluate a life-cycle extension strategy for zileuton in 2007 that could enhance the intellectual property position of zileuton and evaluate its applicability to other inflammatory conditions.

We are also developing other product candidates to regulate the excessive inflammatory response that can damage vital internal organs and, in the most severe cases, result in multiple organ failure and death. The inflammatory response occurs following stimuli such as infection or trauma. Our product candidates target the production and release into the bloodstream of proteins called cytokines that play a fundamental role in the body's inflammatory response.

We are collaborating with MedImmune, Inc. on preclinical development of monoclonal antibodies directed toward a cytokine called HMGB1, or high mobility group box protein 1, which we believe may be an important target for the development of products to treat diseases mediated by the inflammatory response. In addition, we are collaborating with Beckman Coulter, Inc. on the development of a diagnostic directed toward measuring HMGB1 in the bloodstream.

We are conducting preclinical work in our small molecule alpha-7 program through a small team of scientists. We believe the successful development of a product candidate targeting the nicotinic alpha-7 cholinergic receptor, or alpha-7 receptor, could lead to a novel treatment for severe acute inflammatory disease, as well as an oral anti-cytokine therapy that could be directed at chronic inflammatory diseases such as asthma and rheumatoid arthritis. We plan to seek a collaborator for our alpha-7 program and do not currently expect to conduct clinical trials with the alpha-7 program without entering into such an arrangement.

We were incorporated in Delaware on July 14, 2000 as Medicept, Inc. and changed our name to 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 Global Market.

Since our inception, we have incurred significant losses each year. As of December 31, 2006, we had an accumulated deficit of $154.4 million. We expect to incur significant losses for the foreseeable future and we may never achieve profitability. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect our operating losses to continue over the next several years as we fund our development programs, market and sell ZYFLO and prepare for the potential commercial launch of our product candidates. Since inception, we have raised proceeds to fund our operations through our initial public offering of common stock, private placements of equity securities, debt financings, the

receipt of interest income, payments from our collaborators MedImmune and Beckman Coulter, and, beginning in the fourth quarter of 2005, revenue from sales of ZYFLO.

Our Strategy

In October 2006, we decided to focus our resources on the commercialization of zileuton CR and on the clinical development of zileuton injection, while significantly reducing our net cash expenditures through lower spending on our existing sales force as well as on our discovery and research programs.

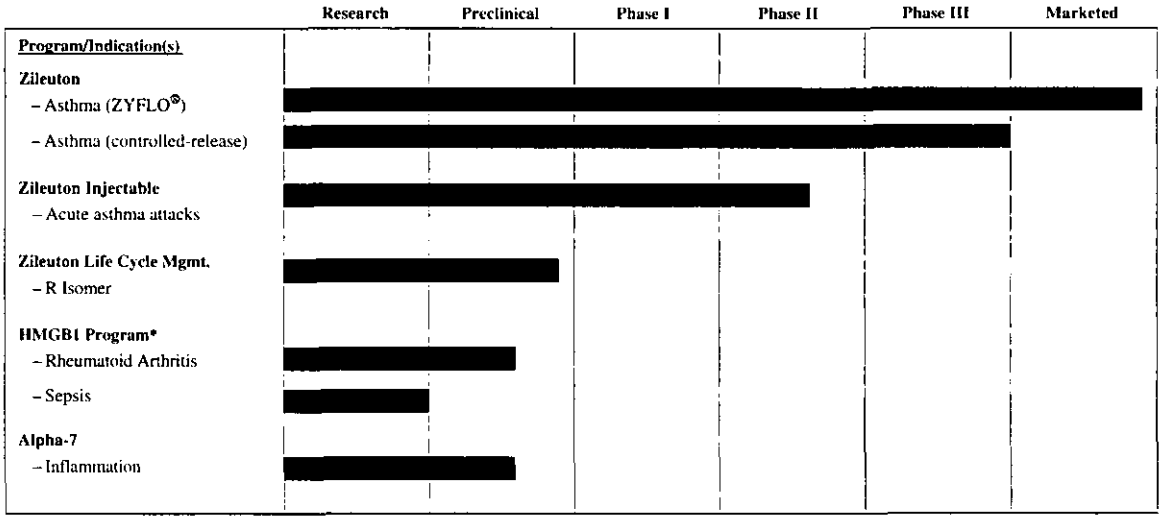
As part of this new business strategy, we eliminated 60 positions. This headcount reduction reflects a downsizing of our sales force that markets ZYFLO. We have retained a respiratory sales force of approximately 18 representatives who are focused on continued promotion to prescribing physicians within the major metropolitan markets across the United States and increasing prescriptions from our existing base of prescribers. We also have a direct marketing call center that contacts prescribers who are not in the markets where we have representatives. The headcount reductions also included 17 research and development employees. As a result of this restructuring, we had approximately 61 employees as of December 31, 2006.

We believe that the feedback from physicians to date indicates that ZYFLO's current dosing regimen of four times daily will continue to make it difficult to gain broad acceptance in the asthma market. With the twice-daily formulation, we expect increased usage by prescribing physicians while offering patients another treatment option for their asthma. We are, therefore, taking steps to prepare for the commercialization of zileuton CR. In addition to recently establishing our co-promotion arrangement with DEY for ZYFLO and zileuton CR, we are conducting additional clinical studies of zileuton CR to build market position, implementing a publication strategy and initiating a clinical trial to evaluate a life-cycle extension strategy to enhance the intellectual property position of zileuton and evaluate its applicability to other inflammatory conditions. In addition, we are developing zileuton injection initially for use in emergency room or urgent care centers for patients who suffer acute exacerbations of asthma. We plan to initiate a Phase II clinical trial in the second half of 2007 with zileuton injection in asthma patients.

We are conducting preclinical work in our alpha-7 program through a small team of scientists. We plan to seek a collaborator for our alpha-7 program and do not currently plan to conduct clinical trials with the alpha-7 program without entering into such an arrangement. In collaboration with MedImmune, we expect to continue to support the development of HMGB1 antibodies for chronic and acute inflammatory diseases.

Our Product Pipeline

The following table sets forth the current status of our product candidates in development and our research and development programs:



* Being developed with MedImmune under an exclusive license and collaboration agreement. Diagnostic assays directed towards HMGB1 are being developed with Beckman Coulter under a license agreement.

Zileuton

We acquired from Abbott exclusive worldwide rights to develop and market ZYFLO and other formulations of zileuton for multiple diseases and conditions. ZYFLO, a tablet formulation of zileuton, is an FDA-approved product for the prevention and chronic treatment of asthma that was developed and previously sold by Abbott. The FDA approved our supplemental new drug application, or sNDA, for ZYFLO on September 28, 2005 and we began selling ZYFLO in the United States in late October 2005.

Zileuton blocks the activity of the 5-lipoxygenase enzyme, which is the main enzyme responsible for formation of a family of lipids known as leukotrienes. There are many different leukotrienes, and the mechanism of action of ZYFLO blocks production of the entire leukotriene family. Leukotrienes are in part responsible for the inflammatory response associated with asthma and are known to cause many of the biological effects that contribute to inflammation, mucus production and closing of the lung airways of asthmatic patients. Leukotrienes are also implicated in the disturbance of normal lung airway function in certain other diseases, including chronic obstructive pulmonary disease, or COPD. ZYFLO is the only FDA-approved product that blocks the activity of the 5-lipoxygenase enzyme.

Therapeutic 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 estimates that in 2004 approximately 20.5 million people in the United States had asthma and approximately 11.7 million people in the United States had asthma attacks. Severe asthma attacks can be life threatening. According to the American Lung Association, in 2004, approximately 1.8 million hospital emergency room visits in the United States involved asthma attacks and approximately 497,000 hospital discharges were attributable to asthma. According to the National Institutes of Health, the direct healthcare costs associated with treating asthma in the United States reached an estimated $11.5 billion in 2004.

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 Serevent®, leukotriene receptor antagonists, or LTRAs, such as Singulair®, inhaled corticosteroids, such as Flovent® and combination products such as Advair®, which is a combination of an inhaled corticosteroid and a long-acting bronchodilator. We believe many prescribing physicians are dissatisfied with the treatment options available for patients with uncontrolled or severe, persistent asthma due to the inability of these treatments to control symptoms reliably. As a result, these patients, who we believe constitute approximately 20% of the asthma population, often have severe asthma attacks requiring emergency room visits and, in many cases, further hospitalization to stabilize airway function. Despite the approval in 2003 of Xolair® to treat severe allergic asthma, we believe patients with severe asthma remain underserved and in need of effective medication.

We believe that many patients with asthma may benefit from therapy with zileuton. Zileuton actively inhibits the main enzyme responsible for the production of a broad spectrum of lipids responsible for the symptoms associated with asthma, including all leukotrienes. We are marketing ZYFLO as a treatment for asthma patients who do not gain adequate symptomatic control from currently available medications.

Zileuton Product Development

ZYFLO: The Tablet Formulation of Zileuton

ZYFLO is the only 5-lipoxygenase inhibitor drug to be approved for marketing by the FDA. In 1996, ZYFLO was approved by the FDA 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. The FDA approved our sNDA for ZYFLO on September 28, 2005, and we began selling ZYFLO in the United States in October 2005. We recognized $387,000 in revenue from sales of ZYFLO for the year ended December 31, 2005 and $6.6 million in revenue from sales of ZYFLO for the year ended December 31, 2006.

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.

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 the liver enzyme alanine transaminase, or ALT, to 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. In 61.0% of the patients with ALT levels greater than three times the level normally seen in the bloodstream, the elevation was seen 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. The overall rate of patients with ALT levels greater than three times the level normally seen in the bloodstream was 3.2% in the approximately 5,000 patients who received ZYFLO in placebo-controlled and open-label trials combined. 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.

Controlled-Release Formulation of Zileuton

We believe that zileuton CR, if approved, will be more convenient for patients because of its twice daily, two tablets per dose dosing regimen, as compared to ZYFLO's current four times daily dosing regimen, and may increase patient drug compliance. Abbott completed Phase III clinical trials for this formulation in asthma, but did not submit an NDA. Based upon data provided to us, we believe this decision was not based upon the clinical efficacy or safety data generated during the program. We submitted an NDA for zileuton CR that was accepted for filing by the FDA as of September 29, 2006. This NDA was based on safety and efficacy data generated from the 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:

- In a three-month pivotal efficacy trial, in which 397 patients received either zileuton CR or placebo, patients taking zileuton CR demonstrated statistically significant improvements over placebo in objective measures of asthma control, such as mean forced expiratory volume in one second, or FEV_1. In the trial, patients taking zileuton 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 zileuton 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 zileuton CR and their usual asthma medications or a combination of placebo and their usual asthma medications, 1.78% of the patients taking zileuton 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.

To be able to rely on the results of Abbott's pivotal clinical trials, we conducted two comparative bioavailability studies intended to show that the pharmacokinetic profile of zileuton CR tablets that we have manufactured is similar to the pharmacokinetic profile of the zileuton CR tablets previously manufactured by Abbott and used in Abbott's clinical trials. We conducted both a single-dose and a multiple-dose pharmacokinetic study. The studies assessed the pharmacokinetics of zileuton CR in volunteers under both fed and fasting conditions. We believe that the results of the bioavailability studies are sufficient to allow us to bridge to the results of Abbott's prior clinical trials to support our NDA filing.

The FDA has confirmed that this is a significant review issue. If the FDA disagrees with our conclusions regarding the sufficiency of the results from the bioavailability studies, we could be required to conduct additional clinical trials to support our NDA, which could lead to unanticipated costs and delays or to the termination of our program for zileuton CR.

Under PDUFA guidelines, the PDUFA date for our NDA is May 31, 2007, which is the date by which we expect to receive an action letter from the FDA on this filing. If we receive regulatory approval on a timely basis, we expect to launch zileuton CR in the second half of 2007. We recently entered into

an agreement with DEY, L.P., an affiliate of Merck KGaA, under which we and DEY have agreed to jointly co-promote ZYFLO and, if approved by the FDA, zileuton CR.

Injectable Formulation of Zileuton

We are developing zileuton injection for use in severe acute asthma attacks. According to the American Lung Association, in 2004, approximately 1.8 million hospital emergency room visits in the United States involved asthma attacks and approximately 497,000 hospital discharges were attributable to asthma. Currently, most patients suffering severe asthma attacks are treated with bronchodilators inhaled via a nebulizer, typically for 20 minutes or more. Nebulizers attempt to restore airway function by delivering the bronchodilatory drug directly into the lungs. However, the patient's ability to get the drug into his or her lungs may be impaired by his or her inability to breathe efficiently due to the severe asthma attack. Clinical data demonstrate that zileuton exhibits its maximum effect on lung function when the blood drug concentration reaches its peak level and that the effect can be achieved after a single oral dose of zileuton. We believe that an injectable formulation of zileuton that would deliver zileuton directly to the bloodstream would have a rapid onset of action, reaching peak blood concentration within minutes of the injection. We believe that this rapid delivery of the drug to the patient's bloodstream may lead to more rapid symptom improvements, and potentially reduce the number of hospital admissions of patients arriving in the emergency room suffering from a severe asthma attack.

In the second quarter of 2006, we completed a Phase I/II clinical trial of zileuton injection in patients with asthma. The trial included measurements to detect evidence of improvement in lung function. The double-blind, placebo-controlled trial enrolled 60 patients at 10 clinical sites in the United States. Patients enrolled in the trial had a mean FEV_1 of 63 percent of predicted normal at baseline and a mean age of 40 years. Patients enrolled in the trial were randomized into four escalating dose groups (75 mg, 150 mg, 300 mg, and 600 mg), each receiving one infusion of either zileuton injection or placebo. Each of the four dose groups enrolled 15 patients, of whom 12 received zileuton injection and three received placebo. All 60 patients who were randomized completed the trial.

Patients in each of the four zileuton injection cohorts showed a greater mean percentage improvement in FEV_1 than patients in the placebo group when measured at 10, 30 and 60-minute intervals after dosing. The 300 mg dose was predicted to approximate the currently approved oral dose of ZYFLO (zileuton tablets). In this trial, the 300 mg dose group showed a mean improvement in FEV_1 from baseline of 13.7 percent at 60 minutes after dosing. In addition, zileuton injection was well tolerated at all doses tested with no serious adverse events reported in the trial. We plan to initiate a Phase II clinical trial in the second half of 2007 aimed at identifying the optimal dose to be used in potential Phase III clinical trials.

Under the co-promotion agreement with DEY, we granted DEY the exclusive right to negotiate with us for the development and commercialization, including co-promotion, of additional zileuton products in the United States for the treatment of asthma and, subject to FDA approval, other respiratory conditions. These exclusive negotiation rights are effective until September 1, 2007 with respect to zileuton injection and December 31, 2007 with respect to other zileuton products.

Commercialization Strategy

In October 2006, we decided to focus our resources on the commercialization of zileuton CR and on the clinical development of zileuton injection, while significantly reducing our net cash expenditures through lower spending on our existing sales force as well as on our discovery and research programs. As part of this new business strategy, we eliminated 60 positions. This headcount reduction reflects a downsizing of our sales force that markets ZYFLO. We have retained a respiratory sales force of approximately 18 representatives as of February 28, 2007 who are focused on continued promotion to prescribing physicians within major metropolitan markets across the United States and increasing prescriptions from our existing base of prescribers. We also have a direct marketing call center that contacts prescribers who are not in the markets where we have representatives to help maintain brand awareness and arrange for delivery of samples. If we successfully complete the development of, and receive

regulatory approval for, zileuton CR, we will seek to convert prescribing and usage of ZYFLO to this formulation.

In March 2007, we entered into a co-promotion agreement with DEY, an affiliate of Merck KGaA, under which we and DEY have agreed to jointly promote ZYFLO and, if approved by the FDA, zileuton CR. DEY has a respiratory sales force consisting of approximately 200 clinical sales representatives as of March 1, 2007. Under the co-promote agreement, DEY is required to provide a specified number of details per month for ZYFLO, and if approved, zileuton 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. Subject to FDA approval of zileuton CR, we expect to expand the size of our sales force to approximately 40 sales representatives. Under the co-promotion agreement, we have agreed to provide a specified number of details per month for ZYFLO and zileuton CR in the first position. We anticipate that our sales representatives and DEY's sales representatives will promote zileuton CR to a total of approximately 15,000 physicians prescribing high levels of asthma medications. From 2008 through 2010, we and DEY each have agreed to contribute 50 percent of out-of-pocket promotion expenses for zileuton CR that are accrued or paid to third-parties and approved by a joint commercial committee. We and DEY each have agreed to contribute a minimum of $3.0 million per year for these promotion expenses. We will be responsible for third-party promotion costs during 2007. DEY also has agreed to provide the support of its managed care group to negotiate contracts and engage in other activities with third-party payors for favorable managed care access. This managed care support will include advice and logistical support regarding managed care strategy.

We believe that there is a market opportunity for the use of ZYFLO and zileuton CR as an add-on therapy option for patients whose asthma symptoms are not adequately controlled with the use of inhaled corticosteroids and other conventional therapies, including LTRAs. Our belief is based on information that we have gathered through extensive direct interactions and market research with respiratory specialists, including allergists and pulmonologists:

- over 24 months of in-depth interaction between our team of medical science liaisons, or MSLs, and key opinion leaders in the treatment of respiratory diseases, including asthma;
- more than a year of interaction between our sales force and respiratory specialists who treat asthma; and
- qualitative and quantitative market research that we have conducted since 2004.

Following the launch of ZYFLO in October 2005, we conducted market research with 95 previously detailed allergists and pulmonologists in December 2005 and January 2006 to assess the early impact of the launch promotional efforts of ZYFLO. This market research study included the following findings:

- 79% of respondents indicated that ZYFLO is an effective add-on therapy for patients who are still symptomatic on moderate to high-dose inhaled steroids;
- 84% of respondents indicated that ZYFLO and Merck's Singulair® work differently; and
- 90% of respondents indicated ZYFLO should be used in patients who are dependent on or non-responsive to oral steroids.

We are positioning ZYFLO, and expect to position zileuton CR, if approved, as an alternative treatment for asthma patients who do not gain adequate control of their symptoms with other currently available medications, including inhaled corticosteroids, long-acting beta agonists and LTRAs. We are promoting ZYFLO, and expect to promote zileuton CR, if approved, to respiratory specialists, managed care decision makers and some primary care physicians who treat large volumes of asthma patients. If we receive approval for zileuton CR, we expect to promote zileuton CR more broadly to primary care physicians who treat large volumes of asthma patients. As part of our marketing strategy, we continue to attempt to educate key opinion leaders and physicians on the scientific data that differentiates the mechanism of action of ZYFLO from other asthma treatments and emphasize clinical data that show safety and efficacy for ZYFLO in asthma.

We are also attempting to maximize patient and physician access to ZYFLO by addressing the position of ZYFLO on managed care formularies. We believe that in many managed care formularies, as a result of the previous lack of a sustained marketing effort, ZYFLO has been removed or relegated to third-tier status, which requires the highest co-pay for patients prescribed the product.

While we continue to pursue sales of ZYFLO, we believe that the feedback from physicians to date indicates that ZYFLO's current dosing regimen of four times daily will continue to make it difficult to gain broad acceptance in the asthma market. With zileuton CR's twice daily formulation, we expect increased usage by prescribing physicians while offering patients another treatment option for their asthma.

In addition to recently establishing our co-promotion arrangement with DEY for ZYFLO and zileuton CR, we are taking the following steps to prepare for the commercialization of zileuton CR:

- conducting clinical studies to provide clinicians with clinical data to support zileuton CR's market position;
- implementing a publication strategy that includes the presentation of data from the pivotal studies of zileuton CR at major medical conferences and in various scientific and medical journals; and
- initiating a clinical trial to evaluate a life-cycle extension strategy to enhance the intellectual property position of zileuton and provide for possible development opportunities in other inflammatory conditions.

We are exploring the therapeutic benefits of zileuton in treating a range of diseases and conditions, including acute asthma exacerbations and COPD. We are aware, for instance, of clinical data available in publications of clinical trials and individual patient case studies that indicate zileuton has shown efficacy in the treatment of nasal polyps and acne. We completed a small Phase II clinical trial in patients with moderate to severe inflammatory acne in 2005. Patients receiving zileuton showed positive responses to treatment and a trend toward significance in certain endpoints. However, the responses did not achieve statistical significance as compared to the responses seen by patients receiving placebo. In the trial, zileuton was found to be safe and well tolerated. The data suggested a positive trend toward significance in the more severe acne patients in the study. Although we may consider conducting a future evaluation of zileuton in more severe acne patients, we have no plans to conduct such a clinical trial in 2007. The National Institutes of Health, or NIH, has indicated that NIH will sponsor and fund a clinical trial to evaluate whether using ZYFLO to treat patients admitted to the hospital with acute exacerbations of chronic obstructive pulmonary disease, or COPD, will shorten their hospital stay. The clinical trial is scheduled to begin in 2007 and is being conducted by the COPD Clinical Research Network.

In each case, if we develop zileuton for one of these diseases or conditions, we will need to commence clinical development programs to generate sufficient information to obtain a regulatory label. We also intend to conduct additional trials in specific asthma patient populations to support the use of the product in the target markets.

Life-Cycle Extension Strategy

We have obtained preclinical data that shows a single enantiomer of zileuton possesses higher potency for 5-lipoxygenase inhibition and clinical data after dosing of the racemate that demonstrates this enantiomer exhibits a more prolonged plasma pharmacokinetic exposure profile. We believe that these features offer the opportunity for us to develop a product candidate with a reduced tablet size or less frequent dose administration. In 2007, we plan to continue to evaluate this enantiomer to establish its pharmacokinetic and 5-lipoxygenase inhibitory profiles. We believe this development program could enable us to examine the potential development of a new zileuton tablet product candidate for the treatment of asthma and other indications, such as COPD.

Critical Care: The Inflammatory Response

We are developing product candidates directed towards the inflammatory response that we believe is responsible for the single or multiple organ failures often seen in patients admitted to the emergency room or the intensive care unit, or ICU. Our product development programs in this area center on cytokines and other inflammatory mediators that play a key role in regulating the body's immune system. We believe that the cytokine cascade is responsible for the severe inflammatory response seen in:

- acute diseases and conditions that lead to admission to the ICU, such as sepsis, septic shock and post surgical ileus; and
- acute exacerbations of chronic diseases that frequently lead to hospitalization, such as asthma, rheumatoid arthritis and acute pancreatitis.

In the setting of severe infection, trauma, severe bleeding or a lack of oxygen to the major organs of the body, the overproduction of inflammatory mediators, including cytokines, can lead to organ failure, tissue destruction and, eventually, death. When cytokine levels become elevated, an excessive inflammatory response occurs that may potentially result in damage to vital internal organs and, in the most severe cases, may result in multiple organ failure and death. Many previous therapies directed at cytokines, such as tumor necrosis factor alpha, or TNF alpha, in acute diseases have failed in clinical development.

The individual programs within our portfolio, while targeted toward the inflammatory response, exert their effects through different mechanisms of action. These programs include:

- an HMGB1 program directed towards a newly-discovered pro-inflammatory protein HMGB1; and
- an alpha-7 receptor program directed towards a receptor that we believe regulates the release of the cytokines that play a fundamental role in the inflammatory response, including TNF alpha, in response to an inflammatory stimulus.

We believe the probability of success of any one of our programs is not directly dependent upon the success or failure of any of our other programs. We believe our therapeutic approaches provide multiple opportunities for success and may increase the productivity of our research and development efforts. The programs we currently have directed towards the inflammatory response are as follows:

HMGB1 Program

We are evaluating mechanisms to prevent HMGB1 from effecting its role in inflammation-mediated diseases. HMGB1 has been identified as a potential late mediator of inflammation-induced tissue damage. 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 and we believe therefore 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 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. We have developed in our laboratories monoclonal antibodies directed towards HMGB1 that 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 a goal of selecting candidates for use in clinical testing. In collaboration with MedImmune, we expect to continue to support the development of product candidates based on HMGB1 antibodies for chronic and acute inflammatory diseases.

Therapeutic Opportunity

We believe that HMGB1's delayed and prolonged expression offers a new target for the development of products for acute diseases that can result in multiple organ failure, including sepsis and septic shock, and acute exacerbations of chronic diseases associated with the inflammatory response mediated by cytokines, such as rheumatoid arthritis.

Sepsis is the body's systemic inflammation response to infection or trauma. In animal models of septic shock, monoclonal antibodies targeting HMGB1 were successful in significantly reducing the mortality rate associated with these models. To date, limited clinical investigations have identified that patients with sepsis have elevated levels of HMGB1 in their bloodstream, compared to normal individuals, who do not have detectable levels of HMGB1 in their bloodstream. The elevated HMGB1 levels appeared to be greatest in the patients who subsequently died as a result of their disease.

Similar treatment opportunities also exist with other diseases that include an HMGB1 component, such as rheumatoid arthritis. Elevated levels of HMGB1 have been observed in the synovial fluid in the joints of rheumatoid arthritis patients, and positive symptom responses have been achieved in animal models of rheumatoid arthritis with anti-HMGB1 therapy.

Clinical Strategy

We have generated a number of monoclonal antibodies that bind to HMGB1 and that are active *in vitro* and *in vivo*. A number of these antibodies have demonstrated a dose-dependent benefit on survival in a mouse model of sepsis and a reduction in clinical arthritis symptoms in mouse and rat models of arthritis. In some of these tests, the monoclonal antibodies were administered in a treatment model after disease onset, as opposed to the preventive model in which the drug is administered before disease onset.

We are currently collaborating with MedImmune in the further preclinical investigation of our monoclonal antibodies in a number of animal models. MedImmune is conducting programs necessary to advance potential product candidates into Phase I clinical trials.

Alpha-7 Receptor Program

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 the nicotinic alpha-7 cholinergic receptor, or alpha-7 receptor, on cells involved in the inflammatory process.

Historically, a number of companies have focused on the alpha-7 receptor target for the treatment of central nervous system, or CNS, diseases. 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. We are undertaking a program to develop a small molecule product that inhibits the inflammatory response by stimulating the alpha-7 receptor on human inflammatory cells.

Therapeutic Opportunity

Our successful development of a product candidate targeting the alpha-7 receptor could lead to a novel treatment for severe acute inflammatory disease, as well as an oral anti-cytokine therapy that could be directed at chronic inflammatory diseases such as asthma, rheumatoid arthritis and Crohn's disease. We believe the previous work on the alpha-7 receptor will assist the discovery of new, peripherally acting drugs that selectively stimulate the alpha-7 receptor. We believe a drug candidate taken orally could have a strong market position against current injectable anti-TNF alpha biological therapies, particularly if it avoids the potential immunological response to therapy, which is a known risk with antibody products.

Development Strategy

We are currently completing preclinical evaluations of proprietary small molecule product candidates in our alpha-7 program through a small team of scientists. We have seen positive results with our molecules in animal models of allergic lung inflammation and acute lung injury, including models using alpha-7 knock-out mice. We believe the initial results support the concept that the alpha-7 receptor plays an important role in modulating the severity of inflammation in these models and that our molecules work by stimulating this receptor. We have generated a primary lead molecule that seems promising and we have moved forward with the scale-up synthesis. We expect to test this lead molecule in a pilot rat toxicity study in the first half of 2007. We plan to seek a collaborator for our alpha-7 nicotinic receptor agonist program and do not currently expect to conduct clinical trials with the alpha-7 program without entering into such an arrangement.

Collaborations

DEY Co-Promotion Agreement

On March 13, 2007, we entered into an agreement with DEY, L.P, an affiliate of Merck KGaA, under which we and DEY agreed to jointly co-promote ZYFLO and, if approved by the FDA, zileuton CR. Under the co-promotion and marketing services agreement, we granted DEY an exclusive right and license or sublicense, under patent rights controlled by us, to promote and detail ZYFLO and zileuton CR 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 and zileuton 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 have agreed to provide a minimum number of details per month for ZYFLO and zileuton CR in the first position. From 2008 through 2010, we and DEY each have agreed to contribute 50 percent of approved out-of-pocket promotion expenses for zileuton CR that are accrued or paid to third-parties. We and DEY each have agreed to contribute a minimum of $3.0 million per year for these promotion expenses. We are responsible for third-party promotion costs during 2007. DEY also has agreed to provide the support of its managed care group to negotiate contracts and engage in other activities with third-party payors for favorable managed care access at an initial rate of approximately $70,000 per calendar quarter. This managed care support will include advice and logistical support to us regarding managed care strategy.

Under the co-promotion agreement, DEY paid us a non-refundable upfront payment of $3.0 million upon signing the co-promotion agreement. In addition, DEY has agreed to pay us milestone payments of $4.0 million following approval by the FDA of the NDA for zileuton CR and $5.0 million following commercial launch of zileuton CR. Under the co-promotion agreement, we will retain all quarterly net sales of ZYFLO and zileuton CR, after third party royalties, up to $1.95 million. We have agreed to pay DEY a portion of quarterly net sales of ZYFLO and zileuton CR, after third-party royalties, in excess of $1.95 million. From the date DEY begins detailing ZYFLO through the commercial launch of zileuton CR, we have agreed to pay DEY 70% of quarterly net sales, after third party royalties, in excess of $1.95 million. Following the commercial launch of zileuton CR through December 31, 2010, we have agreed to pay DEY 35% of quarterly net sales, after third-party royalties, in excess of $1.95 million. From January 1, 2011 through December 31, 2013, we have agreed to pay DEY 20% of quarterly net sales, 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 upon mutual agreement by the parties. Beginning three years after the commercial launch of zileuton CR, either party may terminate the co-promotion agreement with six-months advance written notice. If the commercial launch of zileuton CR is delayed beyond May 31, 2008, DEY has the right to terminate the co-promotion agreement on or before July 1, 2008 by providing written notice, which will be effective

60 days after receipt by us. If DEY exercises this termination right, we will be obligated to pay DEY $2.0 million if DEY has paid us the $4.0 million milestone related to approval of the NDA for zileuton CR. In addition, DEY has the right to terminate the co-promotion agreement with two-months prior written notice if zileuton CR cumulative net sales for any four consecutive calendar quarters after commercial launch of zileuton CR are 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.

DEY has agreed not to manufacture, detail, sell, market or promote any product containing zileuton as one of the active pharmaceutical ingredients for sale in the United States until the later of one year after expiration or termination of the co-promotion agreement and March 15, 2012. However, if an AB-rated generic product to zileuton 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 zileuton CR. DEY also will not be subject to these non-competition obligations if DEY terminates the co-promotion agreement either because zileuton CR cumulative net sales for any four consecutive calendar quarters after commercial launch of zileuton CR are less than $25 million or upon the occurrence of a material uncured breach by us.

Under the co-promotion agreement, we granted DEY the exclusive right to negotiate with us for the development and commercialization, including co-promotion, of additional zileuton products in the United States for the treatment of asthma and, subject to FDA approval, other respiratory conditions. These exclusive negotiation rights are effective until September 1, 2007 with respect to zileuton injection and December 31, 2007 with respect to other zileuton products.

A joint commercial committee with two members from Critical Therapeutics and two members from DEY will oversee co-promotion activities under the co-promotion agreement. The co-promotion agreement provides that the joint commercial committee will make decisions by unanimous agreement, with disagreements being referred for resolution by the Chief Executive Officer of each party and further disputes being subject to non-binding mediation.

Binding Letter Agreement for COPD Co-Promotion

As contemplated by the terms of the zileuton co-promotion agreement with DEY, we and DEY entered into a separate binding letter agreement on March 13, 2007 providing for us to co-promote DEY's product candidate for COPD, if approved by the FDA. Under the binding letter agreement, DEY agreed to pay us a co-promotion fee based on a percentage of net retail sales of DEY's product candidate for the number of units in excess of a specified level of unit sales. We agreed to provide a specified minimum number of details per month for DEY's product candidate.

Although we intend to enter into a more detailed written agreement relating to the co-promotion of DEY's product candidate, the terms of the binding letter agreement will govern the co-promotion of DEY's product candidate if we and DEY fail to agree upon a more detailed written agreement. The binding letter agreement provides that we and DEY anticipate that we will negotiate and execute a more detailed written agreement within 90 days of signing the binder letter agreement.

Under the binding letter agreement, the term of the co-promotion arrangement for DEY's COPD product candidate will expire upon termination of the zileuton co-promotion agreement. In addition, we have the right to terminate the binding letter agreement or any more detailed written agreement after June 30, 2008 with 90-days advance notice.

MedImmune Collaboration

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 our 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 has agreed to fund and expend efforts to research and develop at least one HMGB1-inhibiting product for two indications through specified clinical phases.

Under the collaboration, MedImmune has paid us initial fees of $12.5 million. We may also receive under the collaboration research and development payments from MedImmune, including a minimum of $4.0 million of research and development payments through the end of 2006, of which $3.75 million had been paid by December 31, 2006. In addition, we may receive, subject to the terms and conditions of the agreement, other payments upon the achievement of research, development and commercialization milestones up to a maximum of $124.0 million, after taking into account payments that we are obligated to make to The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute) on milestone payments we receive from MedImmune. MedImmune also has agreed to pay royalties to us based upon 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 ten 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, which initially licensed to us patent rights and know-how related to HMGB1. In connection with entering into the collaboration agreement, an affiliate of MedImmune purchased an aggregate of $15.0 million of our series B convertible preferred stock in October 2003 and March 2004, which converted into 2,857,142 shares of our common stock in June 2004 in connection with our initial public offering.

In December 2005, MedImmune agreed that the collaboration demonstrated proof of concept in two preclinical disease models with human HMGB1 monoclonal antibodies. As a result, MedImmune made a $1.25 million milestone payment to us. In December 2005, MedImmune agreed to fund an additional $1.0 million of research work performed by our full-time employees in 2006.

We have agreed to work exclusively with MedImmune in the research and development of HMGB1-inhibiting products. Under the terms of the agreement, MedImmune's license to commercialize HMGB1-inhibiting products generally excludes us from manufacturing, promoting or selling the licensed products. However, we have the option to co-promote in the United States the first product for the first indication approved in the United States, for which we must pay a portion of the ongoing development costs and will receive a proportion of the profits in lieu of royalties that would otherwise be owed to us.

MedImmune has the right to terminate the agreement at any time on six-months written notice. Each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party. Under specified conditions, we or MedImmune may have certain payment or royalty obligations after the termination of the agreement.

Beckman Coulter Collaboration

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

In consideration for the license, Beckman Coulter paid us a product evaluation license fee of $250,000. Beckman Coulter exercised its development option under the license agreement in December 2006 and paid us $400,000 in January 2007. Under the agreement, we may also 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 net sales of licensed products by Beckman Coulter and its affiliates. Beckman Coulter has the right to grant sublicenses under the license, subject to our written consent, which we have agreed not to unreasonably withhold. In addition, Beckman Coulter agreed to pay us a percentage of any license fees, milestone payments or royalties actually received by Beckman Coulter from its sublicensees.

Beckman Coulter has the right to terminate the license agreement at any time on 90-days written notice. Each party has the right to terminate the license agreement upon the occurrence of a material uncured breach by the other party.

Research and Development

In connection with our October 2006 restructuring, we reduced the size of our research and development group by 16 employees. As of December 31, 2006, we had 20 employees engaged in research, development and regulatory affairs. Our research and development group seeks to identify the most promising development candidates and the most appropriate development pathways to maximize our chances of successful development. We also augment our internal research capabilities through sponsored research arrangements with academic and research institutions and individual academics, as well as in-licensed product candidates and technologies.

During the fiscal years ended December 31, 2004, 2005 and 2006, research and development expenses were $25.6 million, $30.0 million and $26.9 million, respectively.

Sales and Marketing

We have a respiratory sales force of approximately 18 representatives as of February 28, 2007 who are focused on promotion of ZYFLO to prescribing physicians within major metropolitan markets across the United States and increasing prescriptions from our existing base of prescribers. We also have a direct marketing call center that contacts prescribers who are not in the markets where we have representatives to help maintain brand awareness and arrange for delivery of samples. Subject to FDA approval of zileuton CR, we expect to expand the size of our sales force to approximately 40 sales representatives. Under our co-promotion agreement with DEY, DEY has agreed to provide a minimum number of details per month for ZYFLO and zileuton 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 have agreed to provide a minimum number of details per month for ZYFLO and zileuton CR in the first position.

We are focusing our sales and marketing efforts for zileuton on respiratory specialists who treat asthma, including allergists and pulmonologists, and primary care physicians who treat large numbers of asthma patients. We believe that we can successfully market zileuton to this target group through the combined efforts of our sales representatives and DEY's sales representatives. These specialists include a group of 100 to 200 national and regional scientific and clinical key opinion leaders who serve to influence the direction of the diagnosis and treatment of asthma through their publications and presentations at scientific and clinical medical conferences. We also expect to focus our medical outreach efforts on local clinically-based key opinion leaders.

Given the importance of the scientific and clinical key opinion leaders, we are directing our scientific message and support to help educate and inform key opinion leaders regarding the scientific rationale and clinical data that support our commercialization strategy. We have entered into consulting arrangements with a number of key opinion leaders who will provide expert advice to the company. We are also expanding our reach to a larger number of key opinion leaders through a group of medical science liaisons who are directed by our chief medical officer.

Part of our overall strategy for zileuton also includes repositioning the product within the managed care market. We have positioned zileuton with managed care medical directors and pharmacists as a treatment alternative when medications have failed to provide adequate symptomatic control. As a result, in addition to the awareness provided by office-based representatives, we believe information regarding zileuton will reach potential prescribing physicians through managed care pharmacies communicating the product's modified formulary status.

We expect that our sales effort for zileuton will expand if we develop and obtain regulatory approval for zileuton injection for treatment of acute exacerbations of asthma. We believe the launch of zileuton injection will increase awareness of zileuton among physicians.

Manufacturing

We have limited experience in manufacturing our product candidates. We currently outsource the manufacturing of ZYFLO for commercial sale and the manufacturing of our product candidates for use in clinical trials to qualified third parties and intend to continue to rely on contract manufacturing from third parties to supply products for both clinical use and commercial sale.

We have established the following manufacturing arrangements for zileuton.

Shasun Pharma Solutions

We originally contracted with Rhodia Pharma Solutions Ltd. for the commercial production of the zileuton active pharmaceutical ingredient, or API. On March 31, 2006, Rhodia SA, the parent company of Rhodia Pharma Solutions, sold the European assets of its pharmaceutical custom synthesis business to Shasun Chemicals and Drugs Ltd. As part of this transaction, Rhodia SA assigned our contract with Rhodia Pharma Solutions Ltd. to Shasun Pharma Solutions. Shasun has agreed to manufacture our commercial supplies of API, subject to specified limitations, through December 31, 2009. The agreement will automatically extend for successive one-year periods after December 31, 2009, unless Shasun provides us with 18-months prior written notice of cancellation. Under this agreement, we agreed to purchase a minimum amount of API by December 31, 2006. We are in negotiations with Shasun to revise the delivery date requirements for this minimum amount of API and other terms in the contract. We have the right to terminate the agreement upon 12-months prior written notice for any reason, provided that we may not cancel prior to January 1, 2008 for the purpose of retaining any other company to act as our exclusive supplier of the API. We also have the right to terminate the agreement upon six-months prior written notice if we terminate our plans to commercialize zileuton for all therapeutic indications. If we exercise our right to terminate the agreement prior to its scheduled expiration, we are obligated to reimburse Shasun for specified raw material and out-of-pocket costs. In addition, if we exercise our right to terminate the agreement due to termination of our plans to commercialize zileuton for all therapeutic indications, then we are also obligated to pay Shasun for all API manufactured by Shasun through that date. Furthermore, each party has the right to immediately terminate the agreement for cause, including a material uncured default by the other party.

Patheon Pharmaceuticals

We have contracted with Patheon Pharmaceuticals Inc. for the manufacture of commercial supplies of ZYFLO immediate release tablets. We have agreed to purchase at least 50% of our commercial supplies of ZYFLO immediate release tablets for sale in the United States from Patheon each year for the term of the agreement. The commercial manufacturing agreement has an initial term of three years beginning on September 15, 2005, 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. In addition, we have the right to terminate the agreement upon 30-days' prior written notice in the event any governmental agency takes any action, or raises any objection, that prevents us from importing, exporting, purchasing or selling ZYFLO. If we provide six-months' advance notice that we intend to discontinue commercializing ZYFLO, we will not be required to purchase any additional quantities of ZYFLO immediate release tablets, provided that we pay Patheon for a portion of specified fees and expenses associated with orders previously placed by us. Furthermore, each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party. If the agreement expires or is terminated for any reason, we have agreed to take delivery of and pay for undelivered quantities of ZYFLO that we previously ordered, purchase, at cost, Patheon's inventory of ZYFLO maintained in contemplation of filling orders previously placed by us and pay the purchase price for components of the ZYFLO immediate release tablets ordered by Patheon from suppliers in reliance on orders previously placed by us.

We have signed a development agreement with Patheon for the coating, packaging, release and stability testing of zileuton CR for clinical trials and regulatory review. We are in negotiations with Patheon regarding a manufacturing services agreement for Patheon to coat, package, and conduct release and stability testing of commercial supplies of zileuton CR. Under the proposed structure of this manufacturing services agreement, we anticipate that we would be responsible for supplying uncoated zileuton CR tablets to Patheon. Patheon would be responsible for coating, packaging, release and stability testing of zileuton CR.

SkyePharma

We have contracted with SkyePharma PLC, through its subsidiary Jagotec AG, for the manufacture of zileuton CR for clinical trials, regulatory review and, upon FDA approval and subject to negotiating a commercial manufacturing agreement, commercial sale. We are in negotiations with SkyePharma for a contract for manufacturing services. SkyePharma's existing manufacturing obligations for zileuton CR are reflected in our license agreement related to our use of SkyePharma's patent rights and know-how related to controlled-release technology used in zileuton CR. Both we and SkyePharma have the right to terminate the agreement upon the occurrence of a material uncured breach by the other party.

Other

We expect to enter into manufacturing arrangements with third parties for the manufacture of our other product candidates for clinical use. For example, we will need to enter into arrangements for the manufacture of product candidates for clinical trials in our alpha-7 program, if we are able to identify a collaboration partner to advance that program. We believe that MedImmune will be responsible for manufacturing of any biologic products that result from our HMGB1 program.

Distribution Network

We currently rely on third parties to distribute ZYFLO to pharmacies. We have contracted with Integrated Commercialization Services, Inc., or ICS, a third-party logistics company, to warehouse ZYFLO and distribute it to three primary wholesalers, AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation, and a number of smaller wholesalers. The wholesalers, in turn, distribute it to chain and independent pharmacies. ICS is our exclusive supplier of commercial distribution logistics services.

We rely on Phoenix Marketing Group LLC to distribute samples of ZYFLO to our sales representatives, who in turn distribute samples to physicians and other prescribers who are authorized under state law to receive and dispense samples. We have contracted with RxHope, Inc. to implement a patient assistance program for ZYFLO. We rely on RxHope to administer our patient assistance program and to distribute ZYFLO to physicians and other prescribers who are authorized under state law to receive and dispense prescription drugs. We believe this patient assistance program will help ensure broader and easier access to ZYFLO for those patients requiring financial assistance.

We expect that we will rely on similar distribution arrangements for zileuton CR, if approved.

This distribution network requires significant coordination with our supply chain, sales and marketing and finance organizations. We do not have our own warehouse or distribution capabilities. We do not intend to establish these functions on our own in the foreseeable future.

License and Royalty 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 agreements summarized below.

Abbott

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 AG, a subsidiary of SkyePharma. In consideration for the license, we paid Abbott an initial $1.5 million 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 completion of the technology transfer from Abbott to us, filing and approval of a product in the United States and specified minimum net sales of licensed products. In addition, we agreed to pay royalties to Abbott based on net sales of licensed products by us, our affiliates and 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 zileuton. Each party has the right to terminate the license upon the occurrence of a material uncured breach by the other party. We also have the right to terminate the license at any time upon 60 days notice to Abbott and payment of a termination fee. Through December 31, 2006, we have paid milestone and license payments totaling $4.0 million to Abbott under this agreement.

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. In consideration for the license and the trademark, we paid Abbott an initial fee of $500,000 and a milestone payment of $750,000 upon approval of the sNDA, which we paid in October 2005, and we agreed to pay royalties based upon net sales of licensed products by us, our affiliates and 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 in a given country, the license will become perpetual, irrevocable and fully paid up with respect to licensed products in that country. Each party has the right to terminate the license upon the occurrence of a material uncured breach by the other party.

Baxter

In June 2004, we entered into an agreement with Baxter Healthcare Corporation to conduct feasibility studies to analyze the various properties of zileuton and determine the most suitable technologies for the development of an injectable formulation of zileuton. In the event that we choose to pursue the commercialization of a specified injectable formulation developed by Baxter that is based on the formulation technology of a third party, Baxter granted us an exclusive, worldwide, non-revocable license to the formulation intellectual property in return for our agreement to pay Baxter royalties based on net sales of that formulation. However, we would need to finalize the license agreement to document such license based on the agreed financial terms, which we may not be able to negotiate on favorable terms, if at all. It is also possible that we may instead determine to pursue the commercialization of an injectable formulation developed by Baxter based on its own proprietary formulation technology. If we determine to do so, we would need to license from Baxter rights to that injectable formulation. In that case, we may not be able to negotiate a license agreement on favorable terms, if at all. Furthermore, although Baxter has filed two U.S. patent applications, one for the specified injectable formulation developed by Baxter based on the formulation technology of a third party and another for an injectable formulation developed by Baxter based on its own proprietary formulation technology, neither of these patent applications may result in issued patents.

The Feinstein Institute

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. The Feinstein Institute retained the right to make and use the licensed products in its own laboratories solely for non-commercial, scientific purposes and non-commercial research. In consideration for the license, we paid an initial license fee of $100,000. We also agreed to make milestone payments to The Feinstein Institute of up to $275,000 for the first product covered by the licensed patent rights and an additional $100,000 for each additional distinguishable product covered by the licensed patent rights, up to $137,500 for the first product covered by the licensed know-how and not the licensed patent rights and an additional $50,000 for each additional distinguishable product covered by the licensed know-how and not the licensed patent rights, 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 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. We also agreed to pay The Feinstein Institute fees if we sublicense our rights under the licensed patent rights and know-how. At December 31, 2006, we accrued $100,000 owed to The Feinstein Institute in accordance with this agreement. Each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party.

We also have entered into two sponsored research and license agreements with The Feinstein Institute. In July 2001, we entered into a sponsored research and license agreement with The Feinstein Institute under which, as amended, we paid The Feinstein Institute $200,000 annually until June 2006 to sponsor research activities at The Feinstein Institute to identify inhibitors and antagonists of HMGB1 and related proteins, including antibodies. In January 2003, we entered into a sponsored research and license agreement with The Feinstein Institute under which, as amended, we agreed to pay The Feinstein Institute to sponsor research activities at The Feinstein Institute in the field of cholinergic anti-inflammatory technology. We paid the Feinstein Institute $200,000 annually until January 2006 and $150,000 in 2006 for this sponsored research and have agreed to pay the Feinstein Institute $120,000 in 2007. Any future research terms under either of these agreements are subject to agreement between The Feinstein Institute and us. 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. The Feinstein Institute retained the right under each of these agreements to make and use the licensed products in its own laboratories solely for non-commercial, scientific purposes and non-commercial research.

In connection with the July 2001 sponsored research and license agreement, we issued The Feinstein Institute 27,259 shares of our common stock and agreed to make milestone payments to The Feinstein Institute of $200,000 for the first product covered by the licensed patent rights, and an additional $100,000 for each additional distinguishable product covered by the licensed patent rights, $100,000 for the first product covered by the licensed know-how and not the licensed patent rights and an additional $50,000 for each additional distinguishable product covered by the licensed know-how and not the licensed patent rights, in each case upon the achievement of specified development and regulatory approval milestones with respect to the applicable licensed product. In connection with the January 2003 sponsored research and license agreement, we paid The Feinstein Institute an initial license fee of $175,000 and 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 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 January 2003 sponsored research and license agreement, we agreed to pay minimum annual royalties to The Feinstein Institute beginning in the first year after termination of research activities regardless of whether we sell any licensed products. 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. In connection with our sublicenses to MedImmune and Beckman Coulter of our rights with respect to HMGB1, we have paid The Feinstein Institute $2.3 million and issued to The Feinstein Institute 66,666 shares of our common stock. Each party has the right to terminate each agreement upon the occurrence of a material uncured breach of that agreement by the other party.

SkyePharma

In December 2003, we entered into an agreement with SkyePharma, through its subsidiary Jagotec AG, under which SkyePharma consented to Abbott's sublicense to us of rights to make, use and sell zileuton CR covered by SkyePharma's patent rights and know-how. Under the terms of the agreement, SkyePharma also agreed to manufacture zileuton CR for clinical trials, regulatory review and, upon FDA approval and subject to negotiating a manufacturing agreement, commercial sale. In consideration for SkyePharma's prior work associated with the licensed patent rights and know-how, we paid SkyePharma an upfront fee of $750,000. We also agreed to make aggregate milestone payments to SkyePharma of up to $6.6 million upon the achievement of various development and commercialization milestones. Through December 31, 2006, we have made milestone payments totaling $1.6 million to SkyePharma under this agreement. In addition, we agreed to pay royalties to SkyePharma based upon net sales of the product by us and our affiliates. We also agreed to pay royalties to SkyePharma under the license agreement between SkyePharma and Abbott based upon net sales of the product by us and our affiliates. We also agreed to pay SkyePharma fees if we sublicense our rights under the licensed patent rights and know-how. In 2005, SkyePharma agreed to allow us to sublicense our rights to Patheon to permit Patheon to manufacture a portion of our annual requirements for zileuton CR tablets. Each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party.

Innovative Metabolics

In January 2007, we entered into an exclusive license agreement with Innovative Metabolics, Inc., or IMI, under which we granted to IMI an exclusive worldwide license under patent rights and know-how controlled by us relating to the 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. The licensed field includes mechanical and electrical stimulation of the vagus nerve and excludes pharmacological modulation of a cholinergic receptor, including the alpha-7 receptor. In consideration for the license, IMI agreed to pay us an initial license fee of $500,000 in cash following the completion of a financing by IMI that results in gross proceeds in excess of $5.0 million. In addition, in connection with any such financing, IMI agreed to issue to us a number of shares of preferred stock of IMI equal to the number of shares of preferred stock that could be purchased for $500,000 in such financing. The preferred stock issued to us will have a liquidation preference subordinate to the preferred stock issued in such financing. Under this license agreement, IMI also agreed to:

- make a one-time milestone payment to us of $1.0 million upon the achievement of all regulatory approvals from the FDA or any foreign counterpart agency required for the marketing and sale in the applicable country of any product or method covered by the licensed patent rights;

- pay us royalties based on net sales of licensed products and methods by IMI and its affiliates until the expiration of the patent rights covering the licensed product or method in the country of actual or intended use; and

- pay us a percentage of any royalties, fees and payments actually received from third parties, with limited exceptions, in connection with sublicenses by IMI of its rights under the licensed patent rights and know-how.

The patent rights and know-how licensed by us to IMI include patent rights and know-how arising from research conducted by The Feinstein Institute under the sponsored research and license agreement, as amended, that we entered into with The Feinstein Institute in January 2003.

Under this license agreement, IMI agreed to be responsible for specified obligations we owe to The Feinstein Institute pursuant to our sponsored research and license agreement. IMI 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 IMI license agreement. IMI 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.

Each party has the right to terminate the license agreement upon the occurrence of a material uncured default by the other party. IMI has the right to terminate the IMI license agreement at any time on 90-days prior written notice to us, provided that IMI pays a termination fee of $50,000 if it has not yet paid the $500,000 initial license fee. We have the right to terminate the license agreement if IMI fails to sell or otherwise issue securities in a financing as described above on or before June 30, 2007.

Two of our co-founders, Kevin J. Tracey, M.D. and H. Shaw Warren, M.D., are founders of IMI. Dr. Warren served as a member of our Board of Directors until October 2006. Dr. Tracey is a member of the medical staff at The Feinstein Institute. In addition, we are a party to consulting agreements with Dr. Tracey and Dr. Warren. These consulting agreements terminate on January 1, 2008. Under our consulting agreement with Dr. Tracey, we agreed to pay certain royalties to Dr. Tracey in connection with selling or sublicensing certain licensed alpha-7 products as defined in the agreement.

Proprietary Rights

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.

As of February 28, 2007, we own or exclusively license for one or more indications or formulations a total of 10 issued U.S. patents, 60 issued foreign patents, 34 pending U.S. patent applications and 93 pending foreign patent applications consisting of:

	U.S.		Foreign		Program Total
	Issued	Pending	Issued	Pending	
Zileuton	2	3	37	6	48
HMGB1	6	15	17	53	91
CTI-01	0	2	5	9	16
Alpha-7	2	14	1	25	42
Total	10	34	60	93	197

The U.S. patent covering the composition of matter of zileuton that we licensed from Abbott expires in 2010. The patent for zileuton CR will expire in 2012 and relates only to the controlled-release technology used to control the release of zileuton. The U.S. issued patents that we own or exclusively license covering our product candidates other than zileuton expire on various dates between 2019 and 2021.

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.

Trademarks, Trade Secrets and Other Proprietary Information

We have registered the Critical Therapeutics name and logo in both the United States and the European Community. We have also filed trademark applications to register CRTX and CT2 in the United States. In March 2004, we acquired the U.S. trademark for ZYFLO® from Abbott.

In addition, we depend upon trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, it is our general practice to enter into confidentiality agreements with our employees, consultants, strategic partners, outside scientific collaborators and sponsored researchers and other advisors. These agreements are designed to protect our proprietary information. These agreements are designed to deter, but may not prevent, unauthorized disclosure of our trade secrets, and any such unauthorized disclosure would have a material adverse effect on our business, for which monetary damages from the party making such unauthorized disclosure may not be adequate to compensate us.

Regulatory Matters

The research, testing, manufacture and marketing of drug and biologic products are extensively regulated in the United States and abroad. In the United States, drugs and biologics are subject to rigorous regulation by the FDA. The Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, record keeping, packaging, labeling, advertising and promotion, sampling and distribution of pharmaceutical and biologic products. The failure to comply with the applicable regulatory requirements may subject us to a variety of administrative or judicially imposed sanctions, including the FDA's refusal to file new applications or to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

The steps ordinarily required before a new pharmaceutical or biologic product may be marketed in the United States include preclinical laboratory tests, animal tests and formulation studies, the submission to the FDA of an investigational new drug application, or IND, which must become effective prior to

commencement of human clinical testing, and adequate and well-controlled clinical trials to establish that the product is safe and effective for the indication for which FDA approval is sought. Satisfaction of FDA approval requirements typically takes several years and the actual time taken may vary substantially depending upon the complexity of the product, disease or clinical trials required. Government regulation may impose costly procedures on our activities, and may delay or prevent marketing of potential products for a considerable period of time or prevent such marketing entirely. Success in early stage clinical trials does not necessarily assure success in later stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or even prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in marketing or sales restrictions on the product or even complete withdrawal of the product from the market.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of compounds for testing must comply with federal regulations and requirements. The results of preclinical testing are submitted to the FDA as part of an IND during the IND stage of development and as part of the NDA.

An IND must become effective prior to the commencement of clinical testing of a drug or biologic in humans. An IND will automatically become effective 30 days after receipt by the FDA if the FDA has not commented on or questioned the application during this 30-day waiting period. If the FDA has comments or questions, these may need to be resolved to the satisfaction of the FDA prior to commencement of clinical trials. In addition, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. The IND process can result in substantial delay and expense.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations and requirements, under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the safety and effectiveness criteria to be evaluated. Each protocol for an unapproved drug involving testing human subjects in the United States must be submitted to the FDA as part of the IND. The trial protocol and informed consent information for subjects in clinical trials must be submitted to institutional review boards for approval.

Clinical trials to support new drug or biologic product applications for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the product candidate into healthy human subjects or patients, the product is tested to assess metabolism, pharmacokinetics, safety, including side effects associated with increasing doses, and, at times, pharmacological actions. Phase II usually involves trials in a limited patient population, to determine dosage tolerance and optimum dosage, identify possible adverse effects and safety risks, and provide preliminary support for the efficacy of the product in the indication being studied.

If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to evaluate further clinical efficacy and to test further for safety within an expanded patient population, typically at geographically dispersed clinical trial sites. Phase I, Phase II or Phase III testing of any product candidates may not be completed successfully within any specified time period, if at all. Furthermore, the FDA, an institutional review board or we may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

After successful completion of the required clinical testing for a drug, generally an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all clinical and preclinical safety testing and a compilation of the data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of NDAs

are additionally subject to substantial application user fees, currently exceeding $600,000, the fee for submission of supplemental applications exceeds $300,000 and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, currently exceeding $40,000 per product and up to $250,000 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the NDA is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The review process is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. The FDA normally also will conduct a pre-approval inspection to ensure the manufacturing facility, methods and controls are adequate to preserve the drug's identity, strength, quality, purity and stability, and are in compliance with regulations governing current good manufacturing practices. In addition, the FDA usually conducts audits of the clinical trials for new drug applications and efficacy supplements to ensure that the data submitted reflects the data generated by the clinical sites.

If the FDA's evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue an approval letter, or, in some cases, an approvable letter followed by an approval letter. An approvable letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require post-approval trials and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions and restricted distribution, which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Supplemental applications must be filed for many post-approval changes, including changes in manufacturing facilities.

Some of our products may be regulated as biologics under the Public Health Service Act. Biologics must have a biologics license application, or BLA, approved prior to commercialization. Like NDAs, BLAs are subject to user fees. To obtain BLA approval, an applicant must provide preclinical and clinical evidence and other information to demonstrate that the biologic product is safe, pure and potent and that the facilities in which it is manufactured processed, packed or held meet standards, including good manufacturing practices and any additional standards in the license designed to ensure its continued safety, purity and potency. Biologics establishments are subject to preapproval inspections. The review process for BLAs is time consuming and uncertain, and BLA approval may be conditioned on post-approval testing and surveillance. Once granted, BLA approvals may be suspended or revoked under certain circumstances, such as if the product fails to conform to the standards established in the license.

Once the NDA or BLA is approved, a product will be subject to certain post-approval requirements, including requirements for adverse event reporting and submission of periodic reports. In addition, the FDA strictly regulates the promotional claims that may be made about prescription drug products and biologics. In particular, the FDA requires substantiation of any claims of superiority of one product over another, including that such claims be proven by adequate and well-controlled head-to-head clinical trials. To the extent that market acceptance of our products may depend on their superiority over existing therapies, any restriction on our ability to advertise or otherwise promote claims of superiority, or requirements to conduct additional expensive clinical trials to provide proof of such claims, could negatively affect the sales of our products or our costs.

We must also notify the FDA of any change in an approved product beyond variations already allowed in the approval. Certain changes to the product, its labeling or its manufacturing require prior FDA approval, including conduct of further clinical investigations to support the change. Major changes in manufacturing site require submission of an sNDA and approval by the FDA prior to distribution of the product using the change. Such supplements, referred to as Prior Approval Supplements, must contain information validating the effects of the change. An applicant may ask the FDA to expedite its review of such a supplement for public health reasons, such as a drug shortage. Approvals of labeling or manufacturing changes may be expensive and time-consuming and, if not approved, the product will not be allowed to be marketed as modified.

If the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA and issue a not approvable letter. The not approvable letter outlines the deficiencies in the submission and often requires additional testing or information in order for the FDA to reconsider the application. Even after submitting this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, the FDA may withhold approval of an NDA regardless of prior advice it may have provided or commitments it may have made to the sponsor.

Once an NDA is approved, the product covered thereby becomes a "listed drug" that can, in turn, be cited by potential competitors in support of approval of an abbreviated NDA. An abbreviated NDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. There is no requirement, other than the requirement for bioequivalence testing, for an abbreviated NDA applicant to conduct or submit results of preclinical or clinical tests to prove the safety or efficacy of its drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, are listed as such by the FDA, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage, dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor. During such three-year exclusivity period, the FDA cannot grant effective approval of an abbreviated NDA to commercially distribute a generic version of the drug based on that listed drug. However, the FDA can approve generic equivalents of that listed drug based on other listed drugs, such as a generic that is the same in every way but its indication for use, and thus the value of such exclusivity may be undermined. Federal law also provides a period of five years following approval of a drug containing no previously approved active ingredients. During such five-year exclusivity period, abbreviated NDAs for generic versions of those drugs cannot be submitted unless the submission accompanies a challenge to a listed patent, in which case the submission may be made four years following the original product approval. Additionally, in the event that the sponsor of the listed drug has properly informed the FDA of patents covering its listed drug, applicants submitting an abbreviated NDA referencing that drug are required to make one of four certifications, including certifying that it believes one or more listed patents are invalid or not infringed. If an applicant certifies invalidity or non-infringement, it is required to provide notice of its filing to the NDA sponsor and the patent holder. If the patent holder then initiates a suit for patent infringement against the abbreviated NDA sponsor within 45 days of receipt of the notice, the FDA cannot grant effective approval of the abbreviated NDA until either 30 months has passed or there has been a court decision holding that the patents in question are invalid or not infringed. If the NDA holder and patent owners do not begin an infringement action within 45 days, the ANDA applicant may bring a declaratory judgment action to determine patent issues prior to marketing. If the abbreviated NDA applicant certifies that it does not intend to market its generic product before some or all listed patents on the listed drug expire, then FDA cannot grant effective approval of the abbreviated NDA until those patents expire. If more than one applicant files a substantially complete ANDA on the same day for a previously unchallenged drug, each such "first applicant" will be entitled to share the 180-day exclusivity period, but there will only be one such period, beginning on the date of first

marketing by any of the first applicants. The first abbreviated NDA submitting substantially complete applications certifying that listed patents for a particular product are invalid or not infringed may qualify for a period of 180 days after the first marketing of the generic product, during which subsequently submitted abbreviated NDAs cannot be granted effective approval.

Violation of any FDA requirements could result in enforcement actions, such as withdrawal of approval, product recalls, product seizures, injunctions, total or partial suspension of production or distribution, fines, consent decrees, civil penalties and criminal prosecutions, which could have a material adverse effect on our business.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the development, approval, manufacturing and marketing of drug products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

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.

Under European Union regulatory systems, marketing authorization applications may be submitted at a centralized, a decentralized or a national level. The centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all European Union member states. As of January 1995, a mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure. We will choose the appropriate route of European regulatory filing to accomplish the most rapid regulatory approvals. However, our chosen regulatory strategy may not secure regulatory approvals on a timely basis or at all.

Hazardous Materials

Our research and development processes involve the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. We are subject to 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.

Competition

The pharmaceutical and biotechnology industries in which we operate are characterized by rapidly advancing technologies and intense competition. Our competitors include pharmaceutical companies, biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. All of these competitors currently engage in or may engage in the future in the development, manufacture and commercialization of new pharmaceuticals, some of which may compete with our present or future products and product candidates. Many of our competitors have greater development, financial, manufacturing, marketing and sales experience and resources than we do, and they may develop new products or technologies that will render our products or technologies obsolete or noncompetitive. We cannot assure you that our products will compete successfully with these

newly emerging technologies. In some cases, competitors will have greater name recognition and may offer discounts as a competitive tactic.

Zileuton, including our marketed product, ZYFLO, faces heavy competition in the asthma field. A number of large pharmaceutical and biotechnology companies currently market and sell products to treat asthma that compete with ZYFLO and would compete with zileuton CR, if it is approved for sale by the FDA. Many established therapies currently command large market shares in the asthma market, including LTRAs such as Merck & Co., Inc.'s Singular®, inhaled corticosteroid drugs, and combination products such as GlaxoSmithKline plc's Advair®.

The severe asthma market, where we believe zileuton has greater potential, is currently served by the therapies developed for mild to moderate asthma and oral, inhaled and injectable steroid treatments. One product, Xolair®, an anti-IgE antibody developed jointly by Novartis, Genentech and Tanox, is approved for severe allergic asthma. Xolair is a monoclonal antibody delivered in a monthly or semi-monthly subcutaneous injection for the treatment of moderate to severe allergic asthma that acts by blocking the immunoglobin E antibody that is an underlying cause of allergic asthma. The FDA approved the product in June 2003 and as of the end of 2004 was used to treat over 30,000 patients. Xolair is an injectable product, and, according to a 2005 article in the Journal of Managed Care Pharmacy, the annual cost for treatment ranges from approximately $7,388 to $44,328, depending on the dose. Xolair is targeted to patients with severe allergic asthma, particularly those patients who do not respond to therapies such as steroids. However, many managed care plans restrict its use through extensive prior authorization and step care requirements, such as a prior, failed course of therapy on Singulair, Accolate®, Advair or, in some cases ZYFLO, before Xolair can be considered.

If zileuton is developed as a treatment for COPD, it will also face intense competition. COPD is a disease treated predominantly with asthma drugs, anti-cholinergic drugs and lung reduction surgery. Many physicians regard bronchodilators and inhaled steroids as effective in the treatment of mild to moderate COPD. Advair, which has a new approved indication for COPD, is also now being promoted as a treatment for this indication by GlaxoSmithKline. Spiriva®, a once-a-day muscarinic antagonist from Boehringer Ingleheim and Pfizer, is approved in the United States. Other novel approaches are also in the development process. GlaxoSmithKline is developing a neurokinin-3 receptor antagonist and a neurokinin-4 integrin antagonist. Because both are in early development, their potential impact on the market is difficult to assess.

We are developing zileuton injection for use in severe acute asthma attacks. We may face intense competition from companies seeking to develop new drugs for use in severe acute asthma attacks. For example, Merck & Co., Inc. is conducting clinical trials of an intravenous formulation of its product Singulair®.

If our therapeutic programs directed toward the body's inflammatory response result in commercial products, such products will compete predominantly with therapies that have been approved for diseases such as rheumatoid arthritis, like Amgen, Inc.'s Enbrel® and Johnson & Johnson's Remicade®, and diseases such as sepsis, such as Eli Lilly and Company's Xigris®. While non-steroidal, anti-inflammatory drugs like ibuprofen are often used for the treatment of rheumatoid arthritis and offer efficacy in reducing pain and inflammation, we believe that our cytokine-based therapeutic programs will compete predominantly with the anti-TNF alpha therapies that have been approved for diseases such as rheumatoid arthritis, like Enbrel and Remicade. Xigris, a product developed by Eli Lilly for sepsis, has received regulatory approval for severe sepsis patients. Other than a wide range of anti-infective drugs, Xigris is one of the only drugs approved by the FDA for the treatment of sepsis. Other companies are developing therapies directed towards cytokines. We do not know whether any or all of these products under development will ever reach the market and if they do, whether they will do so before or after our products are approved.

Employees

As of December 31, 2006, we had 61 full-time employees, 27 of whom were engaged in marketing and sales, 20 of whom were engaged in research, development and regulatory affairs, and 14 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 Securities and Exchange Commission. In addition, we intend to post on our web site all disclosures that are required by applicable law, the rules of the Securities and Exchange Commission 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 Securities and Exchange Commission, in evaluating Critical 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 Our Business

Our business depends heavily on obtaining approval for and the commercial success of zileuton CR.

ZYFLO is our only commercial product and it has not achieved broad market acceptance. Other than zileuton CR, our product candidates are in early clinical, preclinical and research stages of development and are a number of years away from commercialization. Our NDA for zileuton CR was accepted for filing by the FDA as of September 29, 2006. Under the PDUFA guidelines, the PDUFA date for our NDA is May 31, 2007, which is the date by which we expect to receive an action letter from the FDA on this filing. If zileuton CR is not approved on a timely basis or at all, it would have a material adverse effect on our business, financial condition and results of operations. If approved for sale, we expect zileuton CR would account for a significant portion of our revenues for the foreseeable future, and that sales of ZYFLO would decline as patients convert to zileuton CR.

Research and development of product candidates is a lengthy and expensive process. Our early-stage product candidates in particular will require substantial funding for us to complete preclinical testing and clinical trials, initiate manufacturing and, if approved for sale, initiate commercialization. If zileuton CR is not approved and commercially successful, we may be forced to find additional sources of funding earlier than we anticipated. If we are not successful in obtaining additional funding on acceptable terms, we may be forced to significantly delay, limit or eliminate one or more of our research, development or commercialization programs.

If we do not obtain the regulatory approvals or clearances required to market and sell zileuton CR, our business may be unsuccessful.

We may not market zileuton CR in the United States, Europe or any other country without marketing approval from the FDA or the equivalent foreign regulatory agency. We have submitted an NDA to the FDA for zileuton CR, which was accepted for filing as of September 29, 2006. Abbott Laboratories conducted the pivotal clinical trials on zileuton CR before we in-licensed the product candidate. We are relying on the results of these prior pivotal clinical trials to support our NDA. If the

pivotal trial data are not considered sufficient by the FDA or if the clinical sites do not pass FDA audits, we could be required to repeat some or all of the clinical trials, which would lead to unanticipated costs and delays. To be able to rely on the results of Abbott's pivotal clinical trials, we conducted two comparative bioavailability studies intended to show that the pharmacokinetic profile of the controlled-release zileuton tablets that we have manufactured is similar to the pharmacokinetic profile of the controlled-release zileuton tablets previously manufactured by Abbott and used in Abbott's clinical trials. We conducted both a single-dose and a multiple-dose pharmacokinetic study. The studies assessed the pharmacokinetics of zileuton CR in volunteers under both fed and fasting conditions. We believe that the results of the bioavailability studies are sufficient to allow us to bridge to the results of Abbott's prior clinical trials to support our NDA filing. The FDA has confirmed that this is a significant review issue. If the FDA disagrees with our conclusions regarding the sufficiency of the results from the bioavailability studies, we could be required to conduct additional clinical trials to support our NDA, which could lead to unanticipated costs and delays or to the termination of our program for zileuton CR. If we do not receive required regulatory approval or clearance to market zileuton CR, our ability to generate product revenues and achieve profitability, our reputation and our ability to raise additional capital will be materially impaired.

If zileuton CR is not approved for sale or the market is not receptive to it, we may not be able to generate significant revenues unless we are able to successfully develop and commercialize other product candidates.

The commercial success of zileuton CR, if it is approved for sale, will depend upon its acceptance by the medical community, third-party payors and patients. Physicians will prescribe zileuton CR only if they determine, based on experience, clinical data, side effect profiles or other factors, that this product either alone or in combination with other products is appropriate for managing their patient's asthma. If approved, we believe that the primary advantage of zileuton CR over ZYFLO would relate to a more convenient dosing schedule, but this advantage may not result in broad market acceptance of zileuton CR, and we may experience the same type of difficulties with zileuton CR that we have experienced with ZYFLO.

Despite being approved by the FDA since 1996, ZYFLO, our first marketed zileuton product, has not achieved broad market acceptance. During the period between our commercial launch of ZYFLO in October 2005 through the week ending December 31, 2006, prescription data for ZYFLO indicates that approximately 3,656 physicians prescribed the product. For the year ended December 31, 2006, we recorded revenue from the sale of ZYFLO of only $6.6 million. We have had difficulty expanding the prescriber and patient base for ZYFLO, in part, we believe, because some physicians view ZYFLO as less effective than other products on the market or view its clinical data as outdated and because it requires dosing of one pill 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. In addition, if physicians do not prescribe zileuton CR for the recommended dosing regimen of two pills twice daily or if patients do not comply with the dosing schedule and take less than the prescribed number of tablets, our sales of zileuton CR would be limited and our revenues would be adversely affected.

Market perceptions about the safety of ZYFLO may limit the market acceptance of zileuton 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 a liver enzyme called alanine transaminase, or ALT, of over three times the levels normally seen in the bloodstream. In these trials, one patient developed symptomatic hepatitis with jaundice, which resolved upon discontinuation of therapy, and three patients developed mild elevations in bilirubin. In clinical trials for zileuton CR, 1.94% of the patients taking zileuton CR in a three-month efficacy trial and 2.6% of the patients taking zileuton 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 can elevate liver enzyme levels, periodic liver function tests are recommended for patients taking ZYFLO. Given the results of the zileuton CR clinical

trials, these periodic liver function tests also are likely to be advisable for patients taking zileuton CR. Some physicians and patients may perceive liver function tests as inconvenient or indicative of safety issues, which could make them reluctant to prescribe or accept ZYFLO and other zileuton product candidates, including zileuton CR. As a result, many physicians may have negative perceptions about the safety of ZYFLO and other zileuton product candidates, including zileuton CR, which could limit their commercial acceptance. The absence of ZYFLO from the market prior to our commercial launch in October 2005 may have exacerbated any negative perceptions about ZYFLO if physicians believe the absence of ZYFLO from the market was related to safety or efficacy issues. These negative perceptions could carry over to zileuton CR.

The position of ZYFLO in managed care formularies, which are lists of approved products developed by managed care organizations, has also made it more difficult to expand the current market share for this product. As a result of a lack of a sustained sales and marketing effort prior to our commercial launch in October 2005, in many instances ZYFLO had been relegated to a third-tier status, which typically requires the highest co-pay for patients. Similarly, we expect zileuton CR to have third-tier status in many instances as well. In some cases, managed care organizations, or MCOs, may require additional paperwork or prior authorization from the MCO before approving reimbursement for ZYFLO or, if approved, zileuton CR.

If any existing negative perceptions about ZYFLO persist, we will have difficulty achieving market acceptance for zileuton CR, if approved. If we are unable to achieve market acceptance of zileuton CR, we will not generate significant revenues unless we are able to successfully develop and commercialize other product candidates.

If our marketing and sales infrastructure and presence are not adequate or our collaborative marketing arrangements are not successful, our ability to market and sell our products will be impaired.

We reduced the size of our sales force as part of the cost reduction program that we announced in May 2006 and then further reduced the size of our sales force in the fourth quarter of 2006 in connection with our October 2006 restructuring. As of December 31, 2006, we had 18 sales representatives. In addition, our Senior Vice President of Sales and Marketing resigned in June 2006, and our Vice President of Sales resigned in July 2006. Due to our difficulty in achieving market acceptance of ZYFLO since its commercial launch in October 2005, the reduction in the size of our sales force, and the resignations of our Senior Vice President of Sales and Marketing and Vice President of Sales, it may be difficult for us to retain qualified sales and marketing personnel and maintain an effective sales force.

We have only recently entered into a co-promotion agreement with DEY, L.P., and we cannot predict whether the co-promotion arrangement will lead to increased sales for ZYFLO or, if approved by the FDA, zileuton CR. Because DEY has not yet initiated promotional or detailing activities for ZYFLO, the potential success of the co-promotion arrangement is uncertain.

In connection with the anticipated launch of zileuton CR, we expect to increase the size of our sales force to approximately 40 sales representatives, which would involve significant time and expense. In addition, we may not be able to attract, hire, train and retain qualified sales and marketing personnel to rebuild the sales force. If we are not successful in our efforts to rebuild this sales force, our ability to launch and market zileuton CR independently would be impaired.

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

We purchased quantities of raw materials and supplies of ZYFLO tablets in connection with the commercial launch of ZYFLO. These purchases were made consistent with our forecasts of inventory levels of ZYFLO that we based on our estimate of expected customer orders in combination with limited historical information regarding actual sales. Because product demand for ZYFLO has been less than we anticipated, our inventory levels of the API for ZYFLO have been higher than anticipated. In addition, we are subject to minimum purchase obligations under our supply agreements with our third-party manufacturers, which could require us to buy additional inventory. We plan to use a portion of the API manufactured for ZYFLO to manufacture zileuton CR. If ZYFLO demand does not increase or the

approval and commercial launch of zileuton CR is delayed, we may not be able to reduce these inventories or use the additional inventory we are required to purchase. 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, it could have a material adverse effect on our financial condition and results of operations during the period in which we recognize charges for excess inventory.

If we fail to maintain an adequate inventory of ZYFLO, API, or zileuton CR, if it is approved, or if our inventory were to be destroyed or damaged or reach its expiration date, patients may not have access to our products, our reputation and our brand could be harmed and physicians may be less likely to prescribe our products in the future.

If the market is not receptive to our product candidates, we will be unable to generate revenues from sales of these products.

The probability of commercial success of each of our product candidates is subject to significant uncertainty. Factors that we believe will materially affect market acceptance of our product candidates under development include:

- the timing of our receipt of any marketing approvals, the terms of any approval and the countries in which approvals are obtained;
- the safety, efficacy and ease of administration;
- the therapeutic benefit or other improvement over existing comparable products;
- pricing and cost effectiveness;
- the ability to be produced in commercial quantities at acceptable costs;
- the availability of reimbursement from third-party payors such as state and Federal governments, under programs such as Medicare and Medicaid, and private insurance plans and managed care organizations; and
- the extent and success of our sales and marketing efforts.

The failure of our product candidates to achieve market acceptance would prevent us from ever generating meaningful revenues from sales of these product candidates.

We may not be successful in our efforts to advance and expand our portfolio of product candidates.

An element of our strategy is to develop and commercialize product candidates that address large unmet medical needs. We seek to do so through:

- internal research programs;
- sponsored research programs with academic and other research institutions and individual doctors, chemists and researchers; and
- collaborations with other pharmaceutical or biotechnology companies with complementary clinical development or commercialization capabilities or capital to assist in funding product development and commercialization.

A significant portion of the research that we are conducting involves new and unproven technologies. Research programs to identify new product candidates, whether conducted by us or by academic or other research institutions under sponsored research agreements, require substantial technical, financial and

human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a variety of reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- the time, money and other resources that we devote to our research programs may not be adequate, including as a result of our May 2006 and October 2006 cost reduction programs; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be effective products.

In addition, subject to having sufficient cash and other resources to develop or commercialize additional products, we may seek to in-license or acquire product candidates or approved products. However, we may be unable to license or acquire suitable product candidates or products from third parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical products is competitive. A number of more established companies are also pursuing strategies to license or acquire products. These established companies may have a competitive advantage over us due to their size, cash resources or greater clinical development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable product candidates or approved products include the following:

- we may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return from the product;
- companies that perceive us as a competitor may be unwilling to assign or license their product rights to us;
- we may be unable to identify suitable products or product candidates within our areas of expertise; and
- we may have inadequate cash resources or may be unable to access public or private financing to obtain rights to suitable products or product candidates from third parties.

If we are unable to develop suitable potential product candidates through internal research programs, sponsored research programs or by obtaining rights from third parties, we will not be able to increase our revenues in future periods, which could result in significant harm to our financial position and adversely impact our stock price.

We face substantial competition. If we are unable to compete effectively, ZYFLO, zileuton CR and our other product candidates may be rendered noncompetitive or obsolete.

The development and commercialization of new drugs is highly competitive. We will face competition with respect to the development of product candidates and for ZYFLO, zileuton CR, if approved, and any other products that we commercialize in the future from pharmaceutical companies, biotechnology companies, specialty pharmaceutical companies, companies selling low-cost generic substitutes, academic institutions, government agencies or research institutions. A number of large pharmaceutical and biotechnology companies currently market and sell products to treat asthma that compete with ZYFLO and will compete with, if approved for sale, zileuton CR. Many established therapies currently command large market shares in the mild to moderate asthma market, including Merck & Co., Inc.'s Singulair®, GlaxoSmithKline plc's Advair® and inhaled corticosteroid products. We will also face competition in the severe asthma market. The severe asthma market is currently served by the therapies developed for mild to moderate asthma, as these therapies (Singulair®, Advair® and inhaled corticosteroids) are used in combination or add-on therapies in severe asthma, along with oral and injectable steroid treatments. One product, Xolair®, developed jointly by Novartis AG, Genentech, Inc. and Tanox, Inc., was approved in 2004 for severe allergic asthma and had U.S. sales of $320 million in 2005 and $427 million in 2006. In addition, we may face competition from pharmaceutical companies seeking to develop new drugs for the asthma market. For example, in July 2006, AstraZeneca announced the approval of Symbicort®, a twice-daily asthma therapy combining budesonide, an inhaled corticosteroid, and formoterol, a beta2-agonist, that

is expected to compete in the moderate and severe asthma markets. AstraZeneca has stated it expects to launch Symbicort® in mid-2007.

Zileuton will also face intense competition if we are able to develop it as a treatment for chronic obstructive pulmonary disease, or COPD. COPD is currently treated predominantly with drugs that are indicated for use in asthma only or asthma and COPD, anti-cholinergic drugs and lung reduction surgery. Spiriva®, a once daily muscarinic antagonist from Boehringer Ingleheim GmbH and Pfizer, has been approved in Europe and the United States. Other novel approaches are also in the development process.

We are developing an injectable formulation of zileuton, or zileuton injection, for use in severe acute asthma attacks. We may face intense competition from companies seeking to develop new drugs for use in severe acute asthma attacks. For example, Merck & Co., Inc. is conducting clinical trials of an intravenous formulation of its product Singulair®.

If our therapeutic programs directed toward the body's inflammatory response result in commercial products, such products will compete predominantly with therapies that have been approved for diseases such as rheumatoid arthritis, like Amgen, Inc.'s Enbrel®, Johnson & Johnson's Remicade®, and Abbott Laboratories' Humira®, and diseases such as sepsis, like Eli Lilly and Company's Xigris®.

Our competitors' products may be safer, more effective, more convenient or more effectively marketed and sold, than any of our products. Many of our competitors have:

- significantly greater financial, technical and human resources than we have and may be better equipped to discover, develop, manufacture and commercialize products;
- more extensive experience than we have in conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;
- competing products that have already received regulatory approval or are in late-stage development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

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 obtain more effective patent protection, than we are able to. 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 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.

Our operating results may be harmed if our restructuring and cost reduction measures do not achieve the anticipated results or cause undesirable consequences.

In 2006, we implemented cost reduction measures, which have included, among other things, significant workforce reductions. Because of the nature and extent of the restructuring actions we have taken, we may have difficulty marketing and promoting ZYFLO or, if approved, zileuton CR. If we fail to achieve the desired results of our cost reduction measures, we may suffer material harm to our business.

Our cost reduction initiatives may result in unintended consequences, such as attrition beyond our planned reduction in workforce, reduced employee morale and reduced support from physicians. As a result of these factors, our employees may seek alternate employment. Attrition beyond our planned reduction in workforce could have a material adverse effect on our financial performance. In addition, as a result of these cost reduction programs and the reduction in our workforce, we face an increased risk of employment litigation.

If we are unable to retain key personnel and hire additional qualified management and scientific personnel, we may not be able to achieve our goals.

We depend on the principal members of our management and scientific staff, including Frank E. Thomas, our President and Chief Executive Officer, Dana Hilt, M.D., our Chief Medical Officer and Senior Vice President of Clinical Development, and Trevor Phillips, Ph.D., our Chief Operating Officer and Senior Vice President of Operations. The loss of any of these individuals' services would diminish the knowledge and experience that we, as an organization, possess and might significantly delay or prevent the achievement of our research, development or commercialization objectives and could cause us to incur additional costs to recruit replacement executive personnel. We do not maintain key person life insurance on any of these individuals or any of our other scientific and management staff.

In June 2006, Paul D. Rubin, M.D. stepped down from his position as our President and Chief Executive Officer and resigned from our board of directors, and Frederick Finnegan resigned from his position as our Senior Vice President of Sales and Marketing. In July 2006, Anne M. Fields resigned from her position of Vice President of Sales. In October 2006, Walter Newman, Ph.D. resigned from his position as our Senior Vice President of Research and Development and Chief Scientific Officer. We put in place a new management structure, with a smaller management team that does not include a chief scientific officer, and have promoted individuals already employed by us to assume additional responsibilities. If we are unsuccessful in transitioning our management staff to compensate for the loss of these executives, the achievement of our research, development and commercialization objectives could be significantly delayed or may not occur. In addition, our focus on transitioning to our new management structure could divert our management's attention from other business concerns. Furthermore, if we decide to recruit new executive personnel, we will incur additional costs.

Our success depends in large part on our ability to attract and retain qualified scientific, commercial and management personnel. Any expansion into areas and activities requiring additional expertise, such as clinical trials, governmental approvals, contract manufacturing and sales and marketing, will place additional requirements on our management, operational and financial resources. These demands may require us to hire additional management and scientific 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 research, development, regulatory approval and commercialization of our product candidates.

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.

We are subject to extensive regulation by Federal and state governments. The laws that directly or indirectly affect our business include, but are not limited to, the following:

- Federal Medicare and Medicaid anti-kickback laws, which prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under Federal healthcare programs such as the Medicare and Medicaid programs;
- other Medicare laws and regulations that establish the requirements for coverage and payment for our products, including the amount of such payments;
- the Federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program, including private payors and, further, requires us to comply with standards regarding privacy and security of individually identifiable health information and conduct certain electronic transactions using standardized code sets;

- the Federal False Statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the Federal Food, Drug and Cosmetic Act, which regulates development, manufacturing, labeling, marketing, distribution and sale of prescription drugs and medical devices;
- the Federal Prescription Drug Marketing Act of 1987, which regulates the distribution of drug samples to physicians and other prescribers who are authorized under state law to receive and dispense drug samples;
- state and foreign law equivalents of the foregoing;
- state food and drug laws, pharmacy acts and state pharmacy board regulations, which govern sale, distribution, use, administration and prescribing of prescription drugs; and
- state laws that prohibit practice of medicine by non-physicians and fee-splitting arrangements between physicians and non-physicians, as well as state law equivalents to the Federal Medicare and Medicaid anti-kickback laws, which may not be limited to government reimbursed items or services.

On January 1, 2006, we became 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.

If our past or present operations are found to be in violation of any of the laws described above or other laws or governmental regulations to which we or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from Medicare and Medicaid programs and curtailment or restructuring of our operations. Similarly, if our customers are found non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. In addition, if we are required to obtain permits or licenses under these laws that we do not already possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims of a violation. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations, and additional legal or regulatory change.

If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to enforcement action by the FDA. For example, we received a warning letter from the FDA in November 2005 relating to certain promotional material that included an illustration of the mechanism of action for ZYFLO. The FDA asserted that the promotional material incorporating the illustration was false or misleading because it presented efficacy claims for ZYFLO, but failed to contain fair balance by not communicating the risks associated with its use and failing to present the approved indication for ZYFLO. In response to the warning letter, and as requested by the FDA, we stopped disseminating the promotional material containing the mechanism of action and we provided a written response to the FDA. As part of our response, we provided a description of our plan to disseminate corrective messages about the promotional material to those who received this material. We revised the promotional material containing the mechanism of action to address the FDA's concerns regarding fair balance. If our promotional activities fail to comply with the FDA's regulations or guidelines, we could be subject to

additional regulatory actions by the FDA, including product seizure, injunctions, and other penalties and our reputation and the reputation of ZYFLO in the market could be harmed.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from operating our business and damage our reputation or our brands. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change or discontinue our business practices or our existing business practices could be challenged as unlawful, which could materially harm our business, financial condition and results of operations.

State pharmaceutical marketing and promotional compliance and reporting requirements may expose us to regulatory and legal action by state governments or other government authorities.

In recent years, several states, including California, Maine, Minnesota, New Mexico, Vermont and West Virginia, as well as the District of Columbia have enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs and file periodic reports with the state on sales, marketing, pricing, reporting pricing and other activities. 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 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 compliance program must establish a specific annual dollar limit on gifts or other items given to individual healthcare professionals in California.

Maine, Minnesota, New Mexico, Vermont, West Virginia and the District of Columbia have also enacted statutes of varying scope that impose reporting and disclosure requirements upon pharmaceutical companies pertaining to drug pricing and payments and costs associated with pharmaceutical marketing, advertising and promotional activities, as well as restrictions upon the types of gifts that may be provided to healthcare practitioners. Similar legislation is being considered in a number of other states. Many of these requirements are new and uncertain, and available guidance is limited. We are in the process of identifying the universe of state laws applicable to pharmaceutical companies and are taking steps to ensure that we come into compliance with all such laws. 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.

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 ZYFLO, zileuton CR and our other product candidates, together with our general operations, are subject to extensive regulation by Federal, state and other authorities within the United States and numerous entities outside of the United States. We are a relatively small company and had approximately 61 employees as of December 31, 2006. We rely heavily on third parties to conduct many important functions. While we have developed and instituted a corporate compliance program based on what we believe are the current best practices and continue to update the program in response to newly implemented and changing regulatory requirements, it is possible that we may not be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations, we could be subject to a range of regulatory actions, including significant fines, litigation or other sanctions. Any action against us for a violation of these regulations, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention and harm our reputation.

As a publicly traded company, we are subject to significant legal and regulatory requirements, including the Sarbanes-Oxley Act of 2002 and related regulations, some of which have either only recently become applicable to us or are subject to change. For example, we are incurring additional expenses and devoting significant management time and attention to evaluating our internal control systems in order to

allow our management to report on, and our registered public accounting firm to attest to, our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. If the controls and procedures that we have implemented do not comply with all of the relevant rules and regulations of the Securities and Exchange Commission, or SEC, and The NASDAQ Global Market, we may be subject to sanctions or investigation by regulatory authorities, including the SEC or The NASDAQ Global Market. This type of action could adversely affect our financial results or investors' confidence in our company and our ability to access the capital markets. If we fail to develop and maintain adequate controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner, which could cause a decline in our stock price.

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

Our sales of ZYFLO are, and sales of our product candidates including zileuton CR will be, dependent, in part, on the availability of reimbursement from third-party payors such as state and Federal governments, under programs such as Medicare and Medicaid, and private insurance plans. There have been, there are and we expect there will continue to be, state and Federal legislative and administrative proposals that could limit the amount that state or Federal governments will pay to reimburse the cost of pharmaceutical and biologic products. The Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, was signed into law in December 2003. Legislative or administrative acts that reduce reimbursement for our products could adversely impact our business. In addition, we believe that private insurers, such as managed care organizations, or MCOs, may adopt their own reimbursement reductions in response to 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 drug product is approved, governmental and private reimbursement 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, including zileuton CR, and current reimbursement policies for marketed products may change at any time.

The MMA also established a prescription drug benefit that became effective in 2006 for all Medicare beneficiaries. We cannot be certain that our product candidates, including zileuton CR, will be included in the Medicare prescription drug benefit. Even if our products are included, the MCOs, health maintenance organizations, or HMOs, preferred provider organizations, or PPOs, and private health plans that administer the Medicare drug benefit have the ability to negotiate price and demand discounts from pharmaceutical and biotechnology companies that may implicitly create price controls on prescription drugs. On the other hand, the drug benefit may increase the volume of pharmaceutical drug purchases, offsetting at least in part these potential price discounts. In addition, MCOs, HMOs, PPOs, healthcare institutions and other government agencies continue to seek price discounts. Because MCOs, HMOs and PPOs and private health plans will administer the Medicare drug benefit, managed care and private health plans will influence prescription decisions for a larger segment of the population. In addition, certain states have proposed and certain other states have adopted various programs to control prices for senior citizen and drug programs for people with low incomes, including price or patient reimbursement constraints, restrictions on access to certain products, and bulk purchasing of drugs.

If we succeed in bringing products in addition to ZYFLO 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 other than zileuton CR are in the development stage, 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 their cost-effectiveness. Sales of prescription drugs are highly dependent on the availability and level of reimbursement to the consumer from third-party payors, such as government and private insurance plans. These third-party payors frequently require that drug companies provide them with predetermined discounts or rebates from list prices, and third-party payors are increasingly challenging

the prices charged for medical products. Because our product candidates other than zileuton CR are in the development stage, we do not know the level of reimbursement, if any, we will receive for those product candidates if they are successfully developed. If the reimbursement we receive for any of our product candidates is inadequate in light of our development and other costs, our ability to realize profits from the affected product candidate would be limited. If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce use of our products or cause us to reduce the price of our products.

Our business has a substantial risk of product liability claims. If we are unable to obtain appropriate levels of insurance, a product liability claim against us could interfere with the development and commercialization of our product candidates or subject us to unanticipated damages or settlement amounts.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing and sale of drugs. If the use of ZYFLO, zileuton CR or one or more of our other product candidates harms people, we may be subject to costly and damaging product liability claims. We currently have a $20.0 million annual aggregate limit for insurance covering both product liability claims for ZYFLO and clinical trial liability claims for our product candidates. We may seek additional product liability insurance prior to marketing zileuton CR or any of our other product candidates. However, our insurance may not provide adequate coverage against potential liabilities. Furthermore, product liability and clinical trial insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage, obtain additional insurance or obtain sufficient insurance at a reasonable cost to protect against losses that we have not anticipated in our business plans. Any product liability claim against us, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention and harm our reputation.

We handle hazardous materials and must comply with laws and regulations, which can be expensive and restrict how we do business. If we are involved in a hazardous waste spill or other accident, we could be liable for damages, penalties or other forms of censure.

Our research and development work involves, and any future manufacturing processes that we conduct may involve, the use of hazardous, controlled and radioactive materials. We are subject to Federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. Despite precautionary procedures that we implement for handling and disposing of these materials, we cannot eliminate the risk of accidental contamination or injury. In the event of a hazardous waste spill or other accident, we could be liable for damages, penalties or other forms of censure.

In addition, we may be required to incur significant costs to comply with laws and regulations in the future, or we may be materially and adversely affected by current or future laws or regulations related to hazardous materials or wastes.

While we have a property insurance policy that covers bio-contamination up to a $25,000 per-occurrence limit and radioactive contamination up to a $25,000 per-occurrence limit, this policy may not provide adequate coverage against potential losses, damages, penalties or costs relating to accidental contamination or injury as a result of hazardous, controlled or radioactive materials.

Risks Relating to Development, Clinical Testing and Regulatory Approval of Our Product Candidates

If we do not obtain the regulatory approvals or clearances required to market and sell our product candidates under development, our business may be unsuccessful.

Neither we nor any of our collaborators may market any of our products in the United States, Europe or in any other country without marketing approval from the FDA or the equivalent foreign regulatory agency. ZYFLO is currently our only commercial product and can only be marketed in the United States.

The regulatory process to obtain market approval or clearance for a new drug or biologic takes many years, requires expenditures of substantial resources, is uncertain and is subject to unanticipated delays. We have had only limited experience in preparing applications and obtaining regulatory approvals and clearances. Adverse side effects of a product candidate in a clinical trial could result in the FDA or foreign regulatory authorities refusing to approve or clear a particular product candidate for any or all indications for use.

The FDA and foreign regulatory agencies have substantial discretion in the drug approval process and can deny, delay or limit approval of a product candidate for a variety of reasons. If we do not receive required regulatory approval or clearance to market zileuton CR or any of our other product candidates under development, our ability to generate product revenue and achieve profitability, our reputation and our ability to raise additional capital will be materially impaired.

If clinical trials for our product candidates are not successful, we may not be able to develop, obtain regulatory approval for and commercialize these product candidates successfully.

Our product candidates are still in development and remain subject to clinical testing and regulatory approval or clearance. In order to obtain regulatory approvals or clearances for the commercial sale of our product candidates, we and our collaborators will be required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of our product candidates. We may not be able to obtain authority from the FDA, institutional review boards or other regulatory agencies to commence or complete these 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 have other unexpected characteristics that may delay or preclude submission and regulatory approval or clearance or limit commercial use if approved or cleared. Furthermore, we, one of our collaborators, institutional review boards, or regulatory agencies may hold, 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, in March 2006, we announced that we had discontinued a Phase II clinical trial of ethyl pyruvate, which we refer to as CTI-01, a small molecule product candidate that we had been developing for prevention of complications that can occur in patients after cardiopulmonary bypass, a procedure commonly performed during heart surgery. After reviewing the final data from the trial, we decided to discontinue further development of CTI-01. Effective February 6, 2007, we terminated the license agreements between us and the University of Pittsburgh and Xanthus Pharmaceuticals, Inc., formerly Phenome Sciences, Inc., related to certain patent rights related to CTI-01 controlled by University of Pittsburgh and Xanthus.

Preclinical testing and clinical trials of new drug and biologic candidates are lengthy and expensive and the historical failure rate for such candidates is high. We may not be able to advance any more product candidates into clinical trials. Even if we do successfully enter into clinical trials, the results from preclinical testing of a product candidate may not predict the results that will be obtained in human clinical trials. In addition, positive results demonstrated in preclinical studies and clinical trials that we complete may not be indicative of results obtained in additional clinical trials. Clinical trials may take several years to complete, and failure can occur at any stage of testing.

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 a submission or approval for a narrower indication. If clinical trials fail, our product candidates would not become commercially viable. In particular, if our planned Phase IIIb clinical trial for zileuton CR fails or produces results that are adverse or inconclusive, our ability to commercialize zileuton CR successfully and our financial results could be materially and adversely affected.

If clinical trials for our product candidates are delayed, we would be unable to 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 cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause regulatory authorities, institutional review boards or us to delay or suspend those clinical trials, or delay the analysis of data from our ongoing clinical trials.

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

- ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays or the inability to obtain required approvals from institutional review boards or other governing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients and volunteers into clinical trials;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- the need to repeat clinical trials as a result of inconclusive or negative results or poorly executed testing;
- insufficient supply or deficient quality of product candidate materials or other materials necessary to conduct our clinical trials;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- serious and unexpected drug-related side effects experienced by participants in ongoing or past clinical trials for the same or a different indication;
- serious and unexpected drug-related side effects observed during ongoing or past preclinical studies; or
- the placement of a clinical hold on a trial.

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 our clinical trials and thereby impair the validity or statistical significance of the trials.

We expect to rely on academic institutions and clinical 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.

As a result of these factors, we or third parties on whom we rely may not successfully begin or complete our clinical trials in the time periods we have forecasted, if at all. If the results of our ongoing or planned clinical trials for our product candidates are not available when we expect or if we encounter any delay in the analysis of data from our preclinical studies and clinical trials, we may be unable to submit for regulatory approval or clearance or conduct additional clinical trials on the schedule we currently 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.

Even if we obtain regulatory approvals or clearances, our product candidates will be subject to ongoing regulatory requirements and review. If we fail to comply with continuing U.S. and applicable foreign regulations, we could lose permission to manufacture and distribute our products and the sale of our product candidates could be suspended.

Our product candidates are subject to continuing regulatory review after approval, including the review of spontaneous adverse drug experiences and clinical results from any post-market testing required as a condition of approval that are reported after our product candidates become commercially available. The manufacturer and the manufacturing facilities we use to make any of our product candidates will also be subject to periodic review and inspection by the FDA. The subsequent discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer or facility, including withdrawal of the product from the market. Our product promotion and advertising will also be subject to regulatory requirements and continuing FDA review.

If we or our third-party manufacturers or service providers fail to comply with applicable laws and regulations, we or they could be subject to enforcement actions, which could adversely affect our ability to market and sell our product candidates and may harm our reputation.

If we or our third-party manufacturers or service providers fail to comply with applicable Federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could adversely affect our ability to develop, market and sell our product candidates successfully and could harm our reputation and hinder market acceptance of our product candidates. These enforcement actions include:

- product seizures;
- voluntary or mandatory recalls;
- suspension of review or refusal to approve pending applications;
- voluntary or mandatory patient or physician notification;
- withdrawal of product approvals;
- restrictions on, or prohibitions against, marketing our product candidates;
- restrictions on applying for or obtaining government bids;
- fines;
- restrictions on importation of our product candidates;
- injunctions; and
- civil and criminal penalties.

Risks Relating to Our Dependence on Third Parties

We will depend on DEY to jointly promote and market ZYFLO and, if approved by the FDA, zileuton CR. This co-promotion arrangement may not be successful.

We are relying on DEY to jointly promote and market ZYFLO and, if approved by the FDA, zileuton CR. ZYFLO is our only commercial product and it has not achieved broad market acceptance. Our sales force has not been successful to date in significantly expanding the market for ZYFLO. As a result, our ability to generate meaningful near-term revenues from product sales is substantially dependent on the success of our co-promotion arrangement with DEY.

Beginning three years after the commercial launch of zileuton CR, DEY may terminate the co-promotion agreement with six-months advance written notice. If the commercial launch of zileuton CR is delayed beyond May 31, 2008, DEY has the right to terminate the co-promotion agreement on or before July 1, 2008 by providing written notice, which will be effective 60 days after receipt by us. If DEY exercises this termination right, we will be obligated to pay DEY $2.0 million. In addition, DEY has the

right to terminate the co-promotion agreement with two-months prior written notice if zileuton CR cumulative net sales for any four consecutive calendar quarters after commercial launch of zileuton CR are 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 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 particular, both we and DEY have agreed to provide a minimum number of details per month for ZYFLO and zileuton 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 or zileuton CR, our sales of ZYFLO and zileuton 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 or zileuton CR beyond the minimum required by the terms of the co-promotion agreement. Any decision not to devote sufficient resources to the co-promotion arrangement or any future reduction in efforts under the co-promotion arrangement would limit our ability to generate significant revenues from product sales.

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 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. All of our revenues prior to October 2005, when we commercially launched ZYFLO, were derived from our collaboration agreements with MedImmune and Beckman Coulter. Additional payments due to us under the collaboration agreements with MedImmune and Beckman Coulter are generally based on our achievement of specific development and commercialization milestones that we may not meet. 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 from third parties. Accordingly, we cannot predict if our collaborations with MedImmune and Beckman Coulter will continue to generate revenues for us.

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. Under the collaboration agreement, we are obligated to use commercially reasonable, good faith efforts to conduct the collaboration in accordance with rolling three-year research plans that describe and allocate between MedImmune and us responsibility for, among other things, the proposed research, preclinical studies, toxicology formulation activities and clinical studies for that time period. In addition, we and MedImmune 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 our 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 our HMGB1 program likely would be delayed, curtailed or terminated. The delay, curtailment or termination of our HMGB1 program could significantly harm our future prospects. We intend to enter into collaboration agreements with other parties in the future that relate to other product candidates, and we are likely to have similar risks with regard to any such future collaborations.

Our license agreement with Beckman Coulter generally is terminable by Beckman Coulter on 90-days written notice. Each party has the right to terminate the license agreement upon the occurrence of a material uncured breach by the other party. If Beckman Coulter were to terminate or breach our arrangement, 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 collaborative arrangements that we enter into with third parties may not be scientifically or commercially successful. Factors that may affect the success of our collaborations include the following:

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

We rely on third parties to manufacture and supply the zileuton API, ZYFLO and our product candidates. We expect to continue to rely on these sole source suppliers for these purposes and would incur significant costs to independently develop manufacturing facilities.

We have no manufacturing facilities and limited manufacturing experience. In order to continue to develop product candidates, apply for regulatory approvals and commercialize products, we need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities. We currently rely on third parties for production of the zileuton API and zileuton CR, commercial supplies of ZYFLO and preclinical and clinical supplies of our product candidates. These third parties are currently our sole source suppliers, and we expect to continue to rely on them for these purposes for the foreseeable future.

We have a contract with Shasun Pharma Solutions Ltd. for commercial production of the zileuton API, subject to specified limitations, through December 31, 2009. The manufacturing process for the zileuton API involves an exothermic reaction that generates heat and, if not properly controlled by the safety and protection mechanisms in place at the manufacturing sites, could result in unintended combustion of the product. The manufacture of the zileuton API could be disrupted or delayed if a batch is discontinued or damaged, if the manufacturing sites are damaged, or if local health and safety regulations require a third-party manufacturer to implement additional safety procedures or cease production. In addition, Sumitomo is currently the only qualified supplier of a chemical known as 2-ABT one of the starting materials for zileuton, and if Sumitomo stops manufacturing, 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 ZYFLO and zileuton CR.

We have contracted with Patheon Pharmaceuticals Inc. for the manufacture of commercial supplies of ZYFLO tablets. We have contracted with Patheon for a technology transfer program to enable Patheon to coat and package the core tablets of zileuton CR for clinical trials and regulatory review, and, subject to negotiation of a commercial manufacturing agreement, commercial supplies.

We have contracted with SkyePharma PLC, through its subsidiary Jagotec AG, for the manufacture of tablets of zileuton CR for clinical trials, regulatory review and commercial supplies. In January 2007, following a decision to concentrate on oral and pulmonary products, SkyePharma announced that it had

reached an agreement for the sale of its injectable business. If SkyePharma sells all or parts of its remaining business, our ability to produce zileuton CR may be impaired.

We have not secured a long-term commercial supply arrangement for any of our product candidates other than the zileuton API. The manufacturing process for our product candidates is an element of the FDA approval process. We will need to contract with manufacturers who can meet the FDA requirements, including current Good Manufacturing Practices, on an ongoing basis. As part of obtaining regulatory approval for zileuton CR, we are required to engage a commercial manufacturer to produce registration and validation batches of the drug consistent with regulatory approval requirements. In addition, if we receive the necessary regulatory approval for our product candidates, we also expect to rely on third parties, including our collaborators, to produce materials required for commercial production. We may experience difficulty in obtaining adequate manufacturing capacity or timing for our needs. If we are unable to obtain or maintain contract manufacturing of these product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully.

We are dependent upon Shasun Pharma Solutions, Patheon and SkyePharma as sole providers, and will be dependent on any other third parties who manufacture our product candidates, to perform their obligations in a timely manner and in accordance with applicable government regulations. For example, during the quarter ended June 30, 2006, one of our contract manufacturers failed to meet our manufacturing specifications relating to certain manufacturing batches of ZYFLO. If third-party manufacturers with whom we contract fail to perform their obligations, we may be adversely affected in a number of ways, including the following:

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

If we were required to change manufacturers for the zileuton API, ZYFLO or zileuton CR, we would be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and all applicable regulations and guidelines, including FDA requirements and approved NDA product specifications. In addition, we would be required to conduct additional clinical bioequivalence trials to demonstrate that zileuton CR manufactured by the new manufacturer is equivalent to zileuton CR manufactured by our current manufacturer. Any delays associated with the verification of a new manufacturer or conducting additional clinical bioequivalence trials could adversely affect our production schedule or increase our production costs.

Any failure to manage and maintain our distribution network could compromise sales of ZYFLO and, if approved, zileuton CR and harm our business.

We rely on third parties to distribute ZYFLO and, if approved, zileuton CR, to pharmacies. We have contracted with Integrated Commercialization Services, Inc., or ICS, a third-party logistics company, to warehouse ZYFLO and distribute it to three primary wholesalers, AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation, and a number of smaller wholesalers. If zileuton CR is approved for sale by the FDA, we expect to contract with ICS to warehouse and distribute zileuton CR. The wholesalers in turn distribute it to chain and independent pharmacies. ICS is our exclusive supplier of commercial distribution logistics services. We rely on Phoenix Marketing Group LLC to distribute samples of ZYFLO and, if approved, zileuton CR, to our sales representatives, who in turn distribute samples to physicians and other prescribers who are authorized under state law to receive and dispense samples. We have contracted with RxHope, Inc. to implement a patient assistance program for ZYFLO. We rely on RxHope to administer our patient assistance program and to distribute ZYFLO to physicians and other prescribers who are authorized under state law to receive and dispense samples.

This distribution network requires significant coordination with our supply chain, sales and marketing and finance organizations. Failure to maintain our contracts with our logistics company, the wholesalers, Phoenix and RxHope, or the inability or failure of any of them to adequately perform as agreed under their respective contracts 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 were unable to replace ICS, AmerisourceBergen, Cardinal, McKesson, Phoenix or RxHope in a timely manner in the event of a natural disaster, failure to meet FDA and other regulatory requirements, business failure, strike or any other difficulty affecting any of them, the distribution of ZYFLO and, if approved, zileuton CR could be delayed or interrupted, which would damage our results of operations and market position. Failure to coordinate financial systems could also negatively impact our ability to accurately report and forecast product sales and fulfill our regulatory obligations. If we are unable to effectively manage and maintain our distribution network, sales of ZYFLO and, if approved, zileuton CR, could be severely compromised and our business could be harmed.

If we are unable to enter into additional collaboration agreements, we may not be able to continue development of our product candidates.

Our drug development programs and potential commercialization of our product candidates will require substantial additional cash to fund expenses to be incurred in connection with these activities. We may seek to enter into additional collaboration agreements with pharmaceutical companies to fund all or part of the costs of drug development and commercialization of product candidates. For example, we have determined to seek to enter into a collaboration arrangement with respect to the development of our alpha-7 product candidate. We do not plan to proceed with clinical development of our alpha-7 product candidate without entering into such an arrangement. We face, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, collaboration agreements are complex and time consuming to negotiate, document and implement. We may not be able to enter into future collaboration agreements, and the terms of the collaboration agreements, if any, may not be favorable to us. If we are not successful in efforts to enter into a collaboration arrangement with respect to a product candidate, we may not have sufficient funds to develop any of our product candidates internally. If we do not have sufficient funds to develop our product candidates, we will not be able to bring these product candidates to market and generate revenue. In addition, our inability to enter into collaboration agreements could delay or preclude the development, manufacture and/or commercialization of a product candidate and could have a material adverse effect on our financial condition and results of operations because:

- we may be required to expend our own funds to advance the product candidate to commercialization;
- revenue from product sales could be delayed; or
- we may elect not to commercialize the product candidate.

We plan to rely significantly on third parties to market some product candidates, and these third parties may not successfully commercialize these product candidates.

For product candidates with large target physician markets, we plan to rely significantly on sales, marketing and distribution arrangements with third parties. For example, we plan to rely on MedImmune for the commercialization of any anti-HMGB1 products that we develop 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.

Risks Relating to Intellectual Property and Licenses

If we or our licensors are not able to obtain and enforce patent and other intellectual property protection for our discoveries or discoveries we have in-licensed, our ability to prevent third parties from using our inventions and proprietary information will be limited and we may not be able to operate our business profitably.

Our success depends, in part, on our ability to protect proprietary products, methods and technologies that we invent, develop or license 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. The composition of matter patent for zileuton in the United States will expire in 2010. The patent for zileuton CR, which relates only to the controlled-release technology used to control the release of zileuton, will expire in 2012. We are exploring strategies to extend and expand the patent protection for our zileuton products, but we may not be able to obtain additional patent protection.

Because certain U.S. patent applications are confidential until patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date that will not be filed in foreign countries and for which a request for non-publication is filed, and because even patent applications for which no request for non-publication is made are not published until approximately 18 months after filing, third parties may have already filed patent applications for technology covered by our pending patent applications, and our patent applications may not have priority over any such patent applications of others. There may also be prior art that may prevent allowance of our patent applications or enforcement of our or our licensors' issued patents.

Our patent strategy depends on our ability to rapidly identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely or successful manner. Moreover, the mere issuance of a patent does not guarantee that it is valid or enforceable. As a result, even if we obtain patents, they may not be valid or enforceable against third parties.

Our pending patent applications and those of our licensors may not result in issued patents. In addition, the patent positions of pharmaceutical or biotechnology companies, including ours, are generally uncertain and involve complex legal and factual considerations. The standards that the U.S. Patent and Trademark Office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others with respect to our products in the future.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to, or independently developed by a competitor, any competitive advantage that we may have had in the development or commercialization of our product candidates would be minimized or eliminated.

Our confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Litigation regarding patents, patent applications and other proprietary rights is expensive and time consuming. If we are unsuccessful in litigation or other adversarial proceedings concerning patents or patent applications, we may not be able to protect our products from competition or we may be precluded from selling our products. If we are involved in such litigation, it could cause delays in, or prevent us from, bringing products to market and harm our ability to operate.

Our success will depend in part on our ability to uphold and enforce the patents or patent applications owned or co-owned by us or licensed to us that cover our products and product candidates. Litigation, interferences or other adversarial proceedings relating to our patents or patent applications could take place in the United States' or foreign courts or in the United States' or foreign patent offices or other administrative agencies. Proceedings involving our patents or patent applications could result in adverse decisions regarding:

- the patentability of our applications, including those relating to our products; or
- the enforceability, validity or scope of protection offered by our patents, including those relating to our products.

These proceedings are costly and time consuming. 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 time and attention of our management and scientific personnel in pursuit of these proceedings, which could have a material adverse effect on our business.

If it is determined that we do infringe a patent right of another, we may be required to seek a license, defend an infringement action or challenge the validity of the patent in court. In addition, if we are not successful in infringement litigation brought against us and we do not license or develop non-infringing technology, we may:

- incur substantial monetary damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights;
- encounter significant delays in bringing our product candidates to market; or
- be precluded from participating in the manufacture, use or sale of our products or methods of treatment.

If any parties should successfully claim that our creation or use of proprietary technologies infringes upon their intellectual property rights, we might be forced to pay damages. In addition to any damages we might have to pay, a court could require us to stop the infringing activity. Moreover, any legal action against us or our collaborators claiming damages and seeking to enjoin commercial activities relating to the affected products and processes could, in addition to subjecting us to potential liability for damages, require us or our collaborators to obtain a license in order to continue to manufacture or market the affected products and processes. Any such required license may not be made available on commercially acceptable terms, if at all. In addition, some licenses may be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us.

If we fail to obtain a required license or are unable to design around a patent, we may be unable to effectively market some of our technology or products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, our MedImmune collaboration 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.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

We in-license a significant portion of our principal proprietary technologies, and if we fail to comply with our obligations under any of the related agreements, we could lose license rights that are necessary to develop and market our zileuton products, our HMGB1 products and some of our other product candidates.

We are a party to a number of licenses that give us rights to third-party intellectual property that is necessary for our business. In fact, we acquired the rights to each of our product candidates under licenses with third parties. These licenses impose various development, commercialization, funding, royalty, diligence and other obligations on us. If we breach these obligations, our licensors may have the right to terminate the licenses or render the licenses non-exclusive, which would result in our being unable to develop, manufacture and sell products that are covered by the licensed technology, or at least to do so on an exclusive basis.

Risks Relating to Our Financial Results and Need for Additional Financing

We have incurred losses since inception and we anticipate that we will continue to incur losses for the foreseeable future. If we do not generate significant revenues, we will not be able to achieve profitability.

We have experienced significant operating losses in each year since our inception in 2000. We had net losses of $48.8 million in the year ended December 31, 2006 and $47.1 million in the year ended December 31, 2005. As of December 31, 2006, we had an accumulated deficit of approximately $154.4 million. For the year ended December 31, 2006, we recorded $6.6 million of revenue from the sale of ZYFLO and have not recorded revenue from any other product. We expect that we will continue to incur substantial losses for the foreseeable future as we spend significant amounts to fund our research, development and commercialization efforts. We expect that the losses that we incur will fluctuate from quarter to quarter and that these fluctuations may be substantial. We will need to generate significant revenues to achieve profitability. Until we are able to generate such revenues, we will not be profitable and will need to raise substantial additional capital to fund our operations.

We will require substantial additional capital to fund our operations. If additional capital is not available, we may need to delay, limit or eliminate our development and commercialization processes.

We expect to devote substantial resources to support the anticipated commercial launch of zileuton CR, to fund addition clinical trials and pilot studies on zileuton CR and to fund the development of our other product candidates. Our funding requirements will depend on numerous factors, including:

- the timing and costs of the regulatory approval and the commercial launch of zileuton CR, if and when it is approved by regulatory authorities;
- the scope, costs and results of our clinical trials on zileuton CR and zileuton injection;
- if approved, the amount and timing of sales of zileuton CR;
- the timing and amount of sales from ZYFLO;
- the costs of ongoing sales, marketing and manufacturing activities for ZYFLO and, if approved, zileuton CR;
- the time and costs involved in preparing, submitting, obtaining and maintaining regulatory approvals for our other product candidates;
- the timing, receipt and amount of milestone and other payments, if any, from MedImmune, Beckman Coulter or future collaborators;
- the timing, receipt and amount of sales and royalties, if any, from our potential products;
- continued progress in our research and development programs, as well as the magnitude of these programs, including milestone payments to third parties under our license agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;

- the cost of obtaining and maintaining licenses to use patented technologies;
- potential acquisition or in-licensing of other products or technologies;
- our ability to establish and maintain additional collaborative or co-promotion arrangements; and
- the ongoing time and costs involved in certain corporate governance requirements, including work related to compliance with the Sarbanes-Oxley Act of 2002.

Other than payments that we receive from our collaborations with MedImmune and Beckman Coulter, we expect that sales of ZYFLO will represent our only source of revenue until we commercially launch zileuton CR, if it is approved for sale by the FDA. We believe that our ability to access external funds will depend upon the regulatory status of zileuton CR, market acceptance of zileuton CR, if approved, market acceptance of ZYFLO, the success of our other preclinical and clinical development programs, the receptivity of the capital markets to financings by biopharmaceutical companies, our ability to enter into additional strategic collaborations with corporate and academic collaborators and the success of such collaborations.

The extent of our future capital requirements is difficult to assess and will depend largely on our ability to obtain regulatory approval for and successfully commercialize zileuton CR and to sell ZYFLO. Based on our operating plans, we believe that our available cash and cash equivalents and anticipated cash received from product sales and anticipated payments received under collaboration agreements will be sufficient to fund anticipated levels of operations into 2009, assuming we receive FDA approval for and commercially launch zileuton CR in 2007. If zileuton CR is not approved and commercially launched in 2007, we believe that our available cash and cash equivalents and anticipated cash received from product sales and anticipated payments received under collaboration agreements will be sufficient to fund anticipated levels of operations into the third quarter of 2008.

For the year ended December 31, 2006, our net cash used for operating activities was $51.4 million, and we had capital expenditures of approximately $370,000. If our existing resources are insufficient to satisfy our liquidity requirements or if we acquire or license rights to additional product candidates, we may need to raise additional external funds through collaborative arrangements and public or private financings. Additional financing may not be available to us on acceptable terms or at all. In addition, the terms of the financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities, further dilution to our then-existing stockholders will result. If we are unable to obtain funding on a timely basis, we may be required to significantly delay, limit or eliminate one or more of our research, development or commercialization programs, which could harm our financial condition and operating results. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.

If the estimates we make, or the assumptions on which we rely, in preparing our financial statements prove inaccurate, our 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 these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, 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. We cannot assure you, however, that our estimates, or the assumptions underlying them, will be correct. If our estimates are inaccurate, this could adversely affect our stock price.

Risks Relating to Our 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.

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:

- the regulatory status of zileuton CR;
- if approved, the amount and timing of sales of zileuton CR;
- the amount and timing of sales of ZYFLO;
- the timing of operating expenses, including selling and marketing expenses and the costs of maintaining a direct sales force;
- the availability and timely delivery of a sufficient supply of ZYFLO or, if approved, zileuton CR;
- the amount of rebates, discounts and chargebacks to wholesalers, Medicaid and managed care organizations related to ZYFLO or, if approved, zileuton CR;
- the amount and timing of product returns for ZYFLO or, if approved, zileuton CR;
- 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 agreement;
- 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 which may subject the price of our common stock to substantial volatility include announcements regarding:

- the regulatory status of zileuton CR;
- if approved, the amount and timing of sales of zileuton CR;
- our operating results, including the amount and timing of sales of ZYFLO;

- 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.

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

As of February 28, 2007, our directors, executive officers and 10% or greater stockholders, together with their affiliates, to our knowledge, beneficially owned, in the aggregate, approximately 37.8% 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 management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

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

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 to which we are subject include provisions in our by-laws providing that stockholders' meetings may be called only by our president or the majority of our board of directors and a provision in our certificate of incorporation providing that our stockholders may not take action by written consent.

Additionally, our 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 our stockholders. The rights of holders of our common stock are subject to the rights of the holders of any preferred stock that we issue. As a result, our issuance of preferred stock could cause the market value of our 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 may use this provision to prevent changes in our management. Also, under applicable Delaware law, our board of directors may adopt additional anti-takeover measures in the future.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

Not applicable.

ITEM 2. *PROPERTIES*

We lease a facility that contains approximately 40,200 square feet of laboratory and office space in Lexington, Massachusetts. The lease expires on April 1, 2009. We believe our facilities are sufficient to meet our needs for the foreseeable future.

ITEM 3. *LEGAL PROCEEDINGS*

We are not currently a party to any material legal proceedings.

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

No matters were submitted to a vote of our security holders, through solicitation of proxies or otherwise, during the fourth quarter of the year ended December 31, 2006.

EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers, their ages and their positions as of February 28, 2007 are as follows:

Name	Age	Position
Frank E. Thomas	37	President and Chief Executive Officer
Dana C. Hilt, M.D.	54	Senior Vice President of Clinical Development and Chief Medical Officer
Trevor Phillips, Ph.D.	45	Chief Operating Officer and Senior Vice President of Operations
Scott B. Townsend, J.D.	40	Senior Vice President of Legal Affairs, General Counsel and Secretary
Jeffrey E. Young	34	Vice President of Finance, Chief Accounting Officer and Treasurer

Frank E. Thomas has served as our President since June 2006 and as our Chief Executive Officer since October 2006. Mr. Thomas has served as a member of our board of directors since June 2006. Mr. Thomas functions as both our principal executive officer and our principal financial officer. Mr. Thomas served as our Chief Financial Officer from April 2004 to June 2006, as our Treasurer from May 2004 to June 2006, as our Senior Vice President of Finance from December 2004 until June 2006 and as our Vice President of Finance from June 2004 to December 2004. From February 2000 to April 2004, Mr. Thomas served in a variety of finance positions with Esperion Therapeutics, Inc., a biopharmaceutical company, including most recently as Chief Financial Officer. Esperion was acquired by Pfizer Inc. in February 2004. From September 1997 to March 2000, Mr. Thomas served as Director of Finance and Corporate Controller for Mechanical Dynamics, Inc., a publicly-held software company. Prior to that, Mr. Thomas was a manager with Arthur Andersen LLP where he was a certified public accountant. Mr. Thomas holds a Bachelor in Business Administration from the University of Michigan.

Dana C. Hilt, M.D. has served as Chief Medical Officer and Senior Vice President of Clinical Development since April 2006. From November 2002 to March 2006, Dr. Hilt served as Senior Vice President of Drug Development and Chief Medical Officer, Ascend Therapeutics, a biopharmaceutical company. From August 1998 to July 2002, Dr. Hilt served of Vice President, Clinical Research, Drug Metabolism, and Toxicology and Chief Medical Officer for Guilford Pharmaceuticals, a pharmaceutical company. Dr. Hilt holds a B.S. in Chemistry from the University of Maine and an M.D. from Tufts University School of Medicine.

Trevor Phillips, Ph.D. has served as our Chief Operating Officer since November 2003 and as our Senior Vice President of Operations since December 2004. Dr. Phillips served as our Secretary from March 2004 to September 2004, as our Treasurer from September 2003 to May 2004 and as our Vice President of Operations from October 2002 to December 2004. From November 2001 to September 2002, Dr. Phillips served as Senior Program Director for Sepracor, Inc., a pharmaceutical company. From October 1999 to November 2001, Dr. Phillips served as Director of Drug Development, Strategy and Planning for Scotia Holdings plc, a biotechnology company. From March 1997 to October 1999, Dr. Phillips served as a Senior Manager, Strategic Planning for Accenture Ltd. (formerly known as Andersen Consulting), a management consulting company. From March 1990 to March 1997, Dr. Phillips served in a variety of positions, including Director of Strategic Direction, for GlaxoWellcome plc, a pharmaceutical company. Dr. Phillips holds a B.Sc. in Microbiology from the University of Reading, a Ph.D. in Microbial Biochemistry from the University of Wales and an M.B.A. from Henley Management College.

Scott B. Townsend, J.D. has served as our Senior Vice President of Legal Affairs since March 2007, as our Secretary since September 2004 and as our General Counsel since June 2006. 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.

Jeffrey E. Young has served as our Vice President of Finance, Chief Accounting Officer and Treasurer since June 2006. Mr. Young served as our Senior Director of Finance from April 2006 to June 2006 and as our Director of Financial Planning and Analysis from April 2005 to March 2006. From March 2003 to April 2005, Mr. Young served in a variety of finance positions with PerkinElmer, Inc., a life and analytical science and photonic instrument company, including most recently as Senior Manager of Consolidation and Technical Accounting. From September 1996 to March 2003, Mr. Young was employed by the registered public accounting firm PricewaterhouseCoopers LLP, including as a manager from 2000 to March 2003. Mr. Young is a certified public accountant and holds a B.S.B.A. from Georgetown University.

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 Critical Therapeutics' Common Stock and Related Stockholder Matters

Our common stock trades on the NASDAQ Global Market under the symbol "CRTX." Prior to July 2006, our common stock traded on the NASDAQ National 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.

Year Ended December 31, 2006	High	Low
First Quarter (from January 1 to March 31)	$7.20	$4.92
Second Quarter (from April 1 to June 30)	$5.43	$3.37
Third Quarter (from July 1 to September 30)	$4.14	$2.15
Fourth Quarter (from October 1 to December 31)	$2.79	$1.52

Year Ended December 31, 2005	High	Low
First Quarter (from January 1 to March 31)	$8.05	$6.27
Second Quarter (from April 1 to June 30)	$7.06	$5.00
Third Quarter (from July 1 to September 30)	$9.42	$5.51
Fourth Quarter (from October 1 to December 31)	$9.18	$6.11

On February 28, 2007, the closing price per share of our common stock as reported on the NASDAQ Global Market was $1.67, and we had approximately 108 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. Pursuant to our credit agreement with Silicon Valley Bank, we are required to obtain Silicon Valley Bank's prior written consent before paying any dividends.

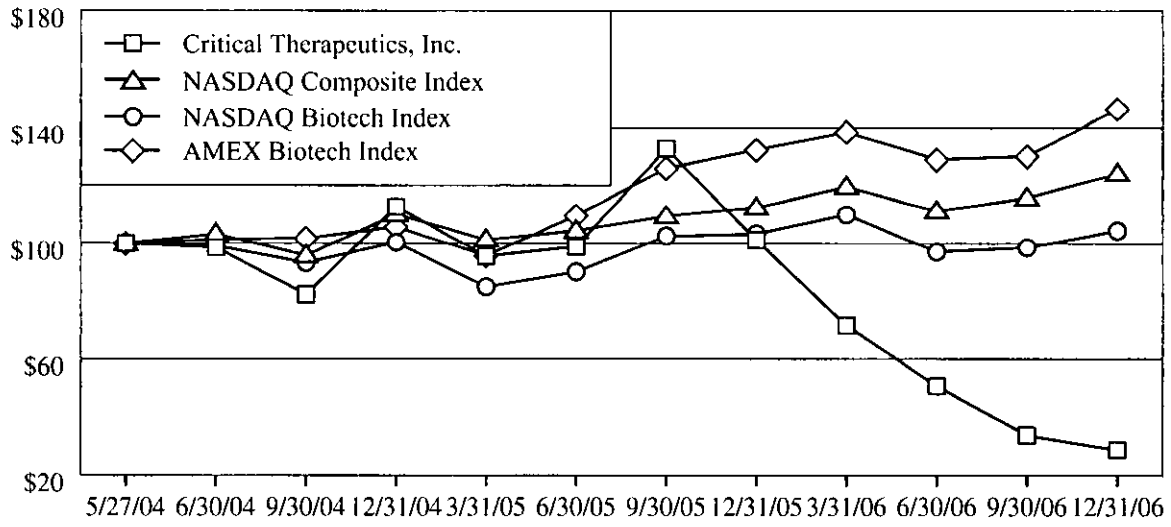
Recent Sales of Unregistered Securities; Uses of Proceeds From Registered Securities

Not applicable.

Stock Performance Graph

The stock performance graph below compares the cumulative total stockholder return for our common stock with the cumulative total return of the NASDAQ Composite Index, the NASDAQ Biotechnology Index, which we refer to as the NASDAQ Biotech Index, and the American Stock Exchange Biotechnology Index, which we refer to as the AMEX Biotech Index. The comparison assumes the investment of $100.00 on May 27, 2004, the date our common stock was first publicly traded, in each of our common stock, the NASDAQ Composite Index, the NASDAQ Biotech Index and the AMEX Biotech Index and assumes the reinvestment of dividends.

The graph below and related information shall not be deemed "soliciting material" or "filed" with the Securities and Exchange Commission or otherwise subject to the liabilities of Section 18 of the Exchange Act, nor shall such information be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent we specifically request that such information be treated as soliciting material or specifically incorporate such information by reference into a document filed under the Securities Act or the Exchange Act.



	5/27/04	6/30/04	9/30/04	12/31/04	3/31/05	6/30/05	9/30/05	12/31/05	3/31/06	6/30/06	9/30/06	12/31/06
Critical Therapeutics, Inc.	$100.00	$ 98.59	$ 82.39	$112.68	$ 95.63	$ 98.87	$132.68	$101.13	$ 71.69	$ 50.70	$ 33.80	$ 28.73
NASDAQ Composite Index	$100.00	$103.30	$ 95.82	$110.06	$101.31	$104.42	$109.41	$112.40	$119.55	$111.18	$115.78	$124.06
NASDAQ Biotech Index	$100.00	$ 99.17	$ 93.34	$100.39	$ 84.99	$ 90.21	$102.56	$103.28	$109.94	$ 97.10	$ 98.61	$104.39
AMEX Biotech Index	$100.00	$101.39	$101.84	$105.72	$ 95.73	$109.64	$125.97	$132.26	$138.49	$128.96	$130.08	$146.51

ITEM 6. *SELECTED FINANCIAL DATA*

This section presents our historical consolidated financial data. You should read carefully the following selected consolidated financial data together with our consolidated financial statements and the related notes included in this annual report on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this report. The selected consolidated financial data in this section are not intended to replace our consolidated financial statements.

We derived the statements of operations data for the years ended December 31, 2006, 2005 and 2004 and the balance sheet data as of December 31, 2006 and 2005 from our audited consolidated financial statements, which are included at the end of this report. We derived the statements of operations data for the years ended December 31, 2003 and 2002 and the balance sheet data as of December 31, 2004, 2003 and 2002 from our audited consolidated financial statements not included in this report. Historical results are not necessarily indicative of future results. You should read the notes to our consolidated financial statements for an explanation of the method used to determine the number of shares used in computing basic and diluted net loss per share.

Effective January 1, 2006, we adopted SFAS 123(R), using the modified prospective method, which requires us to recognize compensation cost for granted, but unvested, awards, new awards and awards modified, repurchased, or cancelled after January 1, 2006 and granted after we became a public company. The amounts for prior periods do not include the impact of SFAS 123(R). In the notes to our consolidated financial statements included herein, we have provided pro forma disclosures for the years ended December 31, 2005 and 2004 in accordance with SFAS 123 since those periods have not been restated to conform to the 2006 presentation.

	Year Ended December 31,				
	2006	2005	2004	2003	2002
	(In thousands, except share and per share data)				
Statements of Operations Data:					
Net product sales	$ 6,647	$ 387	$ —	$ —	$ —
Revenue under collaboration agreements	6,431	5,837	4,436	1,021	—
Total revenues	13,078	6,224	4,436	1,021	—
Cost of products sold	2,222	514	—	—	—
Research and development expenses	26,912	29,959	25,578	17,458	3,284
Sales and marketing expenses	18,284	13,671	1,199	—	—
General and administrative expenses	13,456	11,406	9,679	3,771	1,792
Restructuring charges	3,498	—	—	—	—
Total costs and expenses	64,372	55,550	36,456	21,229	5,076
Loss from operations	(51,294)	(49,326)	(32,020)	(20,208)	(5,076)
Interest income	2,726	2,427	1,098	191	149
Interest expense	(214)	(191)	(172)	(93)	(8)
Net loss	(48,782)	(47,090)	(31,094)	(20,110)	(4,935)
Accretion of dividends and offering costs on preferred stock	—	—	(2,209)	(2,264)	(1,032)
Net loss available to common stockholders	$ (47,782)	$ (47,090)	$ (33,303)	$22,374)	$(5,967)
Net loss per common share:					
Basic and diluted	$ (1.37)	$ (1.61)	$ (2.28)	$(33.99)	$(23.74)
Weighted-average basic and diluted shares outstanding	35,529,048	29,276,243	14,631,371	658,204	251,346

	As of December 31,				
	2006	2005	2004	2003	2002
			(In thousands)		
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 49,038	$ 82,811	$ 78,829	$ 40,078	$13,539
Working capital	47,738	70,005	64,357	25,218	13,017
Total assets	58,182	91,819	83,114	45,054	14,382
Long term debt, net of current portion	421	1,489	1,367	720	202
Redeemable convertible preferred stock	—	—	—	51,395	21,080
Accumulated deficit	(154,399)	(105,617)	(58,527)	(27,433)	(7,323)
Total stockholders' equity (deficit)	49,906	72,247	65,408	(24,851)	(7,554)

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 the "Selected Consolidated Financial Data" section of this annual report on Form 10-K and our consolidated financial statements and the related notes included in this report. 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 report.

Summary

Critical Therapeutics, Inc. is a biopharmaceutical company focused on the development and commercialization of products designed to treat respiratory, inflammatory and critical care diseases linked to the body's inflammatory response. Our marketed product is ZYFLO, an immediate-release tablet formulation of zileuton, which the FDA approved in 1996 for the prevention and chronic treatment of asthma in adults and children 12 years of age or older. We licensed from Abbott Laboratories exclusive worldwide rights to ZYFLO and other formulations of zileuton for multiple diseases and conditions. We began selling ZYFLO in the United States in October 2005; and we are developing a controlled-release formulation of zileuton, or zileuton CR, and an injectable formulation of zileuton, or zileuton injection. In connection with the restructuring announced in October 2006, we decided to focus our resources on these formulations.

We are currently developing zileuton CR, a tablet designed to be taken twice daily, two tablets per dose. We have submitted an NDA for zileuton CR that was accepted for filing by the FDA as of September 29, 2006. Under the Prescription Drug User Fee Act, or PDUFA, guidelines, the PDUFA date for our NDA is May 31, 2007, which is the date by which we expect to receive an action letter from the FDA on this filing. If we receive regulatory approval on a timely basis, we expect to launch zileuton CR in the second half of 2007.We recently entered into an agreement with DEY, L.P., an affiliate of Merck KGaA, under which we and DEY have agreed to jointly promote ZYFLO and, if approved by the FDA, zileuton CR.

In addition, we are developing zileuton injection initially for use in emergency room, or urgent care centers for patients who suffer acute exacerbations of asthma. In August 2006, we announced results from our Phase I/II clinical trial designed to evaluate safety, tolerability and pharmacokinetics of zileuton injection in patients with asthma. We plan to initiate a Phase II clinical trial in the second half of 2007 with zileuton injection in asthma patients.

We are also developing other product candidates to regulate the excessive inflammatory response that can damage vital internal organs and, in the most severe cases, result in multiple organ failure and death. The inflammatory response occurs following stimuli such as infection or trauma. Our product candidates target the production and release into the bloodstream of proteins called cytokines that play a fundamental role in the body's inflammatory response.

We are collaborating with MedImmune, Inc. on preclinical development of monoclonal antibodies directed toward a cytokine called high mobility group box protein 1, or HMGB1, which we believe may be an important target for the development of products to treat diseases mediated by the body's inflammatory response. In addition, we are collaborating with Beckman Coulter, Inc. on the development of a diagnostic directed toward measuring HMGB1 in the bloodstream.

We are conducting preclinical work in our small molecule alpha-7 program through a small team of scientists. We believe the successful development of a product candidate targeting the nicotinic alpha-7 cholinergic receptor, or alpha-7 receptor, could lead to a novel treatment for severe acute inflammatory disease, as well as an oral anti-cytokine therapy that could be directed at chronic inflammatory diseases such as asthma and rheumatoid arthritis. We plan to seek a collaborator for our alpha-7 program and do

not currently expect to conduct clinical trials with the alpha-7 program without entering into such an arrangement.

We were incorporated in Delaware on July 14, 2000 as Medicept, Inc. and changed our name to Critical Therapeutics, Inc. 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 Global Market.

Since our inception, we have incurred significant losses each year. As of December 31, 2006, we had an accumulated deficit of $154.4 million. We expect to incur significant losses for the foreseeable future and we may never achieve profitability. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect our operating losses to continue over the next several years as we fund our development programs, market and sell ZYFLO and prepare for the potential commercial launch of our product candidates. Since our inception, we have raised proceeds to fund our operations through public offerings of common stock, private placements of equity securities, debt financings, the receipt of interest income, payments from our collaborators MedImmune and Beckman Coulter, and, beginning in the fourth quarter of 2005, revenues from sales of ZYFLO.

In 2003, we entered into an exclusive license and collaboration agreement with MedImmune for the discovery and development of novel drugs for the treatment of acute and chronic inflammatory diseases associated with HMGB1. Under this collaboration, MedImmune paid us initial fees of $10.0 million in late 2003 and $2.5 million in early 2004. In addition, MedImmune paid us $750,000 in 2006, $2.75 million in 2005 and $1.5 million in 2004 for milestone payments and to fund certain research expenses incurred by us for the HMGB1 program.

In 2005, we entered into a license agreement with Beckman Coulter relating to the development of diagnostics for measuring HMGB1. In consideration for the license, Beckman Coulter paid us a product evaluation license fee of $250,000 in February 2005. In December 2006, Beckman Coulter elected to exercise its option for full development of a diagnostic test measuring HMGB1 in the bloodstream. This election triggered a $400,000 milestone payment, which we received in January 2007.

Recent Developments

In May 2006, we recorded charges of $499,000 for a restructuring of our operations that was intended to better align costs with revenue and operating expectations. The restructuring charges pertain to employee severance benefits, outplacement services, automobile lease termination fees and impairment of assets.

In June 2006, we announced that Paul D. Rubin, M.D. had stepped down from his position as our President and Chief Executive Officer and resigned from our board of directors and that Frederick Finnegan had resigned from his position as our Senior Vice President of Sales and Marketing. In October 2006, Walter Newman, Ph.D. resigned from his position as our Senior Vice President of Research and Development and Chief Scientific Officer. In connection with these departures, we were obligated to make aggregate lump sum cash severance payments of approximately $1.3 million to these former executives.

In October 2006, we announced a second restructuring of our operations to focus our resources on the commercialization of zileuton CR and the clinical development of zileuton injection and to significantly reduce our net cash expenditures through lower spending on our existing sales force as well as on our discovery and research programs. As part of this new business strategy, we eliminated 60 positions, or approximately 50% of our workforce. The headcount reduction reflects a downsizing of 38 of our sales and marketing employees. We retained a respiratory sales force of approximately 18 representatives who are focused on continued promotion of ZYFLO to prescribing physicians within the major markets across the United States and increasing prescriptions from our existing base of prescribers. The headcount reductions also included 17 research and development employees and five general and administrative employees. As of December 31, 2006, we had substantially completed the implementation of this restructuring.

On October 31, 2006, we sold 7,455,731 shares of common stock and warrants to purchase 3,727,865 shares of common stock for an aggregate purchase price of $20.0 million, which resulted in net

proceeds to us of $18.5 million. The warrants to purchase common stock have an exercise price of $2.62 per share and are exercisable at any time on or before October 26, 2011.

On March 13, 2007, we entered into an agreement with DEY, L.P, an affiliate of Merck KGaA, under which we and DEY agreed to jointly promote ZYFLO and, if approved by the FDA, zileuton CR. Under the co-promotion agreement, DEY paid us a non-refundable upfront payment of $3.0 million upon signing the co-promotion agreement. In addition, DEY has agreed to pay us milestone payments of $4.0 million following approval by the FDA of the NDA for zileuton CR and $5.0 million following commercial launch of zileuton CR. Under the co-promotion agreement, we will retain all quarterly net sales of ZYFLO and zileuton CR, after third party royalties, up to $1.95 million. We have agreed to pay DEY a portion of quarterly net sales of ZYFLO and zileuton CR, 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 upon mutual agreement by the parties. Beginning three years after the commercial launch of zileuton CR, either party may terminate the co-promotion agreement with six-months advance written notice. If the commercial launch of zileuton CR is delayed beyond May 31, 2008, DEY has the right to terminate the co-promotion agreement on or before July 1, 2008 by providing written notice, which will be effective 60 days after receipt by us. If DEY exercises this termination right, we will be obligated to pay DEY $2.0 million if DEY has paid us the $4.0 million milestone related to approval of the NDA for zileuton CR. In addition, DEY has the right to terminate the co-promotion agreement with two-months prior written notice if zileuton CR cumulative net sales for any four consecutive calendar quarters after commercial launch of zileuton CR are less than $25 million.

As contemplated by the terms of the zileuton co-promotion agreement with DEY, we and DEY entered into a separate binding letter agreement on March 13, 2007 providing for us to co-promote DEY's product candidate for COPD, if approved by the FDA. Under the binding letter agreement, DEY agreed to pay us a co-promotion fee based on a percentage of net retail sales of DEY's product candidate for the number of units in excess of a specified level of unit sales. We agreed to provide a specified minimum number of details per month for DEY's product candidate.

Although we intend to enter into a more detailed written agreement relating to the co-promotion of DEY's product candidate, the terms of the binding letter agreement will govern the co-promotion of DEY's product candidate if we and DEY fail to agree upon a more detailed written agreement. The binding letter agreement provides that we and DEY anticipate that we will negotiate and execute a more detailed written agreement within 90 days of signing the binder letter agreement.

Financial Operations Overview

Revenues. From our inception on July 14, 2000 through the third quarter of 2005, we derived all of our revenues from license fees, research and development payments and milestone payments that we have received from our collaboration agreements with MedImmune and Beckman Coulter. In the fourth quarter of 2005, we began selling, and recognizing revenue, from our first commercial product, ZYFLO. We recorded $6.6 million in net product sales of ZYFLO for the year ended December 31, 2006. As part of our October 2006 restructuring plan, we eliminated 38 positions in our sales and marketing group. This reduction could have a substantial impact on revenue derived from future product sales.

Cost of Products Sold. Cost of products sold consists of manufacturing, distribution and other costs related to our commercial product, ZYFLO. In addition, it includes royalties to third parties related to ZYFLO and any reserves established for excess or obsolete inventory. Most of our manufacturing and distribution costs are paid to third party manufacturers. However, there are some internal costs included in cost of products sold, including salaries and expenses related to managing our supply chain and for certain quality assurance and release testing costs.

Research and Development Expenses. Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for monitoring and analyzing clinical trials, milestone payments to third parties, costs related to the development of our NDA for zileuton CR, costs of contract research and manufacturing and the cost of facilities. In addition, research and development expenses include the cost of our medical affairs and medical information functions, which educate physicians on the scientific aspects of our commercial products and the approved indications, labeling and the costs of monitoring adverse events. After FDA approval of a product candidate, manufacturing expenses associated with a product will be recorded as cost of products sold rather than as research and development expenses. We expense research and development costs and patent related costs as they are incurred. Because of our ability to utilize resources across several projects, many of our research and development costs are not tied to any particular project and are allocated among multiple projects. We record direct costs on a project-by-project basis. We record indirect costs in the aggregate in support of all research and development. Development costs for clinical development stage programs such as the injectable formulation of zileuton tend to be higher than earlier stage programs such as our HMGB1 and alpha-7 programs, due to the costs associated with conducting clinical trials and large-scale manufacturing.

We expect that research and development expenses relating to our portfolio will fluctuate depending primarily on the timing of clinical trials, milestone payments to third parties, and manufacturing initiatives. We expect to incur additional expenses over the next several years for clinical trials of our product development candidates, including the controlled-release and injectable formulations of zileuton. As a result of our October 2006 restructuring, we anticipate that our research and development expenses will decrease in 2007 compared to 2006. We also expect manufacturing expenses for some programs included in research and development expenses to increase as we scale up production of zileuton injection for later stages of clinical development. We also expect to initiate clinical trials related to zileuton CR to examine its potential clinical benefits in particular populations of asthma patients, which, if conducted, would be included in research and development expenses. If the NDA for zileuton CR is approved by the FDA in 2007, we will be obligated to make milestone payments totaling $3.1 million to third parties in the period when the approval is obtained. These milestone payments will be included in research and development expenses in the applicable period.

Sales and Marketing. Sales and marketing expenses consist primarily of salaries and other related costs for personnel in sales, marketing, sales operations and our managed care functions as well as other costs related to ZYFLO. We will also be incurring marketing and other costs in preparation for the anticipated launch of zileuton CR in the second half of 2007. Other costs included in sales and marketing expenses include the cost of product samples of ZYFLO, promotional materials, market research and sales meetings. We expect to continue to incur sales and marketing costs associated with our sales force to support ZYFLO. If zileuton CR is approved for marketing, we expect to incur additional expenses related to enhancing our sales and marketing functions and adding sales representatives.

General and Administrative Expenses. General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance, accounting, legal, business development, information technology and human resource functions. Other costs included in general and administrative expenses include certain facility and insurance costs, including director and officer liability insurance, as well as professional fees for legal and accounting services.

Critical Accounting Policies

The 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 accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments 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 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 financial condition or operating performance is material.

Our significant accounting policies are more fully described in the notes to our consolidated financial statements included in this annual report on Form 10-K. Not all of these significant accounting policies, however, fit the definition of "critical accounting estimates." We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to revenue recognition, inventory, accrued expenses, short-term investments, stock-based compensation and income taxes described below fit the definition of "critical accounting estimates."

Revenue Recognition. In the fourth quarter of 2005, we launched our first commercial product, ZYFLO. We sell ZYFLO to wholesalers, distributors and pharmacies, which have the right to return purchased product. In accordance with Statement of Financial Accounting Standards No. 48, *Revenue Recognition When Right of Return Exists,* or SFAS No. 48, we defer revenue on product shipments until we can reasonably estimate returns relating to these shipments. Because ZYFLO was a new product for us and this was our first commercial product launch, we did not have an objective measurement or history to allow us to estimate returns in 2005 and 2006. Accordingly, we have been deferring the recognition of revenue on product shipments of ZYFLO to our customers until the product is dispensed through patient prescriptions. Since product dispensed to patients through prescription is not subject to return, there is no remaining contingency that would prohibit revenue recognition once delivered through prescription. We have been estimating prescription units dispensed based on distribution channel data provided by external sources through December 31, 2006. In order to match the cost of products shipped to customers with the underlying revenue, we have deferred the recognition of costs related to shipments that have not been recognized as revenue in 2005 and 2006.

During the first quarter of 2007, based on our experience since we launched ZYFLO in October 2005, we believe that we will have adequate historical data to reasonably estimate product returns. Accordingly, we expect to begin recording revenue upon shipment to third parties including wholesalers, distributors and pharmacies. We also expect to provide adequate reserves for potential returns from these third parties based on our product returns experience. In connection with this change, we expect to record a one-time increase in net product sales related to the recognition of revenue previously deferred, net of an estimate for remaining product returns. We estimate that this one-time adjustment will total approximately $1.0 million, which we expect to record in the first quarter of 2007.

Under our collaboration agreements with MedImmune and Beckman Coulter, we are entitled to receive non-refundable license fees, milestone payments and other research and development payments. Payments received are initially deferred from revenue and subsequently recognized in our statement of operations when earned. We must make significant estimates in determining the performance period and periodically review these estimates, based on joint management committees and other information shared by our collaborators with us. We recognize these revenues over the estimated performance period as set

forth in the contracts based on proportional performance and adjusted from time to time for any delays or acceleration in the development of the product. For example, a delay or acceleration of the performance period by our collaborator may result in further deferral of revenue or the acceleration of revenue previously deferred. Because MedImmune and Beckman Coulter can each cancel its agreement with us, we do not recognize revenues in excess of cumulative cash collections. It is difficult to estimate the impact of the adjustments on the results of our operations because, in each case, the adjustment is limited to the cash received.

Inventory. 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. We determine the estimated useful life of our inventory based upon stability data of the underlying product stored at different temperatures or in different environments. As of December 31, 2006, inventory consists of zileuton active pharmaceutical ingredient, or API, which is raw material in powder form, work-in-process and finished tablets to be used for commercial sale. 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 our expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product revenues. As of December 31, 2006, we have a reserve against our inventory of approximately $119,000 for product that is not expected to be sold.

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 service as of each balance sheet date in our consolidated financial statements. Examples of estimated expenses for which we accrue include professional service fees, such as fees paid to lawyers and accountants, rebates to third parties, including government programs such as Medicaid or private insurers, contract service fees, such as amounts paid to clinical monitors, data management organizations and investigators in connection with clinical trials, fees paid to contract manufacturers in connection with the production of clinical materials and restructuring charges.

In connection with rebates, our estimates are based on our estimated mix of sales to various third-party payors, which either contractually or statutorily are entitled to certain discounts off our listed price of ZYFLO. In the event that our sales mix to certain third-party payors is different from our estimates, we may be required to pay higher or lower total rebates than we have estimated. In connection with service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed; however, certain service providers invoice us based upon milestones in the agreement. In the event that we do not identify certain costs that we have begun to incur or we under or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often subject to judgment. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Short-term Investments. Short-term investments consist primarily of U.S. government treasury and agency notes, corporate debt obligations, municipal debt obligations, auction rate securities and money market funds, each of investment-grade quality, which have an original maturity date greater than 90 days. These investments are recorded at fair value and accounted for as available-for-sale securities. We record any unrealized gain (loss) during the year as an adjustment to stockholders' equity unless we determine that the unrealized gain (loss) is not temporary. We adjust the original cost of debt securities for amortization of premiums and accretion of discounts to maturity. Because we have determined that the unrealized gain (loss) on our investments have been temporary, we have not recorded any impairment losses since inception.

It is our intent to hold our short-term investments until such time as we intend to use them to meet the ongoing liquidity needs to support our operations. However, if the circumstances regarding an investment or our liquidity needs were to change, such as a change in an investment's external credit rating, we would consider a sale of the related security prior to the maturity of the underlying investment to minimize any losses.

Stock-Based Compensation. Prior to January 1, 2006, we elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees,* or APB 25, and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value accounting method provided for under Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation,* or SFAS 123. Accordingly, we did not record stock-based compensation expense for stock options issued to employees in fixed amounts with exercise prices at least equal to the fair value of the underlying common stock on the date of grant. Effective January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment,* or SFAS 123(R), using the modified prospective application method, which requires us to recognize compensation cost for granted, but unvested, awards, new awards and awards modified, repurchased, or cancelled after January 1, 2006 if such awards were granted after becoming a public company. In the notes to our consolidated financial statements included herein, we have provided pro forma disclosures for the years ended December 31, 2005 and 2004 in accordance with SFAS 123(R). These years have not been restated to conform to the 2006 presentation.

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 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.

The two factors which most affect charges or credits to operations related to stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded and the volatility of such fair value. Accounting for equity instruments granted by us under SFAS 123(R) and EITF 96-18 requires fair value estimates of the equity instrument granted. If our estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating expenses. 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 stock options and warrants granted to employees or non-employees, we estimate the fair value of the equity instruments based upon the consideration of factors which we deem to be relevant at the time using cost, market or income approaches to such valuations.

Income Taxes. As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax exposure together with assessing temporary differences resulting

from differing treatments of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. In addition, as of December 31, 2006, we had federal and state tax net operating loss carryforwards of approximately $130 million, which expire beginning in 2021 and 2006, respectively. We also have research and experimentation credit carryforwards of approximately $2.1 million, which expire beginning in 2021. We have recorded a full valuation allowance as an offset against these otherwise recognizable net deferred tax assets due to the uncertainty surrounding the timing of the realization of the tax benefit. In the event that we determine in the future that we will be able to realize all or a portion of its net deferred tax benefit, an adjustment to deferred tax valuation allowance would increase net income or additional paid in capital for deferred tax assets related to stock compensation deductions in the period in which such a determination is made. The Tax Reform Act of 1986 contains provisions that may limit the utilization of net operating loss carryforwards and credits available to be used in any given year in the event of significant changes in ownership interest, as defined.

Results of Operations

Years Ended December 31, 2006 and 2005

Revenues

Revenue from Product Sales. We recognized revenue from product sales related to sales of ZYFLO of $6.6 million in 2006 compared to $387,000 in 2005. Product sales in 2005 reflect the period from launch in October through the end of the year. Under Statement of Financial Accounting Standards No. 48, *Revenue Recognition When Rights of Return Exists*, or SFAS No. 48, we recognize revenue from product shipments when we have determined the right to return the product has lapsed or when we can reasonably estimate returns relating to the shipments to third parties. In accordance with SFAS No. 48, in 2005 and 2006, we deferred recognition of revenue on product shipments of ZYFLO to wholesalers, distributors and pharmacies until the product is dispensed through patient prescriptions. Shipments of ZYFLO to third parties that have not been recognized as revenue totaled $1.2 million as of December 31, 2006 and $1.7 million as of December 31, 2005 and are included in deferred product revenue on our balance sheet. We defer the cost of product shipped to third parties that has not been recognized as revenue in accordance with our revenue recognition policy until the product is dispensed through patient prescriptions. This deferred cost of product sold totaled $167,000 as of December 31, 2006, compared to $266,000 as of December 31, 2005, and is included in prepaid expenses and other current assets on our balance sheet.

During the first quarter of 2007, based on our experience since we launched ZYFLO in October 2005, we believe that we will have adequate historical data to reasonably estimate product returns. Accordingly, we expect to begin recording revenue upon shipment to third parties including wholesalers, distributors and pharmacies, and we also expect to provide adequate reserves for potential returns from these third parties based on our product returns experience. In connection with this conversion, we expect to record a one-time increase in net product sales related to the recognition of revenue previously deferred, net of an estimate for remaining product returns. We estimate that this one-time adjustment will total approximately $1.0 million.

Revenue under Collaboration Agreements. We recognized collaboration revenues of $6.4 million in 2006 compared to $5.8 million in 2005. These revenues were primarily due to the portion of the $12.5 million of initial fees MedImmune paid us that we recognized in each period, and the $5.25 million cumulatively billed to MedImmune for milestone payments and development support from the inception of the agreement through December 31, 2006.

Since we entered into the agreement with MedImmune in 2003, we have billed a total of $17.75 million to MedImmune, consisting of the $12.5 million initial payment, a $1.25 million milestone payment and $4.0 million of development support. We have recognized $17.5 million of these amounts as collaboration revenue to date. We have reported the balance of the payments, totaling $275,000, as deferred collaboration revenue and will recognize such amount over the remaining estimated research term of our agreement with MedImmune based on the proportion of cumulative costs incurred as a percentage

of the total costs estimated for the performance period. In 2006, we revised our cost estimate to reflect lower than expected costs to be incurred over the remainder of the contract with MedImmune. The change in estimate resulted in an increase in revenue recognized of approximately $2.0 million in 2006. We currently estimate that the balance in deferred revenue will be recognized during 2007. Our revenue recognized from existing collaborations in 2007 may decline substantially since we have already recognized most of the revenue that we previously deferred. Going forward, our revenue from collaboration agreements will fluctuate each quarter and will be highly dependent upon the achievement of milestones under our existing agreements, or will be dependent upon us entering into new collaboration agreements. As of December 31, 2006, we also had $400,000 in deferred collaboration revenue remaining to be recognized under our collaboration agreements with Beckman Coulter, which we expect to recognize in the first quarter of 2007.

Costs and Expenses

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS 123(R), using the modified prospective method, which requires us to recognize compensation cost for granted after we became a public company, but unvested, stock awards, new stock awards and stock awards modified, repurchased, or cancelled after January 1, 2006. The discussion below is impacted by the fact that 2005 amounts do not include the impact of SFAS 123(R).

Cost of Products Sold. Cost of products sold in 2006 was $2.2 million, compared to $514,000 in 2005. Cost of products sold consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and royalty payments to Abbott under the license agreement for ZYFLO. Cost of products sold includes charges for inventory write-offs of $299,000 during 2006, compared to $280,000 during 2005. The write-offs resulted from excess or obsolete inventory that no longer can be used for commercial sale. Excluding these write-offs, our gross margins from product sales would have been 71% in 2006 and 40% in 2005. This increase in gross margins resulted from our ability to spread some of our fixed costs associated with managing the supply chain over a larger revenue base in 2006. In future periods, we expect that gross margins will be between 70% and 80% for ZYFLO. If we are able to commercially launch zileuton CR, our gross margins could be negatively impacted by an additional royalty obligation to SkyePharma for utilization of their controlled-release technology. However, we expect that overall gross margins will improve with increased product sales of ZYFLO or zileuton CR, if approved.

Research and Development Expenses. Research and development expenses in 2006 were $26.9 million compared to $30.0 million in 2005, a decrease of approximately $3.0 million, or 10%. This decrease was primarily due to lower expenses associated with the technology transfer and manufacturing activities associated with ZYFLO and the zileuton CR, as well as the reduction in the number of employees performing research and development functions following our May and October 2006 restructurings. With the commercial launch of ZYFLO in October 2005, the costs of manufacturing ZYFLO are now included in cost of products sold.

The following table summarizes the primary components of our research and development expenses for the years ended December 31, 2006 and 2005:

	Year Ended December 31,	
	2006	2005
	(In thousands)	
Zileuton (ZYFLO and zileuton CR)	$11,975	$12,670
Zileuton injection	2,336	1,656
CTI-01	2,960	3,045
Alpha-7	3,903	2,434
HMGB1	1,829	2,030
General research and development expenses	2,600	7,260
Stock-based compensation expense	1,309	864
Total research and development expenses	$26,912	$29,959

The following summarizes the expenses associated with our primary research and development programs:

Zileuton (ZYFLO and zileuton CR). During 2006, we incurred $12.0 million in expenses related to our orally-dosed zileuton programs, including ZYFLO and zileuton CR, as compared to $12.7 million during 2005, a 5% decrease. This decrease was primarily due to the following:

- lower manufacturing costs related to the product registration of ZYFLO, which was approved for commercial sale in September 2005;
- reduced costs related to clinical trials of zileuton in 2006 compared to 2005, when we conducted a Phase II clinical trial in patients with moderate to severe inflammatory acne; and

The decreases in the costs described above were partially offset by higher costs associated with the following:

- completion of certain clinical trials related to the pharmacokinetic profile of zileuton CR in the bloodstream;
- initiation of the development of our life cycle extension program for zileuton; and

We anticipate that our research and development expenses of our orally-dosed zileuton programs in future periods will consist primarily of costs related to conducting Phase IIIb or Phase IV clinical trials. We expect that these clinical trials will be designed to examine the utility of zileuton in particular groups of asthma patients. In addition, we expect to continue to incur research and development expenses to maintain and operate our medical affairs, medical information and pharmacovigilance functions in support of ZYFLO and our zileuton CR.

Zileuton Injection. During 2006, we incurred $2.3 million in expenses related to our zileuton injection program, compared to $1.7 million during 2005, an 41% increase. This increase was primarily due to the completion of a Phase I/II clinical trial of zileuton injection in 60 patients during 2006 as well as the costs to manufacture and supply drug in support of that clinical trial. During 2005, our zileuton injection program was still in preclinical stages of development. We expect that our costs associated with the development of zileuton injection will continue to increase as we progress into later stages of clinical development and continue the formulation development to be used in future clinical trials.

CTI-01. During 2006, we incurred $3.0 million in expenses related to our CTI-01 program, which was comparable to the expenses incurred in 2005. The costs incurred in both 2006 and 2005 related primarily to the enrollment and conduct of a Phase II clinical trial of CTI-01 in patients undergoing major cardiac surgery including the use of a cardiopulmonary bypass machine. This

clinical trial was initiated in 2005 and completed during 2006. Effective February 2007, we terminated our license agreement with the University of Pittsburgh related to the development of CTI-01 and our license agreement with Xanthus Pharmaceuticals related to the development of CTI-01. We do not plan to pursue further development or incur additional costs related to CTI-01.

Alpha-7. During 2006, we incurred $3.9 million of expenses in connection with research and development of our alpha-7 program, compared to $2.4 million during 2005, a 60% increase. The increase was primarily due to an increase in laboratory supplies and improved methods of allocating our research and development overhead expenses to our various programs, including the costs related to facilities, such as our laboratory space, and the depreciation expense on our laboratory equipment. In 2005, most of these expenses were included in our general research and development expenses. The number of employees working on alpha-7 during 2006, as compared to 2005, was relatively consistent through most of the year leading up to our October 2006 restructuring. We anticipate that our research and development expenses for our alpha-7 program will not grow substantially in 2007 as we expect increased costs related to preclinical studies conducted by third parties to advance our lead molecule to be offset by the reduction in the number of employees working on the program following our October 2006 restructuring. We anticipate that significant additional expenditures will be required to advance any product candidate through preclinical and clinical development. We plan to seek a collaborator for our alpha-7 program and do not currently expect to conduct clinical trials with the alpha-7 program without entering into such an arrangement. However, because this project is at a very early stage, the actual costs and timing of research, preclinical development, clinical trials and associated activities are highly uncertain, subject to risk, and will change depending upon the project we choose to develop, the clinical indication developed, the development strategy adopted, and the terms of a collaboration, if we are able to enter into one. As a result, we are unable to estimate the costs or the timing of advancing a small molecule from our alpha-7 program through clinical development.

HMGB1. During 2006, we incurred $1.8 million of expenses for our HMGB1 program, compared to $2.0 million during 2005, a 10% decrease. This decrease was primarily due to lower license fees, sponsored research and laboratory supplies for our continued testing under our collaboration agreement with MedImmune as well as lower personnel costs devoted to this program. The decreased expenses were partially offset by increases related to the allocation of our research and development overhead expenses to our various programs. These overhead expenses include the costs related to facilities, including our laboratory space, and the depreciation expense on our laboratory equipment. In 2005, most of these expenses were included in our general research and development expenses. In addition, we paid a $250,000 milestone payment in 2005 to the licensor of HMGB1 for establishing preclinical proof-of-concept. The collaboration revenue recognized by us in 2006 for this program totaled $6.4 million. We currently anticipate that research and development costs relating to HMGB1 in 2007 will be lower following our October 2006 restructuring. In addition, a larger portion of the expenses in our HMGB1 program will be assumed by our partner, MedImmune, as the program advances into later stages of preclinical development. We also anticipate that some of our expenses in the HMGB1 program will be covered by funding and potential milestone payments from MedImmune under our collaboration agreement. Because the HMGB1 program is still in preclinical development, the actual costs and timing of preclinical development, clinical trials and associated activities are highly uncertain, subject to risk and will change depending upon the clinical indication developed and the development strategy adopted. A significant amount of these clinical trial costs will be incurred by MedImmune. The expenses for HMGB1 are reflected in the accompanying statements of operations as part of research and development expenses, while the funding received from MedImmune and Beckman Coulter to fund our research efforts is included in revenue under collaboration agreements.

Our general research and development expenses, which are not allocated to any specific program, were $2.6 million in 2006 compared to $7.3 million in 2005, a decrease of 64%. This decrease was primarily due to improved methods of allocating our research and development overhead expenses to our

various programs, including costs related to personnel, laboratory and other facility costs. Unallocated facility and related costs were $635,000 in 2006, compared to $1.7 million in 2005. Unallocated depreciation expense declined to $59,000 in 2006, compared to $398,000 in 2005. The remaining general research and development expenses, which are incurred in support of all of our research and development programs, are not easily allocable to any individual program, and therefore, have been included in general research and development expenses.

Stock-based compensation expense that is related to research and development increased by $445,000 from $864,000 in 2005 to $1.3 million in 2006. The 2006 amount includes expenses for employee grants under SFAS 123(R) as well as grants made to non-employees who are primarily working on research and development activities. The adjustment to stock-based compensation expense for non-employees is calculated based on the change in fair value of our common stock during the period. The increase in stock-based compensation expense is related primarily to our adoption of SFAS 123(R), offset in part by the change in the market price of our common stock for unvested non-employee grants.

Sales and Marketing Expenses. Sales and marketing expenses for 2006 were $18.3 million, compared to $13.7 million for 2005. The $4.6 million, or 34%, increase in 2006 was primarily attributable to the following:

- approximately $2.2 million in higher salary costs related to our specialty sales force and our sales and customer management team, the majority of whom we hired in August 2005;
- $513,000 of additional stock-based compensation expense primarily related to our adoption of SFAS 123(R) and the increased number of employees during most of 2006;
- higher infrastructure costs to support the sales force including leased vehicle expense, computer and software costs;
- severance costs of $302,000 and additional stock-based compensation expense of $525,000 related to the departure of our former Senior Vice President of Sales and Marketing; and
- higher product samples, promotional materials and other costs associated with ZYFLO that we incurred to support our sales effort.

In May and October 2006, we reduced the size of our sales and marketing efforts substantially to bring our cost structure more in-line with the expected future revenue for ZYFLO. In connection with these two restructurings, we reduced the size of our sales force promoting ZYFLO from approximately 80 sales representatives at the beginning of 2006 to 18 sales representatives at December 31, 2006. In addition, we reduced the size of the sales management team, our customer management, sales operations and marketing functions for similar reasons.

General and Administrative Expenses. General and administrative expenses for 2006 were $13.5 million compared to $11.4 million for 2005. The $2.1 million, or 18%, increase in 2006 was primarily attributable to the following:

- severance costs of $670,000 and additional stock-based compensation expense of $1.3 million related to the departure of our former President and Chief Executive Officer; and
- $1.7 million of additional stock-based compensation expense primarily related to our adoption of SFAS 123(R).

These increases were offset, in part, by expenses related to our June 2005 private placement, lower personnel costs related to our May and October 2006 restructurings and a reduction in expenses related to our compliance with the Sarbanes-Oxley Act of 2002.

Restructuring Charges. Restructuring charges totaled $3.5 million in 2006 related to actions we took in May and October 2006. In May 2006, we recorded charges of $499,000 for a restructuring of our operations that was intended to better align costs with revenue and operating expectations. In October 2006, we announced a second restructuring of our operations to focus our resources on the

commercialization of zileuton CR and on the clinical development of zileuton injection and to significantly reduce our net cash expenditures through lower spending on our existing sales force as well as on our discovery and research programs. The restructuring charges for 2006 were comprised of the following:

- severance, benefit and related payments of approximately $2.1 million;
- asset impairment charges of $501,000 related to computer and laboratory equipment with a net realizable value below its net book value;
- stock-based compensation expense of $622,000 related to the acceleration of vesting stock options from the departure of our former Senior Vice President of Research and Development and Chief Scientific Officer; and
- approximately $335,000 related to the termination of leases on vehicles used by our sales force and outplacement services.

The restructuring charges for 2006 do not include approximately $972,000 of severance expenses and $1.8 million of stock-based compensation related to the departures of our President and Chief Executive Officer and our Senior Vice President of Sales and Marketing. These amounts have been included in general and administrative expenses and sales and marketing expenses, as described above. As of December 31, 2006, we had substantially completed the implementation of these restructurings and approximately $212,000 of accrued restructuring costs remained on our balance sheet to be paid in 2007.

Other

Other Income. Interest income in 2006 was $2.7 million, compared to $2.4 million in 2005. The increase was primarily attributable to higher interest rates and higher cash and investment balances as a result of the financings that we completed in 2005 and 2006. Interest expense amounted to $214,000 and $191,000 in 2006 and 2005, respectively. The interest expense relates to borrowings under our loan with Silicon Valley Bank for capital expenditures.

Years Ended December 31, 2005 and 2004

Revenues

Revenue from Product Sales. We recognized revenue from product sales of $387,000 in 2005 related to sales of ZYFLO following our product launch in October 2005. This is the first period in which we recognized revenue from product sales since our inception. In accordance with SFAS No. 48, we deferred recognition of revenue in 2005 on product shipments of ZYFLO to wholesalers, distributors and pharmacies until the product is dispensed through patient prescriptions. Shipments of ZYFLO to third parties that were not recognized as revenue totaled $1.7 million at December 31, 2005 and are included in deferred product revenue on our balance sheet. This deferred revenue will be recognized as revenue as prescriptions are filled in future periods, or will be reversed if the product is returned in future periods. The cost of product shipped to third parties that has not been recognized as revenue in accordance with our revenue recognition policy is deferred until the product is dispensed through patient prescriptions. This deferred cost of product sold totaled $266,000 at December, 31, 2005 and is included in prepaid expenses and other current assets on our balance sheet.

Revenue under Collaboration Agreements. We recognized collaboration revenues of $5.8 million in 2005 compared to $4.4 million in 2004. These revenues were primarily due to the portion of the $12.5 million of initial fees MedImmune paid us that we recognized in each period and the amounts that we billed to MedImmune for milestone payments and development support, which totaled $2.75 million in 2005 and $1.5 million in 2004. Since we entered into the agreement with MedImmune in 2003 through December 31, 2005, we billed a total of $16.75 million to MedImmune, consisting of the $12.5 million initial payment, a $1.25 million milestone payment and $3.0 million of development support. We recognized $11.2 million of these amounts as collaboration revenue through December 31, 2005. We reported the balance of the payments, totaling $5.6 million, as deferred collaboration revenue and will

recognize such amount over the remaining estimated research term of our agreement with MedImmune based on the amount of cumulative costs incurred as a percentage of the total costs estimated for the performance period. In December 2005, we revised our estimate of remaining total costs and increased the period over which those costs would be allocated under the collaboration agreement with MedImmune. The change in estimate resulted in a decrease in revenue recognized of approximately $237,000 for the three months ended December 31, 2005. As of December 31, 2005, we had a total of $5.7 million in deferred collaboration revenue remaining to be recognized under our collaboration agreements with MedImmune and Beckman Coulter.

Costs and Expenses

Cost of Products Sold. Cost of products sold in 2005 was $514,000. Cost of products sold consisted primarily of the expenses associated with manufacturing and distributing ZYFLO, a royalty payment to Abbott from the license agreement for ZYFLO and a charge of $280,000 for inventory write-offs. The write-offs resulted from excess inventory on-hand at December 31, 2005 with an expiration date in 2006.

Research and Development Expenses. Research and development expenses were $30.0 million in 2005 compared to $25.6 million in 2004, an increase of approximately $4.4 million, or 17%. This increase was primarily due to higher expenses associated with the technology transfer and manufacturing activities associated with ZYFLO and zileuton CR, as well as the growth in the number of employees performing research and development functions and higher facilities, equipment and laboratory expenses associated with our increased research and development activities in 2005 as compared to 2004.

The following table summarizes the primary components of our research and development expenses for the years ended December 31, 2005 and 2004:

	Year Ended December 31,	
	2005	2004
	(In thousands)	
Zileuton	$14,326	$12,369
CTI-01	3,045	3,329
Alpha-7	2,434	1,533
HMGB1	2,030	1,702
General research and development expenses	7,260	4,637
Stock-based compensation expense	864	2,008
Total research and development expenses	$29,959	$25,578

The following summarizes the expenses associated with our primary research and development programs:

Zileuton. During 2005, we incurred $14.3 million in expenses related to our zileuton program as compared to $12.4 million during 2004, a 16% increase. This increase was primarily due to the following:

- manufacturing costs related to the product registration of ZYFLO;
- our completed Phase II clinical trial of ZYFLO for moderate to severe inflammatory acne;
- the initiation of the ZYFLO open-label study in patients with asthma or mastocytosis;
- the development and manufacturing costs related to our injectable and controlled-release formulations; and
- the payment of several milestones related to our license agreements with Abbott and SkyePharma.

CTI-01. During 2005, we incurred $3.0 million in expenses related to our CTI-01 program as compared to $3.3 million during 2004, a 9% decrease. This decrease was primarily due to lower preclinical costs in 2005, partially offset by higher clinical and manufacturing costs.

Alpha-7. During 2005, we incurred $2.4 million of expenses in connection with our alpha-7 program as compared to $1.5 million during 2004, a 59% increase. The increase was primarily due to an increase in the number of employees working on the alpha-7 program and higher contract research costs associated with our efforts to discover and develop small molecule product candidates.

HMGB1. During 2005, we incurred $2.0 million of expenses for our HMGB1 program as compared to $1.7 million during 2004, a 19% increase. This increase was primarily due to higher license fees, sponsored research and laboratory supplies for our continued testing under our collaboration agreement with MedImmune offset in part by lower personnel costs devoted to this program. In 2005, we paid a $250,000 milestone to the licensor of HMGB1 for establishing preclinical proof-of-concept. The collaboration revenue recognized by us in 2005 for this program totaled $5.8 million.

Our general research and development expenses, which are not allocated to any specific program, increased by $2.6 million, or 57%, in 2005 compared to 2004. This increase was primarily due to a $1.2 million increase in personnel costs and a $1.6 million increase in facility and related costs, partially offset by a $624,000 decrease in leasehold amortization expense. These costs, which are incurred in support of all of our research and development programs, are not easily allocable to any individual program, and therefore, have been included in general research and development expenses. In addition, since the launch of ZYFLO in October 2005, we have incurred expenses associated with medical affairs, medical education and medical information, which are part of our general research and development expenses.

Stock-based compensation expense that is related to research and development decreased by $1.1 million from $2.0 million in 2004 to $864,000 in 2005. This includes expenses for certain employee grants as well as grants made to non-employees who are primarily working on research and development activities. The adjustment to stock-based compensation expense for non-employees is calculated based on the change in fair value of our common stock during the period. The fair value of our common stock declined approximately 10% during 2005 resulting in lower overall stock-based compensation expense for research and development activities.

Sales and Marketing Expenses. Sales and marketing expenses for 2005 were $13.7 million compared to $1.2 million for 2004. The $12.5 million increase in 2005 was primarily attributable to the following:

- hiring and training our 80-person specialty sales force, the majority of whom we hired in August 2005;
- hiring our sales and customer management team;
- market research conducted in anticipation of the approval and launch of ZYFLO in October 2005; and
- marketing, product samples, promotional materials and other costs associated with our October 2005 launch of ZYFLO.

The number of employees performing sales and marketing functions increased from 6 employees at December 31, 2004 to 106 employees at December 31, 2005.

General and Administrative Expenses. General and administrative expenses for 2005 were $11.4 million compared to $9.7 for 2004. The $1.7 million, or 18%, increase in 2005 was primarily attributable to the following:

- personnel costs increased $476,000, as a result of an increase in the number of employees performing general and administrative functions;

- directors and officers liability insurance and general business insurance costs increased $291,000 due to an increase in premiums; and
- audit fees related to our Sarbanes-Oxley compliance and consulting increased by $724,000 as we prepared for the audit of our internal controls systems as of December 31, 2005.

Other

Other Income. Interest income in 2005 was $2.4 million compared to $1.1 million in 2004. The increase was primarily attributable to higher interest rates and higher cash and investment balances from our financings completed in 2004 and 2005. Interest expense amounted to $191,000 and $172,000 in 2005 and 2004, respectively. The interest expense relates to borrowings under our loan with Silicon Valley Bank for capital expenditures.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception on July 14, 2000, we have raised proceeds to fund our operations through public offerings and private placements of equity securities, debt financings, the receipt of interest income, payments from our collaborators MedImmune and Beckman Coulter and, beginning in the fourth quarter of 2005, revenues from sales of ZYFLO. As of December 31, 2006, we had $49.0 million in cash, cash equivalents and short-term investments. We have invested our remaining cash balance in highly liquid, interest-bearing, investment grade securities in accordance with our established corporate investment policy.

In October 2006, we sold 7,455,731 shares of common stock and warrants to purchase 3,727,865 shares of common stock for an aggregate purchase price of $20.0 million, which resulted in net proceeds of $18.5 million. The warrants to purchase common stock have an exercise price of $2.62 per share and are exercisable at any time on or before October 26, 2011.

In 2003, we entered into an exclusive license and collaboration agreement with MedImmune for the discovery and development of novel drugs for the treatment of acute and chronic inflammatory diseases associated with HMGB1, a newly discovered cytokine. Under this collaboration, MedImmune paid us initial fees of $12.5 million and an additional $5.0 million through December 31, 2006 for milestone payments and to fund certain research expenses incurred by us for the HMGB1 program. We invoiced MedImmune for an additional $250,000 in 2006, but had not yet received payment as of December 31, 2006.

Under our collaboration with MedImmune, we may receive additional payments upon the achievement of research, development and commercialization milestones up to a maximum of $124.0 million, after taking into account payments we are obligated to make to The Feinstein Institute on milestone payments we receive from MedImmune. We anticipate that by the end of 2007, in addition to payments already received, we will receive $1.0 million in aggregate milestone payments from MedImmune, after taking into account payments we are obligated to make to The Feinstein Institute.

Under our co-promotion agreement with DEY, DEY paid us a non-refundable upfront payment of $3.0 million on March 14, 2007. In addition, DEY has agreed to pay us milestone payments of $4.0 million following approval by the FDA of the NDA for zileuton CR and $5.0 million following commercial launch of zileuton CR. If the commercial launch of zileuton CR is delayed beyond May 31, 2008, DEY has the right to terminate the co-promotion agreement on or before July 1, 2008 by providing written notice, which will be effective 60 days after receipt by us. If DEY exercises this termination right, we will be obligated to pay DEY $2.0 million if DEY has paid us the $4.0 million milestone related to approval of the NDA for zileuton CR.

Credit Agreement with Silicon Valley Bank. We have financed the purchase of general purpose computer equipment, office equipment, fixtures and furnishings, test and laboratory equipment, software

licenses and the completion of leasehold improvements through advances under a credit agreement with Silicon Valley Bank, which was most recently modified as of January 6, 2006. As of December 31, 2006, we had no borrowing capacity available under the modified credit agreement or any other credit agreement. We are currently considering financing alternatives to fund capital expenditures in the future.

We granted Silicon Valley Bank a first priority security interest in substantially all of our assets, excluding intellectual property, to secure our obligations under the credit agreement. As of December 31, 2006, we had $1.4 million in debt outstanding under this credit agreement related to equipment advances. As a result of our October 2006 restructuring, we incurred restructuring charges for the impairment of some of our assets. As a result of these charges, we may be required to pay the outstanding balance owed for these impaired assets.

The equipment advances made prior to the modification of our credit agreement on June 30, 2004 accrue interest at a weighted-average effective interest rate of approximately 8.7% per year. We are required to make equal monthly payments of principal and interest with respect to each advance made prior to June 30, 2004. The total repayment term for equipment advances made prior to June 30, 2004 is 48 months. Upon the maturity of any advance made prior to June 30, 2004, we are required to make a final payment in addition to the repayment of principal and interest. The final payment will be in an amount equal to a specified percentage of the original advance amount up to 8.5% of the original principal and is expected to be paid by the third quarter of 2007. As of December 31, 2006, we had $101,000 in outstanding equipment advances made prior to June 30, 2004.

Advances made under the modified credit agreement, after June 30, 2004, accrue interest at a rate equal to the prime rate plus 2% per year. As of December 31, 2006, outstanding equipment advances under the modified credit agreement had a weighted-average effective interest rate of approximately 10.2% per year. Advances made under the modified credit agreement are required to be repaid in equal monthly installments of principal plus interest accrued through the repayment term, which range from 36 to 42 months. Repayment begins the first day of the month following the advance. No advances were made in 2006 under the modified credit agreement.

Cash Flows

Operating Activities. Net cash used in operating activities was $51.4 million in 2006, compared to $45.1 million in 2005. Net cash used in operations for 2006 consisted of a net loss of $48.8 million, adjusted by the following:

- non-cash depreciation and amortization expense of $939,000;
- non-cash restructuring charges of $1.1 million, consisting of an impairment charge on equipment and certain stock-based compensation;
- non-cash stock-based compensation expense of $6.6 million unrelated to the restructurings; and
- approximately $11.4 million of cash used to fund working capital and other items, including $5.0 million related to the recognition of revenue under collaboration agreements in 2006 from cash that had been paid prior to 2006.

Investing Activities. Investing activities provided $24.7 million of cash in 2006, compared to $38.5 million in 2005. In 2006, we made capital expenditures of $370,000 primarily for laboratory equipment associated with our research and development activities and upgrades to certain software and computer equipment and we sold $36.9 million of our short-term investments which was offset by purchases of $11.8 million of short-term investments. As interest rates have gradually increased, we have maintained more of our proceeds from recent financings as cash equivalents rather than short-term investments.

Financing Activities. Financing activities provided $17.9 million of cash in 2006, compared to $51.9 million of cash in 2005. Net cash provided by financing activities in 2006 related primarily to our registered direct offering of common stock and warrants in October 2006. We sold shares of common stock

and warrants to purchase common stock, resulting in net proceeds of $18.5 million after offering expenses and placement agent fees. Other financing activities included $635,000 generated from option exercises and purchases of stock through our employee stock plans offset by $1.2 million used to repay long-term debt and capital lease obligations.

Income Taxes

We have accumulated net operating losses and tax credits available to offset future taxable income for federal and state income tax purposes as of December 31, 2006. If not utilized, federal net operating loss carryforwards will begin to expire in 2021. State net operating loss carryforwards began to expire in 2006. The federal tax credits expire beginning in 2021. To date, we have not recognized the potential tax benefit of our net operating loss carryforwards or credits on our balance sheet or statements of operations. The future utilization of our net operating loss carryforwards may be limited based upon changes in ownership pursuant to regulations promulgated under the Internal Revenue Code.

Funding Requirements

We expect to devote substantial resources to continue our research and development efforts, including preclinical testing and clinical trials, enhance our sales and marketing infrastructure, achieve regulatory approvals, and, subject to regulatory approval, commercially launch zileuton CR and any future product candidates. We also expect to spend approximately $400,000 in capital expenditures in 2007 for the purchase of software, computer equipment, manufacturing equipment and equipment for our laboratories. We expect to fund our capital expenditures through cash received from product sales and interest income from invested cash and cash equivalents and short-term investments. Our funding requirements will depend on numerous factors, including:

- the timing and costs of the regulatory approval and the commercial launch of zileuton CR, if and when it is approved by regulatory authorities;
- the scope, costs and results of our clinical trials on zileuton CR and zileuton injection;
- if approved, the amount and timing of sales of zileuton CR;
- the timing and amount of sales from ZYFLO;
- the costs of ongoing sales, marketing and manufacturing activities for ZYFLO and, if approved, zileuton CR;
- the time and costs involved in preparing, submitting, obtaining and maintaining regulatory approvals for our other product candidates;
- the timing, receipt and amount of milestone and other payments, if any, from MedImmune, Beckman Coulter or future collaborators;
- the timing, receipt and amount of sales and royalties, if any, from our potential products;
- continued progress in our research and development programs, as well as the magnitude of these programs, including milestone payments to third parties under our license agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the cost of obtaining and maintaining licenses to use patented technologies;
- potential acquisition or in-licensing of other products or technologies;
- our ability to establish and maintain additional collaborative or co-promotion arrangements; and
- the ongoing time and costs involved in certain corporate governance requirements, including work related to compliance with the Sarbanes-Oxley Act of 2002.

Other than payments that we receive from our collaborations with MedImmune and Beckman Coulter, we expect that sales of ZYFLO will represent our only source of revenue until we commercially launch zileuton CR, if it is approved. In addition to the foregoing factors, we believe that our ability to access external funds will depend upon the regulatory status of zileuton CR, market acceptance of zileuton CR, if approved, market acceptance of ZYFLO, the success of our other preclinical and clinical development programs, the receptivity of the capital markets to financings by biopharmaceutical companies, our ability to enter into additional strategic collaborations with corporate and academic collaborators and the success of such collaborations.

The extent of our future capital requirements is difficult to assess and will depend largely on our ability to obtain regulatory approval for, and successfully commercialize, zileuton CR. Based on our operating plans, we believe that our available cash and cash equivalents and anticipated cash received from product sales and anticipated payments received under existing collaboration agreements will be sufficient to fund anticipated levels of operations into 2009, assuming we receive FDA approval for and commercially launch zileuton CR in 2007. If zileuton CR is not approved and commercially launched in 2007, we believe that our available cash and cash equivalents and anticipated cash received from product sales and anticipated payments received under collaboration agreements will be sufficient to fund anticipated levels of operations into the third quarter of 2008.

For the year ended December 31, 2006, our net cash used for operating activities was $51.4 million and we had capital expenditures of $370,000. If our existing resources are insufficient to satisfy our liquidity requirements or if we acquire or license rights to additional product candidates, we may need to raise additional external funds through collaborative arrangements and public or private financings. Additional financing may not be available to us on acceptable terms or at all. In addition, the terms of the financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities, further dilution to our then-existing stockholders will result. If we are unable to obtain funding on a timely basis, we may be required to significantly delay, limit or eliminate one or more of our research, development or commercialization programs, which could harm our financial condition and operating results. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.

Contractual Obligations

We have summarized in the table below our fixed contractual obligations as of December 31, 2006.

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than One Year**	**One to Three Years**	**Three to Five Years**	**More than Five Years**
			(In thousands)		
Short- and long-term debt	$ 1,531	$1,094	$ 437	$ —	$ —
Research and license agreements	6,602	170	534	644	5,254
Consulting agreements	37	37	—	—	—
Severance agreements	217	217	—	—	—
Manufacturing and clinical trial agreements	4,763	2,583	2,180	—	—
Lease obligations	3,219	1,562	1,657	—	—
Total contractual cash obligations	$16,369	$5,663	$4,808	$644	$5,254

The amounts listed for short- and long-term debt represent the principal and interest amounts we owe under our credit agreement with Silicon Valley Bank.

The amounts listed for research and license agreements represent our fixed obligations payable to sponsor research and minimum royalty payments for licensed patents. These amounts do not include any additional amounts that we may be required to pay under our license agreements upon the achievement of scientific, regulatory and commercial milestones that may become payable depending on the progress of scientific development and regulatory approvals, including milestones such as the submission of an

investigational new drug application to the FDA, similar submissions to foreign regulatory authorities and the first commercial sale of our products in various countries.

We are party to a number of agreements that require us to make milestone payments. In particular, under our license agreement with Abbott Laboratories for zileuton, we agreed to make aggregate milestone payments of up to $13.0 million to Abbott upon the achievement of various development and commercialization milestones relating to zileuton, including the completion of the technology transfer from Abbott to us, filing and approval of a product in the United States and specified minimum net sales of licensed products. Through December 31, 2006, we have paid aggregate milestones of $5.3 million to Abbott under our license agreements related to the immediate and controlled-release formulations of zileuton.

In addition, under our manufacturing agreement with SkyePharma, through its subsidiary Jagotec, for zileuton CR, we agreed to make aggregate milestone payments of up to $6.6 million upon the achievement of various development and commercialization milestones. Through December 31, 2006 we have paid aggregate milestones of $2.4 million to SkyePharma under our agreement.

The amounts shown in the table do not include royalties on net sales of our products and payments on sublicense income that we may owe as a result of receiving payments under our collaboration agreement with MedImmune. Our license agreements are described more fully in Note 11 to our consolidated financial statements.

The amounts listed for consulting agreements are for fixed payments due to our scientific and business consultants.

The amounts listed for manufacturing and clinical trial agreements represent amounts due to third parties for manufacturing, clinical trials and preclinical studies. As discussed in Note 11 to our consolidated financial statements included in this report, we entered into a manufacturing and supply agreement with Rhodia Pharma Solutions Ltd. for commercial production of zileuton API, subject to specified limitations, through December 31, 2009. On June 30, 2006, Rhodia SA, the parent company of Rhodia Pharma Solutions Ltd., sold the European assets of its pharmaceutical custom synthesis business to Shasun Chemicals and Drugs Ltd. As part of this transaction, Rhoda SA assigned our contract with Rhodia Pharma Solutions Ltd. to Shasun Pharma Solutions Ltd., or Shasun. Under this agreement, we committed to purchase a minimum amount of API in the fourth quarter of 2006, the first quarter of 2007 and in the first quarter of 2008. The API purchased from Shasun currently has a minimum shelf-life of 24 months. We evaluate the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, we are required to make judgments as to the future demand for current or committed inventory levels and as to the expiration dates of its product. While our purchase commitment for API from Shasun exceeds our current forecasted demand in 2007, we expect that any excess API purchased in 2006 under our agreement with Shasun will be used in commercial production batches in 2007 and 2008 and sold before it requires retesting. Therefore no reserve for this purchase commitment has been recorded as of December 31, 2006.

Significant differences between our current estimates and judgments and future estimated demand for our product and the useful life of inventory may result in significant charges for excess inventory or purchase commitments in the future. These differences could have a material adverse effect on our financial condition and results of operations during the period in which we recognize charges for excess inventory. For example, we recorded charges of $299,000 in 2006 and $280,000 in 2005, respectively, to reserve for excess or obsolete inventory that had an expiration date such that the product was unlikely to be sold. The charge was included in cost of products sold in the accompanying statements of operations.

The amounts listed for research and license agreements, consulting agreements and manufacturing and clinical trial agreements include amounts that we owe under agreements that are subject to cancellation or termination by us under various circumstances, including a material uncured breach by the other party, minimum notice to the other party or payment of a termination fee.

The amounts listed for lease obligations represent the amount we owe under our office, computer, vehicle and laboratory space lease agreements under both operating and capital leases.

Effects of Inflation

Our assets are primarily monetary, consisting of cash, cash equivalents and short-term investments. Because of their liquidity, these assets are not significantly affected by inflation. We also believe that we have intangible assets in the value of our technology. In accordance with generally accepted accounting principles, we have not capitalized the value of this intellectual property on our consolidated balance sheet. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, 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.

Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board, or FASB, issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109*, or FIN 48, which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FAS 109 and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective beginning with the first annual period after December 15, 2006. We do not expect the adoption of FIN 48 to significantly affect our financial condition or results of operations.

In September 2006, the FASB issued Statement No. 157, *Fair Value Measurements*, or FAS 157, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. FAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We do not expect the adoption of FAS 157 to significantly affect our financial condition or results of operations.

In September 2006, the Securities and Exchange Commission released Staff Accounting Bulletin No. 108, or SAB 108, to address diversity in practice regarding consideration of the effects of prior year errors when quantifying misstatements in current year financial statements. The staff of the Securities and Exchange Commission concluded that registrants should quantify financial statement errors using both a balance sheet approach and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. SAB 108 states that if correcting an error in the current year materially affects the current year's income statement, the prior period financial statements must be restated. SAB 108 is effective for fiscal years ending after November 15, 2006. The adoption of SAB 108 did not significantly affect our financial condition or results of operations.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an amendment of SFAS 115*, or FAS 159, which permits companies to choose to measure many financial instruments and certain other items at fair value. FAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We are currently evaluating the effect FAS 159 will have on our consolidated financial position and results of operations.

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

We are exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting of U.S. government treasury and agency notes, corporate debt obligations, municipal debt obligations, auction rate securities and money market funds, directly or through managed funds, with maturities of two years or less. Our cash is deposited in and invested through highly rated financial institutions in North America. Our short-term investments are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10% from levels at December 31, 2006, we estimate that the fair value of our investment portfolio would decline by approximately $6,000. In addition, we could be exposed to losses related to these securities should one of our counterparties default. We attempt to mitigate this risk through credit monitoring procedures. We have the ability to hold our fixed income investments until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

ITEM 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Critical Therapeutics, Inc.
Lexington, Massachusetts

We have audited the accompanying consolidated balance sheets of Critical Therapeutics, Inc. and subsidiary (the "Company") as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity (deficit) and comprehensive loss, and cash flows for each of the three years in the period ended December 31, 2006. 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Critical Therapeutics, Inc. and subsidiary as of December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for stock-based compensation on January 1, 2006, as required by Statement of Financial Accounting Standards No. 123R, *Share-Based Payment.*

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2006, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2007 expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts
March 16, 2007

CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2006	2005
	(In thousands except share and per share data)	
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 48,388	$ 57,257
Short-term investments	650	25,554
Accounts receivable, net	877	1,024
Amount due under collaboration agreements	650	205
Inventory	4,048	1,869
Prepaid expenses and other	980	2,179
Total current assets	55,593	88,088
Fixed assets, net	2,421	3,563
Other assets	168	168
Total assets	$ 58,182	$ 91,819
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Current portion of long-term debt and capital lease obligations	$ 1,012	$ 1,179
Accounts payable	1,049	4,615
Accrued compensation	1,865	1,836
Accrued expenses	2,076	3,040
Revenue deferred under collaboration agreements	675	5,706
Deferred product revenue	1,178	1,707
Total current liabilities	7,855	18,083
Long-term debt and capital lease obligations, less current portion	421	1,489
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, par value $0.001; authorized 5,000,000 shares; no shares issued and outstanding	—	—
Common stock, par value $0.001; authorized 90,000,000 shares; issued and outstanding 42,902,142 and 34,126,977 shares at December 31, 2006 and 2005, respectively	43	34
Additional paid-in capital	204,378	181,718
Deferred stock-based compensation	(99)	(3,794)
Accumulated deficit	(154,399)	(105,617)
Accumulated other comprehensive loss	(17)	(94)
Total stockholders' equity	49,906	72,247
Total liabilities and stockholders' equity	$ 58,182	$ 91,819

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

CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2006	2005	2004
	(In thousands except share and per share data)		
Revenues:			
Net product sales	$ 6,647	$ 387	$ —
Revenue under collaboration agreements	6,431	5,837	4,436
Total revenues	13,078	6,224	4,436
Costs and expenses:			
Cost of products sold	2,222	514	—
Research and development	26,912	29,959	25,578
Sales and marketing	18,284	13,671	1,199
General and administrative	13,456	11,406	9,679
Restructuring charges	3,498	—	—
Total costs and expenses	64,372	55,550	36,456
Operating loss	(51,294)	(49,326)	(32,020)
Other income (expense):			
Interest income	2,726	2,427	1,098
Interest expense	(214)	(191)	(172)
Total other income	2,512	2,236	926
Net loss	(48,782)	(47,090)	(31,094)
Accretion of dividends and offering costs on preferred stock	—	—	(2,209)
Net loss available to common stockholders	$ (48,782)	$ (47,090)	$ (33,303)
Net loss per share available to common stockholders	$ (1.37)	$ (1.61)	$ (2.28)
Basic and diluted weighted-average common shares outstanding	35,529,048	29,276,243	14,631,371

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

CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) AND COMPREHENSIVE LOSS
YEARS ENDED DECEMBER 31, 2006, 2005 AND 2004

	Redeemable Convertible Preferred Stock	Common Stock	Additional Paid-In Capital	Deferred Stock-Based Compensation	Due from Stockholders	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity	Comprehensive Loss
				(In thousands except share data)					
BALANCE — January 1, 2004	$ 51,395	$ 2	$ 11,156	$(8,536)	$ (40)	$ (27,433)	$ —	$(24,851)	
Issuance of 20,055,160 shares of Series B preferred stock for cash	28,050	—	—	—	—	—	—	—	
Issuance of 221,902 shares of common stock, upon exercise of options under stock purchase plan	—	—	175	—	—	—	—	175	
Issuance of 66,666 shares of common stock in connection with license agreement	—	—	485	—	—	—	—	485	
Deferred stock-based compensation to employees	—	—	523	(523)	—	—	—	—	
Deferred stock-based compensation to non-employees	—	—	348	(348)	—	—	—	—	
Accretion of preferred stock dividends and issuance costs	2,209	—	(2,209)	—	—	—	—	(2,209)	
Amortization of deferred stock-based compensation	—	—	—	3,562	—	—	—	3,562	
Reversal of deferred stock based compensation	—	—	(21)	21	—	—	—	—	
Forgiveness of officers notes	145	—	—	—	40	—	—	40	
Issuance of 6,110,000 shares of common stock in initial public offering, net of $2.0 million in offering costs	—	6	37,811	—	—	—	—	37,817	
Conversion of 60,410,327 shares of preferred stock into 16,109,403 shares of common stock	(81,799)	16	81,783	—	—	—	—	81,799	
Issuance of 12,157 shares of common stock related to exercise of warrant	—	—	46	—	—	—	—	46	
Grant of stock options to non-employees	—	—	277	(277)	—	—	—	—	
Net loss	—	—	—	—	—	(31,094)	—	(31,094)	$(31,094)
Unrealized loss on investments	—	—	—	—	—	—	(362)	(362)	(362)
Comprehensive loss									$(31,456)
BALANCE — December 31, 2004	—	24	130,374	(6,101)	—	(58,527)	(362)	65,408	
Issuance of 96,235 shares of common stock, upon exercise of options under stock plan	—	—	158	—	—	—	—	158	
Deferred stock-based compensation to non-employees	—	—	(458)	458	—	—	—	—	
Amortization of deferred stock-based compensation				2,141				2,141	
Reversal of deferred stock based compensation	—	—	(221)	221	—	—	—	—	
Issuance of 9,945,261 shares of common stock and warrants to purchase 3,480,842 shares of common stock in private placement, net of $3.1 million in placement fees	—	10	51,352	—	—	—	—	51,362	
Grant of stock options to non-employees	—	—	513	(513)	—	—	—	—	
Net loss	—	—	—	—	—	(47,090)	—	(47,090)	$(47,090)
Unrealized gain on investments	—	—	—	—	—	—	268	268	268
Comprehensive loss									$(46,822)
BALANCE — December 31, 2005	—	34	181,718	(3,794)	—	(105,617)	(94)	72,247	
Issuance of 752,241 shares of common stock, upon exercise of options under stock plan	—	1	613	—	—	—	—	614	
Issuance of common stock to employees under stock purchase plan	—	—	22	—	—	—	—	22	
Deferred stock-based compensation to non-employees	—	—	(904)	904	—	—	—	—	
Amortization of deferred stock-based compensation	—	—		105	—	—	—	105	
Reversal of deferred stock-based compensation in adopting SFAS No. 123(R)	—	—	(2,686)	2,686	—	—	—	—	
Issuance of 7,455,731 shares of common stock and warrants to purchase 3,727,865 of common stock in a registered offering, net of $1.5 million in issuance costs	—	7	18,479	—	—	—	—	18,486	
Restricted stock buyback	—	—	(1)	—	—	—	—	(1)	
Issuance of restricted stock	—	1	—	—	—	—	—	1	
Stock-based compensation to employees	—	—	7,137	—	—	—	—	7,137	
Net loss	—	—	—	—	—	(48,782)		(48,782)	$(48,782)
Unrealized gain on investments	—	—	—	—	—	—	77	77	77
Comprehensive loss									$(48,705)
BALANCE — December 31, 2006	$ —	$43	$204,378	$ (99)	$ —	$(154,399)	$ (17)	$ 49,906	

CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2006	2005	2004
		(In thousands)	
Cash flows from operating activities:			
Net loss	$(48,782)	$(47,090)	$(31,094)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	939	800	1,092
Amortization of premiums and discounts on short-term investments and other	(69)	903	755
Loss on disposal of fixed assets	86	149	278
Non-cash restructuring charge	1,109	—	—
Stock-based compensation expense	6,620	2,141	3,562
Forgiveness of notes receivable and other	—	—	231
Changes in assets and liabilities:			
Accounts receivable	140	(1,024)	—
Amount due under collaboration agreement	(445)	(189)	2,484
Inventory	(2,179)	(1,869)	—
Prepaid expenses and other	1,199	(283)	(1,144)
Accounts payable	(3,566)	397	3,895
Accrued expenses	(935)	2,135	(2,211)
Revenue deferred under collaboration agreements	(5,031)	(2,837)	(2,935)
Deferred product revenue	(529)	1,707	—
Net cash used in operating activities	(51,443)	(45,060)	(25,087)
Cash flows from investing activities:			
Purchases of fixed assets	(370)	(2,182)	(2,019)
Proceeds from sales and maturities of short-term investments	36,859	72,915	52,900
Purchases of short-term investments	(11,802)	(32,255)	(120,866)
Net cash provided by (used in) investing activities	24,687	38,478	(69,985)
Cash flows from financing activities:			
Net proceeds from private placement of common stock	18,486	51,362	—
Proceeds from exercise of stock options and other	636	158	175
Net proceeds from the initial public offering of common stock	—	—	37,817
Net proceeds from issuance of convertible preferred stock	—	—	28,050
Proceeds from long-term debt and other	—	1,300	1,623
Repayments of long-term debt and capital lease obligation	(1,235)	(961)	(691)
Net cash provided by financing activities	17,887	51,859	66,974
Net (decrease) increase in cash and cash equivalents	(8,869)	45,277	(28,098)
Cash and cash equivalents at beginning of period	57,257	11,980	40,078
Cash and cash equivalents at end of period	$ 48,388	$ 57,257	$ 11,980
Supplemental disclosures of cash flow information:			
Cash paid during the period for:			
Interest	$ 221	$ 172	$ 126
Non-cash investing and financing activities:			
Fixed assets acquired under capital lease obligation	$ —	$ 125	$ —
Unrealized gain (loss) on investments	$ 77	$ 268	$ (362)
Conversion of redeemable convertible preferred stock into common stock	$ —	$ —	$ 81,799
Dividends forfeited on preferred stock conversion into common stock	$ —	$ —	$ 5,713
Accretion of dividends and offering costs on preferred stock	$ —	$ —	$ 2,209
Settlement of accrued licensing fee with common stock	$ —	$ —	$ 485

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

(1) Nature of Business

Critical Therapeutics, Inc. is a biopharmaceutical company focused on the development and commercialization of products designed to treat respiratory, inflammatory and critical care diseases linked to the body's inflammatory response. The Company was incorporated in the state of Delaware on July 14, 2000 under the name Medicept, Inc. On March 12, 2001, the Company changed its name from Medicept, Inc. to Critical Therapeutics, Inc. The Company formed a wholly-owned subsidiary, CTI Securities Corporation, a Massachusetts corporation, in 2003.

The Company is subject to a number of risks similar to other companies in the biopharmaceutical industry, including, but not limited to, risks and uncertainties related to the progress, timing and success of the Company's regulatory filings, regulatory approvals and product launches, including for the controlled-release formulation of zileuton, or zileuton CR; the Company's ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize ZYFLO, and, if approved, zileuton CR; the market acceptance and future sales of ZYFLO and, if approved, zileuton CR; the progress and timing of the Company's drug development programs and related clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the Company's ability to obtain, maintain and enforce patent and other intellectual property protection for ZYFLO, zileuton CR, its discoveries and drug candidates; the Company's ability to successfully enter into additional strategic co-promotion, collaboration or licensing transactions on favorable terms, if at all; the Company's ability to obtain additional financing to conduct research, development and commercialization activities; and the Company's compliance with governmental and other regulations.

The Company will require additional funding in the future and may seek to do so through collaborative arrangements and/or public or private financings. If the Company is unable to obtain funding on a timely basis, the Company may be required to significantly curtail certain of its sales, marketing and development efforts, and the Company may be required to limit, scale back or cease its operations. The Company could be required to seek funds through arrangements with collaborators or others that may require the Company to relinquish rights to some of its technologies, product candidates or products.

(2) Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiary, CTI Securities Corporation. All intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 financial statements and the reported amount of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Cash Equivalents and Short-Term Investments

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

Short-term investments consist primarily of U.S. government treasury and agency notes, commercial paper, corporate debt obligations, municipal debt obligations, auction rate securities and money market funds, each of investment-grade quality, which have an original maturity date greater than 90 days that

can be sold within one year. These securities are held until such time as the Company intends to use them to meet the ongoing liquidity needs to support its operations. These investments are recorded at fair value and accounted for as available-for-sale securities. As of December 31, 2006, the Company's investment portfolio, including its cash, cash equivalents and short-term investments had a weighted average time to maturity of approximately 21 days. The unrealized gain (loss) during the period is recorded within accumulated other comprehensive loss unless it is determined to be other-than-temporary. During the years ended December 31, 2006, 2005 and 2004, the Company recorded a net unrealized gain (loss) on cash equivalents and short-term investments of $77,000, $268,000 and $(362,000) respectively. The original cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization or accretion is included in interest income (expense) in the corresponding period. The Company has determined the unrealized gain (loss) on its investments is temporary; therefore no impairment losses were recorded for the years ended December 31, 2006, 2005 and 2004.

The unrealized losses as of December 31, 2006 and 2005 were primarily caused by interest rate increases. The following table shows, for the years ended December 31, 2006 and 2005, the gross unrealized gains and losses and the fair value of the Company's investments with unrealized gains and losses that are not deemed to be other-than-temporary, aggregated by investment category:

	As of December 31, 2006			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(In thousands)		
Cash and cash equivalents:				
Cash	$12,840	$—	$ —	$12,840
Commercial paper	32,678	1	(18)	32,661
Money market mutual funds	2,887	—	—	2,887
Cash and cash equivalents	48,405	1	(18)	48,388
Short-term investments:				
Auction rate securities	650	—	—	650
Short-term investments	650	—	—	650
Cash and cash equivalents and short-term investments	$49,055	$ 1	$(18)	$49,038

	As of December 31, 2005			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(In thousands)			
Cash and cash equivalents:				
Cash	$ 490	$—	$ —	$ 490
Commercial paper	51,181	3	(43)	51,141
Money market mutual funds	3,231	—	—	3,231
U.S. government and agency securities	2,395	—	—	2,395
Cash and cash equivalents	57,297	3	(43)	57,257
Short-term investments:				
U.S. government and agency securities	2,690	—	(2)	2,688
Corporate bonds	16,668	—	(52)	16,616
Auction rate securities	6,250	—	—	6,250
Short-term investments	25,608	—	(54)	25,554
Cash and cash equivalents and short-term investments	$82,905	$ 3	$(97)	$82,811

Inventory

Inventory is stated at the lower of cost or market with cost determined under the first-in, first-out (FIFO) method. The Company analyzes its inventory levels quarterly and reserves for inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. Expired inventory is disposed of and the related costs are expensed in the period.

Fixed Assets

Fixed assets are stated at cost, net of accumulated depreciation and amortization. Depreciation is computed on a straight-line basis over estimated useful lives commencing upon the date the assets are placed in service. Upon retirement or sale, the cost of the assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in operating income. Repairs and maintenance costs are expensed as incurred.

The useful lives for our major asset categories are as follows:

Asset Description	Useful Life (Years)
Furniture and fixtures	7
Office equipment	5
Lab equipment	5
Computer hardware and software	3

Leasehold improvements are amortized over the shorter of the useful life of the asset or the lease term.

Impairment of Long-Lived Assets

Long-lived assets and, if and when applicable, certain identifiable intangibles held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of

an asset may not be recoverable. In performing the review for recoverability, the Company will estimate the future cash flows expected to result from the use of the asset and its eventual disposition. If the sum of the expected future cash flows (undiscounted and without interest charges) is less than the carrying amount of the asset, an impairment loss is recognized. Measurement of an impairment loss for long-lived assets and identifiable intangibles that the Company expects to hold and use is based on the fair value of the asset. Assets that are being held for sale are recorded at the lower of carrying value or fair value less cost to sell. In 2006, the Company recorded an impairment charge of approximately $488,000 related to computer and laboratory equipment as a result of the Company's 2006 restructurings (See Note 13). As of December 31, 2006, these assets are being held-for-sale with a fair value of approximately $298,000 and are included in fixed assets in the accompanying consolidated balance sheet.

Research and Development

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for monitoring and analyzing clinical trials, milestone payments to third parties, costs related to the development of the Company's NDA for zileuton CR, costs of contract research and manufacturing and the cost of facilities. In addition, research and development expenses include the cost of the Company's medical affairs and medical information functions, which educate physicians on the scientific aspects of its commercial products and the approved indications, labeling and the costs of monitoring adverse events. After FDA approval of a product candidate, manufacturing expenses associated with a product will be recorded as cost of products sold rather than as research and development expenses. The Company expenses research and development costs and patent related costs as incurred. Because of the Company's ability to utilize resources across several projects, many of its research and development costs are not tied to any particular project and are allocated among multiple projects. The Company records direct costs on a project-by-project basis. The Company records indirect costs in the aggregate in support of all research and development. Development costs for clinical development stage programs tend to be higher than earlier stage programs due to the costs associated with conducting clinical trials and large-scale manufacturing.

Revenue Recognition and Deferred Revenue

The Company recognizes revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* (SAB 101), as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104). Specifically, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable and collectibility is reasonably assured. The Company's revenue is currently derived from product sales of its only commercial product, ZYFLO, and its collaboration agreements. These collaboration agreements provide for various payments, including research and development funding, license fees, milestone payments and royalties.

The Company sells ZYFLO, a tablet formulation of zileuton, to wholesalers, distributors and pharmacies, which have the right to return purchased product. In accordance with Statement of Financial Accounting Standards ("SFAS") No. 48, *Revenue Recognition When Right of Return Exists,* the Company cannot recognize revenue on product shipments until it can reasonably estimate returns relating to these shipments. Until the Company has sufficient history to accurately estimate returns, the Company defers recognition of revenue on product shipments of ZYFLO to its customers until the product is dispensed through patient prescriptions because ZYFLO received by patients through prescription is not subject to return. The Company estimates prescription units dispensed based on distribution channel data provided by external, independent sources.

Gross revenue for prescriptions dispensed was $7.1 million for the year ended December 31, 2006, while product revenue net of discounts and rebates was $6.6 million. The Company's product sales are subject to various rebates, discounts and incentives that are customary in the pharmaceutical industry. Product shipments for which revenue has been deferred totaled $1.2 million at December 31, 2006 and is included in deferred product revenue on the accompanying consolidated balance sheet. The cost of product shipped to customers that has not been recognized as revenue in accordance with the Company's policy is deferred until the product is dispensed through patient prescriptions.

Under the Company's collaboration agreements with MedImmune and Beckman Coulter, the Company is entitled to receive non-refundable license fees, milestone payments and other research and development payments. Payments received are initially deferred from revenue and subsequently recognized when earned. The Company must make significant estimates in determining the performance period and periodically review these estimates, based on joint management committees and other information shared by the Company's collaborators. The Company recognizes these revenues over the estimated performance period as set forth in the contracts based on proportional performance and adjusted from time to time for any delays or acceleration in the development of the product. For example, a delay or acceleration of the performance period by the Company's collaborator may result in further deferral of revenue or the acceleration of revenue previously deferred. Because MedImmune and Beckman Coulter can each cancel its agreement with us, the Company does not recognize revenues in excess of cumulative cash collections. It is difficult to estimate the impact of the adjustments on the results of the Company's operations because, in each case, the amount of cash received would be a limiting factor in determining the adjustment.

At December 31, 2006 and 2005, the Company's account receivable balance was net of allowances of $24,000 and $21,000, respectively.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash equivalents, short-term investments, accounts receivable, accounts payable, accrued expenses, long term debt and capital lease obligations, approximate their fair values.

Concentrations of Credit Risk and Limited Suppliers

SFAS No. 105, *Disclosure of Information about Financial Instruments with Off-Balance-Sheet Risk and Financial Instruments with Concentrations of Credit Risk*, requires disclosure of any significant off-balance-sheet and credit risk concentrations. The Company has no off-balance-sheet or concentrations of credit risk related to foreign exchange contracts, options contracts or other foreign hedging arrangements.

The financial instruments that potentially subject the Company to concentrations of credit risk are cash, cash equivalents, short-term investments and accounts receivable. The Company's cash, cash equivalents and short-term investments are maintained with highly-rated commercial banks 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 the zileuton active pharmaceutical ingredient pursuant to a long-term supply agreement with one supplier. 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 ZYFLO or a significant increase in the cost of the active pharmaceutical ingredient

from these sources could have a material adverse effect on the Company's business, financial position and results of operations.

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 summarize the number of customers that individually comprise greater than 10% of total billings, some of which have been recognized as revenue in 2006 and 2005, and their aggregate percentage of the Company's total billings for the year ended December 31, 2006 and 2005 and the number of customers that comprise more than 10% of total account receivable and their aggregate percentage of the Company's total account receivable at December 31, 2006 and 2005:

	Year Ended December 31	
	2006 Billings	2005 Billings
Company A	18%	30%
Company B	37%	29%
Company C	40%	26%
Total	95%	85%

	December 31,	
	2006 Accounts Receivable	2005 Accounts Receivable
Company A	42%	—
Company B	37%	61%
Company C	19%	—
Company D	—	11%
Total	98%	72%

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have previously been included in either the Company's consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the differences between the financial accounting and tax bases of assets and liabilities using tax rates expected to be in effect for the year in which the differences are expected to reverse. A valuation allowance is provided against net deferred tax assets where management believes it is more likely than not that the asset will not be realized.

Stock-Based Compensation

Prior to January 1, 2006, the Company accounted for stock-based awards to employees using the intrinsic-value method as prescribed by Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB No. 25"), and related interpretations and the disclosure provisions of SFAS 123. Accordingly, no compensation expense was recorded for options issued to employees in fixed amounts and with fixed exercise prices at least equal to the fair market value of the Company's common stock at the date of grant. Conversely, when the exercise price for accounting purposes was below fair value of the Company's common stock on the date of grant, a non-cash charge to compensation expense was recorded ratably over the term of the option vesting period in an amount equal to the difference between the value calculated using the exercise price and the fair value. The Company issued options prior to March 19, 2004, the date it filed its initial registration statement on Form S-1 ("Form S-1"), with the Securities and Exchange Commission, at values less than deemed fair market

value. This resulted in recording deferred compensation, which has been, and continues to be, recognized in operations over the respective vesting periods.

Effective January 1, 2006, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payments* ("SFAS No. 123(R)"), using the modified prospective application method, which allows the Company to recognize compensation cost for granted, but unvested, awards, new awards and awards modified, repurchased, or cancelled after the required effective date. In addition, the Company elected the simplified method of calculating the Company's APIC Pool as prescribed by SFAS No. 123(R). Options granted to employees prior to the date of the initial Form S-1 filing continue to be accounted for under APB No. 25.

As a result of adopting SFAS No. 123(R), the Company's net loss for the year ended December 31, 2006 is $7.1 million higher than if it had continued to account for share-based compensation under APB No. 25. Had the Company not adopted SFAS No. 123(R), basic and diluted net loss for the year ended December 31, 2006 would have been $(1.17) per share compared to reported basic and diluted net loss of $(1.37) per share.

For the years ended December 31, 2005 and 2004, had employee compensation expense been determined based on the fair value at the date of grant consistent with SFAS No. 123, the Company's pro forma net loss and pro forma net loss per share would have been as follows:

	Year Ended December 31,	
	2005	2004
	(in thousands, except loss per share data)	
Net loss — as reported	$(47,090)	$(33,303)
Add: Stock-based compensation expense included in reported net loss	1,757	1,784
Deduct: Stock-based compensation expense determined under fair value method	(3,398)	(1,162)
Net loss — pro forma	$(48,731)	$(32,681)
Net loss per share (basic and diluted):		
As reported	$ (1.61)	$ (2.28)
Pro forma	$ (1.67)	$ (2.23)

Estimates of the fair value of future equity awards will be affected by the future market price of the Company's common stock, as well as the actual results of certain assumptions used to value the equity awards. These assumptions include, but are not limited to, the expected volatility of the common stock, the number of stock options to be forfeited and exercised by employees, and the expected term of options granted. The Company has computed the impact under SFAS No. 123(R) for options granted and restricted stock issued using the Black-Scholes option-pricing model for the year ended December 31, 2006. The Company increased its assumption for the year ended December 31, 2006 regarding expected volatility to 61%, from 59% in 2005 based on the Company's actual historical volatility since its initial public offering. In 2006, the Company performed an annual assessment of its forfeiture rate. As a result, the Company increased its forfeiture rate to 10.2% from 4.2% in 2006. In addition, the Company increased its assumption for the year ended December 31, 2006 regarding expected life to 6.25 years from 4 years in

prior years. The expected life of options granted was estimated using the simplified method calculation as prescribed by SFAS No. 123(R). The assumptions used and weighted-average information are as follows:

	Year Ended December 31,		
	2006	2005	2004
Risk free interest rate	4.8%	4.1%	3.3%
Expected dividend yield	0%	0%	0%
Expected forfeiture rate	10.2%	N/A	N/A
Expected life	6.25 years	4 years	4 years
Expected volatility	61%	59%	100%
Weighted-average fair value of options granted equal to fair value	$ 2.58	$ 3.26	$ 4.38
Weighted-average fair value of options granted below to fair value	N/A	N/A	$ 3.73

All stock-based awards to non-employees are accounted for at their fair market value in accordance with SFAS No. 123(R) and Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services,* ("EITF No. 96-18"). The Company periodically remeasures the fair value of the unvested portion of stock-based awards to non-employees, resulting in charges or credits to operations in periods when such remeasurement results in differences between the fair value of the underlying common stock and the exercise price of the options that is greater than or less than the differences, if any, between the fair value of the underlying common stock and the exercise price of the options at their respective previous measurement dates.

Because the Company has accumulated net operating losses as of December 31, 2006, option exercises may result in a tax deduction prior to the actual realization of the related tax benefit. As such, a tax benefit and a credit to additional paid-in capital for the excess deduction would not be recognized until the deduction reduces taxes payable.

Basic and Diluted Loss per Share

Basic and diluted net loss per common share is calculated by dividing the net loss or net loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share, because the effects of potentially dilutive securities are antidilutive for all periods presented. Antidilutive securities that are not included in the diluted net loss per share calculation aggregated 12,992,960, 9,809,751 and 4,776,922 as of December 31, 2006, 2005 and 2004, respectively. These antidilutive securities consist of outstanding stock options, warrants and unvested restricted common stock as of December 31, 2005 and 2006 and outstanding stock options and unvested restricted common stock as of December 31, 2004.

The following table reconciles the weighted-average common shares outstanding to the shares used in the computation of basic and diluted weighted-average common shares outstanding:

	Year Ended December 31,		
	2006	2005	2004
Weighted-average common shares outstanding	35,598,531	29,405,045	15,077,169
Less: weighted-average restricted common shares outstanding	69,483	128,802	445,798
Basic and diluted weighted-average common shares outstanding	35,529,048	29,276,243	14,631,371

Accretion of Dividends and Offering Costs on Preferred Stock

Prior to the Company's initial public offering, holders of preferred stock had a right to receive dividends at a stated rate per share. The Company recorded accretion of these dividends as well as offering costs in order to arrive at the net loss available to common stockholders in the periods prior to the initial public offering. Upon conversion of the preferred stock into common stock, the holders of preferred stock, pursuant to the terms of the preferred stock, forfeited all cumulative accrued dividends which as of June 2, 2004 totaled $5.7 million.

Comprehensive Loss

Comprehensive loss is the total of net loss and all other non-owner changes in equity. The difference between net loss, as reported in the accompanying consolidated statements of operations for the years ended December 31, 2006, 2005 and 2004, respectively, and comprehensive loss is the unrealized gain (loss) on short-term investments for the period. Total comprehensive loss was $48.7 million, $46.8 million and $31.5 million for the years ended December 31, 2006, 2005 and 2004, respectively. The unrealized loss on investments is the only component of accumulated other comprehensive loss in the accompanying consolidated balance sheet as of December 31, 2006 and 2005.

Disclosure about Segments of an Enterprise

The Company follows the provisions of SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*. SFAS No. 131 establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. SFAS No. 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 maker, as defined under SFAS No. 131, is the chief executive officer. The Company believes it operates in one segment which includes its product sales. The financial information disclosed in this report represents all of the material financial information related to the Company's one operating segment. All of the Company's revenues are generated in the United States and all assets are located in the United States.

Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board ("FASB") issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109* ("FIN 48"), which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FAS 109 and prescribes a recognition threshold and measurement attribute

for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective beginning with the first annual period after December 15, 2006. The Company does not expect the adoption of FIN 48 to significantly affect its financial condition or results of operations.

In September 2006, the FASB issued Statement No. 157, *Fair Value Measurements* ("FAS 157"), which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. FAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company does not expect the adoption of FAS 157 to significantly affect its financial condition or results of operations.

In September 2006, the Securities and Exchange Commission released Staff Accounting Bulletin No. 108 ("SAB 108") to address diversity in practice regarding consideration of the effects of prior year errors when quantifying misstatements in current year financial statements. The staff of the Securities and Exchange Commission concluded that registrants should quantify financial statement errors using both a balance sheet approach and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. SAB 108 states that if correcting an error in the current year materially affects the current year's income statement, the prior period financial statements must be restated. SAB 108 is effective for fiscal years ending after November 15, 2006. The adoption of SAB 108 did not significantly affect the Company's financial condition or results of operations.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an amendment of SFAS 115* ("FAS 159"), which permits companies to choose to measure many financial instruments and certain other items at fair value. FAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company is currently evaluating the effect FAS 159 will have on our consolidated financial position and results of operations.

(3) Collaboration Agreements

MedImmune

In July 2003, the Company entered into an exclusive license and collaboration agreement with MedImmune to jointly develop therapeutic products. Under the agreement, the Company has granted MedImmune an exclusive, worldwide royalty bearing license in exchange for a license fee, research funding, research and development milestone payments and royalties on product sales. The Company is required to perform certain research activities under an agreed upon research plan. The original term of the research plan was expected to be approximately 41 months which began on July 30, 2003. In 2005, the Company changed its estimate of the term covered by the research plan to 47 months which resulted in a decrease in revenue recognized of approximately $237,000 in 2005. During the term of the research plan, the Company has received research funding from MedImmune based on the number of full time equivalents employed by the Company for the purposes of executing the research plan. No performance is required of the Company subsequent to the research period. MedImmune will be responsible for subsequent product development and commercialization. All payments made to the Company under the agreement are non-refundable. In 2006, the Company revised its estimate of remaining total costs to be incurred under the collaboration agreement with MedImmune. The change in estimate resulted in a increase in revenue recognized of approximately $2.0 million in 2006.

In connection with this agreement, the Company received $12.5 million in up front license fees and research funding which was paid in two installments: $10.0 million in late 2003 and $2.5 million in early

2004. In 2005 the Company reached a specified milestone and received $1.25 million from MedImmune. In the event that specified research and development and commercialization milestones are achieved, MedImmune will be obligated to make further payments to the Company. In addition, the Company received approximately $1.0 million, $1.5 million and $1.5 million in research funding from MedImmune in each of the years ended December 31, 2006, 2005 and 2004.

Revenue under this arrangement is being recognized under a proportional performance model. During 2006, 2005 and 2004, the Company recognized revenue of approximately $6.3 million, $5.7 million and $4.4 million, respectively, under this agreement. As of December 31, 2006 and 2005, the Company had deferred revenue of approximately $275,000 and $5.6 million, respectively, related to this agreement. The deferred revenue consists of a portion of the up-front payments, milestone and research funding received in advance of revenue recognized under the agreement.

Beckman Coulter

In January 2005, the Company entered into a license agreement with Beckman Coulter, Inc., or Beckman Coulter, under which the Company granted to Beckman Coulter and its affiliates an exclusive worldwide license to patent rights and know-how controlled by the Company relating to the use of high mobility group box protein 1, or 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 or on behalf of the Company.

In consideration for the license, Beckman Coulter paid the Company a product evaluation license fee of $250,000 in February 2005. Beckman Coulter also agreed to pay the Company additional license fees of $400,000 upon the occurrence of the exercise by Beckman Coulter of its option to undertake formal product development and $450,000 upon the achievement of the first commercial sale of a licensed product. Beckman Coulter also agreed to pay the Company royalties based on net sales of licensed products by Beckman Coulter and its affiliates. Beckman Coulter has the right to grant sublicenses under the license subject to the Company's written consent, which the Company has agreed not to unreasonably withhold. Beckman Coulter agreed to pay the Company a percentage of any license fees, milestone payments or royalties actually received by Beckman Coulter from its sublicensees. Beckman Coulter exercised its development option under the license agreement in December 2006 and paid the Company $400,000 in January 2007. This amount is included in amounts due under collaboration agreements and revenue deferred under collaboration agreements in the December 31, 2006 balance sheet.

(4) Inventory

As of December 31, 2006 the Company held $4.0 million in inventory to be used for commercial sales of ZYFLO, net of reserves. At December 31, 2006, the Company had a reserve for inventory of approximately $119,000 related to raw material that did not meet Company specification. In 2005, the Company reserved for inventory approximately $280,000 related to finished goods with an expiration date that would make it unlikely to be sold. Inventory consisted of the following at December 31 (in thousands):

	2006	2005
Raw material	$3,662	$1,425
Work in process	83	332
Finished goods	422	392
Total	4,167	2,149
Less reserve	(119)	(280)
Inventory, net	$4,048	$1,869

(5) Fixed Assets

Fixed assets consisted of the following at December 31 (in thousands):

	2006	2005
Laboratory equipment	$ 1,219	$ 2,087
Computer and office equipment	689	747
Equipment in process	686	599
Furniture and fixtures	488	550
Software	484	443
Leasehold improvements	280	280
Assets held under capital lease	32	125
Total	3,878	4,831
Less accumulated depreciation and amortization	(1,457)	(1,268)
Fixed assets — net	$ 2,421	$ 3,563

In 2005, the Company entered into a capital lease arrangement primarily for computers for its sales force totaling $125,000. Assets acquired under capital lease agreements were initially recorded at the present value of the future minimum rental payments using interest rates appropriate at the inception of the lease. Property and equipment subject to capital lease agreements are amortized over the shorter of the life of the lease or the estimated useful life of the asset. Included in laboratory equipment are assets held for sale valued at $298,000. Depreciation and amortization expense on fixed assets for the years ended December 31, 2006, 2005 and 2004 was approximately $939,000, $800,000 and $1.1 million, respectively. In 2006, the Company adjusted accumulated depreciation by approximately $750,000 related to assets with a net book value of $872,000 that the Company deemed impaired as part of its 2006 restructuring and assets retired during the year ended December 31, 2006.

(6) Long Term Debt

In June 2002, the Company entered into a loan and security agreement (the "Agreement") with a lender that allowed the Company to borrow up to $2.25 million to finance the purchase of equipment and

$750,000 to finance leasehold improvements through June 30, 2003. In connection with the Agreement, the Company issued warrants to purchase 90,000 shares of Series A Redeemable Convertible Preferred Stock. During 2004, the holder exercised the warrants issued under the Agreement.

In June 2004, the Company entered into a modification to the Agreement. The modification gave the Company the ability to borrow up to an additional $3.0 million under the Agreement from July 1, 2004 to December 31, 2004. In 2005, the Company had additional borrowing capacity up to an amount equal to the lesser of (i) $3.0 million minus the principal amount of advances made in 2004 or (ii) $1.3 million. In January 2006, the Company entered into another loan modification agreement that allowed the Company to borrow up to an additional $500,000 under the Agreement through March 31, 2006. No advances were made in 2006 under the modified Agreement. At December 31, 2006, the Company had no borrowing capacity available under the modified Agreement or any other credit agreement. Advances made under the modified Agreement accrue interest at a rate equal to the prime rate plus 2% per year and are required to be repaid in equal monthly installments of principal plus interest accrued through the date of repayment. The repayment terms for advances made under this modification are between 36 and 42 months. In connection with the original Agreement, the Company granted the lender a first priority security interest in substantially all of the Company's assets, excluding intellectual property, to secure the Company's obligations under the Agreement. During the year ended December 31, 2005, the Company borrowed $1.3 million under the modified Agreement.

As of December 31, 2006, there was $1.4 million in debt outstanding under the modified Agreement. The outstanding borrowings bear interest at a weighted average interest rate of approximately 10.1% with rates ranging from 8.6% to 10.25%.

The repayments of principal and interest are scheduled to be made as follows (in thousands):

	Principal	Interest	Total
2007	998	96	1,094
2008	420	17	437
	$1,418	$113	$1,531

(7) Stockholders' Equity (Deficit)

2006 Registered Offering

In October 2006, the Company sold 7,455,731 shares of its common stock at a price of $2.68 per share, together with warrants to purchase an additional 3,727,865 shares of common stock, for a total purchase price of $20.0 million. The sales were made in a registered offering conducted as a direct placement through a placement agent. The net proceeds from the offering were approximately $18.5 million, after deducting placement agents fees and other offering costs of approximately $1.5 million.

The warrants issued in connection with the offering have an exercise price per share of $2.62 per share, with a five-year life and are fully vested and exercisable from October 26, 2006. The warrants have been included in equity at their fair value of $5.7 million. The fair value of the warrants was determined using the Black-Scholes model with the following assumptions: dividend yield of 0%; estimated volatility of 64%; risk-free interest rate of 4.51% and a contractual life of five years. As of December 31, 2006, none of these warrants had been exercised.

2005 Private Placement

In June 2005, the Company sold 9,945,261 shares of its common stock at a price of $5.48 per share, together with warrants to purchase an additional 3,480,842 shares of common stock, for a total purchase

price of $54.5 million in a private placement. The sales were made to institutional and other accredited investors. The net proceeds from the private placement were approximately $51.4 million, after deducting placement agents fees and other offering costs of approximately $3.1 million.

In connection with this private placement, the Company issued and sold an aggregate of 5,200,732 shares of common stock and warrants to purchase 1,820,257 shares of common stock to existing stockholders and affiliated entities associated with four members of the Company's Board of Directors. These holders paid an aggregate consideration of $28.5 million and participated on the same terms as the other purchasers in the private placement.

The warrants issued in connection with the private placement have an exercise price per share of $6.58, with a five-year life and are fully vested and exercisable from June 20, 2005. The warrants may also be exercised on a cashless basis at the option of the warrant holder. The warrants have been included in permanent equity at their fair value of $9.2 million. The fair value of the warrants was determined using the Black-Scholes model with the following assumptions: dividend yield of 0%; estimated volatility of 58%; risk-free interest rate of 3.65% and a contractual life of five years. As of December 31, 2006, none of these warrants had been exercised.

Initial Public Offering of Common Stock

In June 2004, the Company sold 6,000,000 shares of its common stock in its initial public offering at a price to the public of $7.00 per share. The Company sold an additional 110,000 shares at a price to the public of $7.00 per share pursuant to the partial exercise of the underwriters' over-allotment option. The Company received gross proceeds of $42.8 million, of which $3.0 million was paid as an underwriting discount. Additional expenses related to the offering totaled approximately $2.0 million.

Conversion of Preferred Stock into Common Stock

In connection with the Company's initial public offering of common stock, all of the Company's issued and outstanding redeemable convertible preferred stock converted to common stock at a ratio of one share of common stock for each 3.75 shares of preferred stock then outstanding. Accordingly, on June 2, 2004, 60,410,237 shares of preferred stock converted into 16,109,403 shares of common stock. The par value and additional paid-in capital related to the redeemable convertible preferred stock totaling $81.8 million was reclassified to common stock in the Company's balance sheet.

Prior to the Company's initial public offering, holders of preferred stock had a right to receive dividends at a stated rate per share. The Company recorded accretion of these dividends as well as offering costs in order to arrive at the net loss available to common stockholders in the periods prior to the initial public offering. Under the terms of the preferred stock, accrued dividends totaling $5.7 million were forfeited in connection with this conversion to common stock.

Authorized Capital

As of December 31, 2006, the authorized capital stock of the Company consists of 90,000,000 shares of voting common stock ("common stock") with a par value of $0.001 per share, and 5,000,000 shares of undesignated preferred stock ("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.

Restricted Common Stock Issuances to Non-Employees

The Company has made several grants of restricted common stock to non-employees since its inception. Many of these restrictions have lapsed, and therefore, no longer require periodic remeasurement in our financial statements.

During 2002, the Company issued 43,998 shares of common stock to its founders, who are non-employees, subject to restriction, for total proceeds of $16,500. The shares vested as follows: 10,999 of the shares vested in October 2003, with the remaining 32,999 shares vesting monthly from November 2003 through October 2006. As of December 31, 2006, the shares are fully vested.

During 2001, the Company issued 27,259 shares of common stock subject to restrictions and vesting, as partial consideration for a sponsored research and licensing agreement with the Feinstein Institute (see Note 11). 25% of the shares vested immediately, 25% vested in 2001, 25% vested on July 1, 2006, and the remaining 25%, or 6,815 shares, will vest on July 1, 2007.

Compensation to date associated with the restricted stock issued to non-employees has been measured as the difference between the fair value of the shares and the amount paid by the holder. Final measurement occurs when performance is complete which is assumed to be when the restrictions lapse. The Company did not issue restricted stock to non-employees in 2006, 2005 or 2004. The Company reduced by approximately $62,000 and $137,000 its previously recorded deferred stock-based compensation for years ended December 31, 2006 and 2005, respectively, and recorded stock-based compensation expense of $862,000 for the year ended December 31, 2004 related to these shares. These amounts are included in operating expenses in the accompanying consolidated statement of operations.

(8) Equity Incentive Plans

2006 Stock Purchase Plan

On February 23, 2006, the Company's Board of Directors adopted, and on April 25, 2006, the Company's stockholders approved, the Company's 2006 Employee Stock Purchase Plan (the "2006 Stock Purchase Plan") for the issuance of up to 400,000 shares of the Company's common stock to participating employees. The 2006 Stock Purchase Plan is implemented by offering periods with a duration of six months. Offerings begin each June 1 and December 1, or the first business day thereafter, and first commenced June 1, 2006.

On the first day of an offering period, the Company grants to each eligible employee who has elected to participate in this plan a purchase right for shares of common stock. The employee may authorize up to 15% of his or her compensation to be deducted during the offering period. On the last business day of the offering period, the employee will be deemed to have exercised the purchase right, at the applicable purchase price per share, to the extent of accumulated payroll deductions. The purchase price per share under this plan is 85% of the lesser of the closing price per share of the common stock on the NASDAQ Global Market on the first day of the offering period or the last business day of the offering period. The 2006 Stock Purchase Plan may be terminated at any time by the Company's Board of Directors.

For the plan period ended November 30, 2006, the Company issued 13,360 shares of the Company's common stock to participating employees.

2004 Stock Incentive Plan

On April 7, 2004, the Company's Board of Directors adopted, and on May 6, 2004 the Company's stockholders approved, the 2004 Stock Incentive Plan (the "2004 Stock Plan") for the issuance of up to 3,680,000 shares of common stock to be granted through incentive stock options, nonqualified stock

options, and restricted common stock to key employees, directors, consultants, and vendors of the Company and its affiliates.

On March 15, 2005, the Company's Board of Directors adopted, and on June 17, 2005 the Company's stockholders approved, an amendment the 2004 Stock Plan to increase the total number of shares available by 860,000.

Effective January 1, 2006, the Company's Board of Directors amended the 2004 Stock Plan to increase the total number of shares authorized for issuance by an additional 1,333,333, bringing the total authorized under the 2004 Stock Plan to 5,873,333 shares.

The exercise price of stock options is determined by the compensation committee of the 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. Options generally become exercisable over a period of four years from the date of grant, and expire ten years after the grant date.

2003 Stock Incentive Plan

On September 29, 2003, the Company's Board of Directors and stockholders adopted the 2003 Stock Incentive Plan (the "2003 Stock Plan") for the issuance of incentive stock options, nonqualified stock options, and restricted common stock to key employees, directors, consultants, and vendors of the Company and its affiliates. On December 9, 2003, the Company's Board of Directors amended the 2003 Stock Plan to increase the total number of shares available to 1,590,666 from 524,000, plus the 284,739 shares available from the 2000 Equity Plan. On June 2, 2004, in connection with the adoption of the 2004 Stock Plan, the Company transferred the 132,561 remaining shares of common stock available for award in the 2003 Stock Plan to the 2004 Stock Plan, subject to future adjustment based upon further cancellations in the 2003 Stock Plan or the 2000 Equity Plan. Accordingly, there are no shares of common stock available for award under the 2003 Stock Plan at December 31, 2006.

Under the terms of the 2003 Stock Plan, the exercise price of incentive stock options granted was established by the Board of Directors. The vesting provisions for stock options and restricted stock are established by the Board of Directors.

2000 Equity Incentive Plan

On July 14, 2000, the Company's Board of Directors and Company stockholders adopted the 2000 Equity Incentive Plan (the "2000 Equity Plan") for the issuance of incentive stock options, nonqualified stock options, and restricted common stock to key employees, directors, consultants, and vendors of the Company and its affiliates. On October 24, 2002, the Company's Board of Directors amended the 2000 Equity Plan to increase the total number of shares available to 4,000,000 from 2,000,000. On September 29, 2003, in connection with the adoption of the 2003 Stock Plan, the Company transferred the 284,739 remaining shares of common stock available for award in the 2000 Equity Plan to the 2003 Stock Plan, subject to future adjustments. Accordingly, there are no shares of common stock available for award at December 31, 2006.

Under the terms of the 2000 Equity Plan, the exercise price of incentive stock options granted must not be less than the fair market value of the common stock on the date of grant, as determined by the Board of Directors. The exercise price of nonqualified stock options and the purchase price of restricted common stock may be less than the fair market value of the common stock on the date of grant, as determined by the Board of Directors, but in no case may the exercise price or purchase price be less than the statutory minimum. The vesting provisions for stock options and restricted stock are established by the Board of Directors.

The following table summarizes stock option activity under all of the plans:

	Number of Shares	Weighted-Average Exercise Price
Outstanding — January 1, 2004	1,862,229	$0.87
Granted	2,906,621	6.12
Exercised	(221,902)	0.80
Cancelled	(46,678)	4.39
Outstanding — December 31, 2004	4,500,270	4.23
Granted	2,025,900	6.70
Exercised	(96,235)	1.64
Cancelled	(229,829)	5.54
Outstanding — December 31, 2005	6,200,106	5.03
Granted	3,428,000	4.10
Exercised	(752,241)	0.82
Cancelled	(3,161,095)	5.81
Outstanding — December 31, 2006	5,714,770	$4.60
Vested or expected to vest — December 31, 2006	4,640,100	$4.69
Exercisable — December 31, 2004	717,176	$1.10
Exercisable — December 31, 2005	1,809,920	$3.42
Exercisable — December 31, 2006	2,055,785	$4.92

The options outstanding and exercisable at December 31, 2006 under the plans are as follows:

	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
$0.38-$1.05	583,947	6.9	$1.02	488,991	$1.02
$1.88	677,660	10.0	$1.88	10,730	$1.88
$2.05-$3.71	308,000	9.8	$2.69	13,333	$2.57
$3.80	984,999	9.5	$3.80	59,999	$3.80
$4.00-$5.63	815,726	8.2	$5.26	366,269	$5.42
$5.64-$5.78	61,853	8.3	$5.75	30,498	$5.75
$5.99	712,839	7.7	$5.99	421,768	$5.99
$6.00-$6.80	598,294	8.2	$6.46	297,658	$6.50
$6.83-$7.12	687,808	8.7	$7.01	196,429	$6.98
$7.25-$9.05	283,644	8.1	$7.83	170,110	$7.83
	5,714,770	8.6	$4.60	2,055,785	$4.92

The weighted-average fair value of stock option grants using the Black-Scholes option pricing model were $2.58, $3.26 and $4.30 per share in 2006, 2005 and 2004, respectively.

The weighted average remaining contractual term and the aggregate intrinsic value for options outstanding at December 31, 2006 were 8.6 years and $705,000, respectively. The weighted average remaining contractual term and the aggregate intrinsic value for options vested or expected to vest at December 31, 2006 were 8.4 years and $658,000, respectively. The weighted average remaining contractual term and the aggregate intrinsic value for options exercisable at December 31, 2006 were 7.8 years and

$503,000, respectively. The total intrinsic value of the options exercised during the years ended December 31, 2006, 2005 and 2004 was approximately $1.4 million, $567,000 and $242,000, respectively.

During the fourth quarter of 2006, the Company issued 556,100 shares of restricted common stock to employees. These shares vest 50% on the first anniversary of the grant date and 50% on the second anniversary of the grant date. In addition, under the restricted stock agreements, 50% of all unvested restricted common stock vests upon a change in control event, as defined in the Company's 2004 Stock Incentive Plan. During 2002, the Company issued 172,344 shares of restricted common stock to employees for proceeds of $25,130 and a promissory note of $39,500. During 2001, the Company issued 22,666 shares of restricted common stock to employees for proceeds of $8,500. The restricted stock agreements from 2002 and 2001 provide for a repurchase feature, which generally lapses ratably over four years and were deemed to have been purchased by the employees at the then-fair value of the underlying common stock and, accordingly, are not considered to be compensatory. At December 31, 2006, the Company's right to repurchase restricted stock from employees had lapsed as to all shares that contain the repurchase provision.

The following table summarizes the restricted stock activity for the years ended December 31:

	2006		2005		2004	
	Number of Shares	Weighted-Average Grant-Date Fair Value	Number of Shares	Weighted-Average Grant-Date Fair Value	Number of Shares	Weighted-Average Grant-Date Fair Value
Nonvested at beginning of year	40,803	$0.38	103,613	$0.38	173,009	$0.38
Granted	556,100	2.00	—	—	—	—
Vested	(38,536)	0.38	(62,810)	0.38	(69,396)	0.38
Forfeited	(2,267)	0.38	—	—	—	—
Nonvested at end of year	556,100	$2.00	40,803	$0.38	103,613	$0.38

In the years ended December 31, 2006, 2005 and 2004 the Company recorded stock-based compensation of $7.2 million, $2.1 million and $3.6 million, respectively.

The following table summarizes deferred stock-based compensation activity for the years ended December 31:

	2006	2005	2004
Deferred Compensation Balance — Beginning	$(3,794)	$(6,101)	$(8,536)
Employees			
Amortization of deferred stock-based compensation	500	1,757	1,784
Deferred stock-based compensation	—	—	(523)
Reversal of deferred stock-based compensation	2,686	221	—
Non-employees			
Amortization of deferred stock-based compensation	—	384	1,778
Deferred stock-based compensation	(395)	(513)	(625)
Re-measure deferred stock-based compensation	904	458	21
Deferred Compensation Balance — Ending	$ (99)	$(3,794)	$(6,101)

Compensation expense for 2006 related to options issued to employees is included in the accompanying consolidated statement of operations as research and development, sales and marketing,

general and administrative and restructuring expense in the amounts of $1.7 million, $1.1 million, $4.2 million and $622,000, respectively. Compensation expense for 2005 related to these options is included in the accompanying consolidated statement of operations as research and development, sales and marketing and general and administrative expense in the amounts of $489,000, $119,000 and $1.2 million, respectively. Compensation expense for 2004 related to these options is included in the accompanying consolidated statement of operations as research and development and general and administrative expense in the amounts of $198,000 and $1.6 million, respectively.

During 2006 and 2005, all options issued to employees were granted at exercise prices equal to market value on the date of grant. During 2004, the Company issued options to employees to purchase 363,788 shares of common stock at exercise prices deemed for accounting purposes to be below fair market value. The Company has recorded the difference between the exercise price and the fair market value of $523,000 in 2004 as deferred stock-based compensation and is amortizing this deferred compensation as a charge to operations over the vesting periods of the options.

The following table summarizes the Company's stock-based compensation for the years ended December 31:

	2006	2005	2004
		(In thousands)	
Stock-based compensation			
Employees			
Stock-based compensation - adoption of 123R	$7,137	$ —	$ —
Stock compensation — Intrinsic value awards	500	1,757	1,784
Non-employees			
Stock-based compensation (reversals)	(395)	384	1,778
Total	$7,241	$2,141	$3,562

During 2006, 2005 and 2004, the Company granted 230,000, 161,000 and 51,333 options, respectively, to non-employees that are accounted for in accordance with SFAS No. 123(R) and the measurement guidance of EITF No. 96-18. The fair value of these awards was estimated using the Black-Scholes option-pricing methodology and was deemed to be $369,000 for 2006, $513,000 for 2005 and $278,000 for 2004. The Company adjusted its compensation expense by approximately $319,000 for the year ended December 31, 2006 and recorded compensation expense of approximately $520,000 and $916,000 related to these options for the years ended December 31, 2005 and 2004, respectively. The compensation adjustment in 2006 related to these options is included in the accompanying consolidated statement of operations as an adjustment of $330,000 in research and development expense offset by stock-based compensation expense of $11,000 in general and administrative expense. Compensation expense in 2005 related to these options is included in the accompanying consolidated statement of operations as research and development and general and administrative expense in the amounts of $512,000 and $8,000, respectively. Compensation expense in 2004 related to these options is included in the accompanying consolidated statement of operations as research and development and general and administrative in the amounts of $923,000 and ($7,000), respectively.

The total fair value of the options vested and unexercised (other than pre S-1 options vested) and expensed during the year ended December 31, 2006 was $1.7 million. As of December 31, 2006, there was $8.8 million of total unrecognized compensation expense (including the pre S-1 options) related to unvested share-based compensation awards granted under the Company's stock incentive plans, which is expected to be recognized over a weighted average period of 1.5 years.

The Company anticipates recording additional stock-based compensation expense of $3.7 million in 2007, $2.8 million in 2008 and $2.3 million thereafter relating to the amortization of unrecognized compensation expense as of December 31, 2006. These anticipated compensation expenses do not include any adjustment for new or additional options to purchase common stock granted to employees.

In December 2004, the Company entered into employment agreements with its officers. These agreements provide for, among other things, certain severance benefits and acceleration of vesting for stock options and restricted stock contingent upon future events such as a change-of-control of the Company. Because the terms in the employment agreements modified certain provisions of each officer's existing stock awards, a new measurement date was created for the awards. If a change-of-control occurs, the Company would be required to record the intrinsic value of any options or restricted stock that vest on the date of a change-of-control. The intrinsic value is calculated as the difference between the fair value of common stock on the date of remeasurement and the exercise price of the underlying stock option or the purchase price of restricted stock. As of December 31, 2006, there were 2.1 million unvested stock options and restricted stock subject to the modification. If a change-of-control were to occur and all of these securities were to vest, $4.7 million would be recorded as stock-based compensation expense.

(9) Employee Benefit Plan

During 2003, the Company adopted a 401(k) profit sharing plan (the "401(k) Plan") covering all employees of the Company who meet certain eligibility requirements. Under the terms of the 401(k) Plan, the employees may elect to make tax-deferred contributions through payroll deductions within statutory and plan limits and the Company may elect to make matching or voluntary contributions. During 2005 and 2004, the Company matched 100% of employee contributions up to a maximum of $1,000 per employee resulting in expense of $122,000 and $50,000, respectively. In November 2005, the Company's Board of Directors amended the 401(k) Plan, effective January 1, 2006, to provide a matching contribution to each participant of fifty percent of the participant's elective deferrals for a plan year up to six percent of the participant's salary up to a maximum of $3,000, which resulted in expense of $303,000 in 2006.

(10) Income Taxes

The Company's deferred tax accounts consisted of the following at December 31 (in thousands):

	2006	2005
Deferred tax assets:		
Net operating loss carryforward	$ 52,396	$ 30,033
Deferred revenue	756	2,483
Stock compensation	822	—
Research and experimentation credits	2,110	1,245
Start-up expenses	—	98
Depreciation and amortization	673	135
Other	385	(90)
Total	57,142	33,904
Less valuation allowance	(57,142)	(33,904)
Total	$ —	$ —

Because of the Company's limited operating history, management has provided a 100% valuation allowance against the Company's net deferred tax assets. For the year ended December 31, 2006, the

release tablets. The Company had previously contracted with Patheon for the manufacture of ZYFLO for clinical trials and regulatory review. Under the agreement, the Company is responsible for supplying the active pharmaceutical ingredient for ZYFLO to Patheon and Patheon is responsible for manufacturing the ZYFLO immediate release tablets and conducting stability testing. The Company has agreed to purchase at least 50% of its commercial supplies of ZYFLO immediate release tablets for sale in the United States from Patheon each year for the term of the agreement.

The commercial manufacturing agreement has an initial term of three years beginning on the date commercial manufacturing of the ZYFLO immediate release tablets commences and will automatically continue for successive one-year periods thereafter, unless the Company provides Patheon 12-months prior written notice of termination or Patheon provides the Company 18-months prior written notice of termination. If the Company provides six months advance notice that it intends to discontinue commercializing ZYFLO, the Company will not be required to purchase any additional quantities of ZYFLO immediate release tablets, provided that the Company pays Patheon for a portion of specified fees and expenses associated with orders previously placed by the Company.

Shasun Pharma Solutions Ltd.

In February 2005, the Company entered into an agreement with Rhodia Pharma Solutions Ltd ("Rhodia") for the manufacture of commercial supplies of the zileuton active pharmaceutical ingredient, ("API"). The Company had previously contracted with Rhodia to establish and validate a manufacturing process for the zileuton API and to manufacture supplies of the zileuton API sufficient for the Company's clinical trials. Under the new commercial supply agreement, Rhodia has agreed to complete its validation process at sites operated by Rhodia and to manufacture the Company's required commercial supplies of the zileuton API, subject to specified limitations, through December 31, 2009. In June 2006, Rhodia SA, the parent company of Rhodia, sold the European assets of its pharmaceutical custom synthesis business to Shasun Chemicals and Drugs Ltd. As part of this transaction, Rhoda SA assigned the Company's contract with Rhodia to Shasun Pharma Solutions Ltd.("Shasun").

The agreement will automatically extend for successive one-year periods after December 31, 2009, unless Shasun provides the Company with 18-months prior written notice of cancellation. The Company has the right to terminate the agreement upon 12-months prior written notice for any reason, provided that the Company may not cancel prior to January 1, 2008 for the purpose of retaining any other company to act as its exclusive supplier of the API.

In addition, under this agreement, the Company is committed to purchase a minimum amount of API in the fourth quarter of 2006, the first quarter of 2007 and in the first quarter of 2008. The API purchased from Shasun currently has a shelf-life of 24 months and a retest schedule of every 24 months. The Company evaluates the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, the Company is required to make judgments as to the future demand for current or committed inventory levels and as to the expiration dates of its product. While the purchase commitment for API from Shasun exceeds the Company's current forecasted demand in 2007, the Company expects that any excess API purchased in 2006 under its agreement with Shasun will be used in commercial production batches in 2007 and 2008 and sold before it requires retesting. Therefore no reserve for this purchase commitment has been recorded as of December 31, 2006.

Unless otherwise noted all milestone and other payments are included in research and development.

(12) Commitments and Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues for liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. For all periods presented, the Company is not a party to any pending material litigation or other material legal proceedings.

Lease Obligations

The Company leases its facilities, vehicles and certain computer equipment under operating leases. Rent expense under these operating leases for the years ended December 31, 2006, 2005 and 2004 was $1.8 million, $1.6 million and $1.9 million, respectively. The facility lease contains a rent escalation clause that requires the Company to pay additional rental amounts in the later years of the lease term. Rent expense for this lease is recognized on a straight-line basis over the minimum lease term. As such, the Company has recorded a liability for rent expense in excess of payments made-to-date. As of December 31, 2006, this liability totaled $183,000. Operating leases expire from July 2007 to March 2009. In addition, in 2005, the Company entered into a capital lease arrangement primarily for computers for its sales force totaling $125,000.

The minimum aggregate future obligations under non-cancelable lease obligations as of December 31, 2006 are as follows (in thousands):

Year Ending	Operating Leases	Capital Leases
2007	1,503	59
2008	1,436	5
2009	216	—
Total minimum lease payments	$3,155	$64
Less Amount representing interest		(5)
Present value of future minimum lease payments		59
Less current portion		(54)
Long-term portion		$ 5

Founders' Consulting Agreements

In January 2001, as amended in January 2003, each of the Company's three founders, one of whom was a member of the Company's Board of Directors, entered into a separate consulting agreement with the Company in which they contracted to provide consulting services to the Company. For the years ended December 31, 2006, 2005 and 2004, amounts paid under these agreements totaled $320,000, $313,000 and $305,000, respectively. In January 2007, two of the agreements were extended through January 1, 2008 for which the Company is obligated to make payments totaling $37,000.

The Company has entered into various agreements with third parties and certain related parties in connection with the research and development activities of its existing product candidates as well as discovery efforts on potential new product candidates. These agreements include costs for research and development and license agreements that represent the Company's fixed obligations payable to sponsor research and minimum royalty payments for licensed patents. These agreements include costs related to manufacturing, clinical trials and preclinical studies performed by third parties. The estimated amount that may be incurred in the future under these agreements totals approximately $11.4 million as of December 31, 2006. The amount and timing of these commitments may change, as they are largely

dependent on the rate of enrollment in and timing of the development of the Company's product candidates. Some of these agreements have been described in more detail in Note 11.

Consulting Agreement with Director

On October 25, 2006, the Company entered into a consulting agreement with a current member of its Board of Directors, under which the director agreed to provide the Company services related to commercial sales, marketing and business development initiatives and other such related projects. Under the consulting agreement, the Company has agreed to pay $1,800 per day and granted the director an option to purchase 200,000 shares of common stock under the 2004 Stock Plan. This option has an exercise price of $2.63 per share and will vest in 36 equal monthly installments commencing on November 25, 2006. In addition, 50% of the then unvested options will vest upon a change of control or specified transactions as set forth in the consulting agreement. The fair value of these stock options on the date of grant using the Black-Scholes valuation model was $330,000. The fair value of the stock option is expensed over the vesting period. The Company periodically remeasures the fair value of the unvested portion of the stock option, resulting in charges or credits to operations. During 2006, the Company recorded $13,000 in stock-based compensation expense related to this option grant. The consulting agreement has a term of twelve months and automatically renews on a month-to-month basis. The Company may terminate the consulting agreement upon three business days prior written notice to the director. The director may terminate the consulting agreement upon thirty days prior written notice. Through December 31, 2006 the Company paid $65,000 for consulting performed under the agreement and at December 31, 2006, $8,000 of consulting expense was included in accounts payable.

(13) Restructurings Charges

In May 2006, the Company recorded charges of $499,000 for a restructuring of its operations that was intended to better align costs with revenue and operating expectations. The restructuring charges included $95,000 in general and administrative expense, $231,000 in research and development expense and $173,000 in sales and marketing expense.

In connection with the May 2006 restructuring plan, the Company terminated 27 employees, or approximately 16% of the Company's workforce at the time, resulting in severance benefits of $383,000, which were accrued in May 2006. As a result of terminating these employees, the Company recorded automobile lease termination fees of $54,000, outplacement service fees of $39,000 and an impairment charge of $23,000 for computer equipment for which the future use is currently uncertain. At December 31, 2006, the Company had $9,000 remaining in accrued expenses related to the May restructuring.

In October 2006, the Company announced its plan to focus its resources on the commercialization of its controlled-release formulation of zileuton, or zileuton CR, for the chronic treatment of asthma and on the clinical development of the injectable formulation of zileuton and to significantly reduce its net cash expenditures through lower spending on its existing sales force as well as on its discovery and research programs, resulting in a second restructuring. As part of this new business strategy, the Company eliminated 60 positions, or approximately 50% of the Company's workforce at the time. The headcount reduction included 38 sales and marketing employees, 17 research and development employees and 5 employees performing general and administrative functions. The Company substantially completed this restructuring by December 31, 2006.

In connection with the implementation of its October 2006 restructuring, the Company recorded a charge of $3.0 million in the fourth quarter of 2006, consisting of severance benefits of $2.3 million, automobile lease termination fees of $216,000, outplacement service fees of $26,000 and an impairment charge and other related charges of $478,000 for laboratory equipment and computer equipment for which

the future use is currently uncertain. At December 31, 2006, the Company had $204,000 remaining in accrued expenses related to the October 2006 restructuring.

In addition, in 2006, the Company had $972,000 of severance and bonus expenses related to the resignation of its former President and Chief Executive Officer and its former Senior Vice President of Sales and Marketing, which are not included in the restructuring charges above. These amounts were paid in December 2006 in accordance with the contractual terms of the severance and release agreements signed by the individuals.

(14) Subsequent Events

IMI License Agreement

In January 2007, the Company entered into an exclusive license agreement (the "License Agreement") with Innovative Metabolics, Inc. ("IMI") under which the Company granted to IMI an exclusive worldwide license under patent rights and know-how controlled by the Company relating to the 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. The licensed field includes mechanical and electrical stimulation of the vagus nerve and excludes pharmacological modulation of a cholinergic receptor (including the nicotinic alpha-7 cholinergic receptor).

In consideration for the license, IMI agreed to pay the Company an initial license fee of $500,000 in cash and IMI preferred stock valued at $500,000. Under the License Agreement, IMI also agreed to pay $1.0 million upon the achievement of certain regulatory approvals and royalties based on net sales of licensed products and methods by IMI and its affiliates.

In addition, two founders of the Company, Kevin J. Tracey, M.D. and H. Shaw Warren, M.D., are founders of IMI. Dr. Warren served as a member of the Company's Board of Directors until October 2006. Dr. Tracey is a member of the medical staff at The Feinstein Institute. In addition, the Company is currently a party to consulting agreements with Dr. Tracey and Dr. Warren. These consulting agreements terminate on January 1, 2008. For the years ended December 31, 2006, 2005 and 2004, the Company paid consulting fees to Dr. Tracey of $147,000, $144,000 and $142,000, respectively, and paid consulting fees to Dr. Warren of $87,000, $84,000 and $82,000, respectively.

DEY Co-Promotion Agreement

On March 13, 2007, the Company entered into an agreement with DEY, L.P, an affiliate of Merck KGaA ("DEY"), under which the Company and DEY agreed to jointly promote ZYFLO and, if approved by the FDA, the controlled-release formulation of zileuton ("zileuton CR"). Under the co-promotion and marketing services agreement, the Company granted DEY an exclusive right and license to promote and detail ZYFLO and zileuton CR in the United States, together with the Company.

From 2008 through 2010, the Company and DEY each have agreed to contribute 50 percent of approved out-of-pocket promotion expenses for zileuton CR that are accrued or paid to third-parties. The Company and DEY each have agreed to contribute a minimum of $3.0 million per year for these promotion expenses. The Company is responsible for third-party promotion costs during 2007.

Under the co-promotion agreement, DEY paid the Company a non-refundable upfront payment of $3.0 million in March 2007. In addition, DEY has agreed to pay the Company milestone payments of $4.0 million following approval by the FDA of the NDA for zileuton CR and $5.0 million following commercial launch of zileuton CR. Under the co-promotion agreement, the Company will retain all quarterly net sales of ZYFLO and zileuton CR, after third party royalties, up to $1.95 million. The Company agreed to pay DEY a portion of quarterly net sales of ZYFLO and zileuton CR, after third-party royalties, in excess of $1.95 million. From the date DEY begins detailing ZYFLO through the commercial launch of zileuton CR, the Company has agreed to pay DEY 70% of quarterly net sales of

ZYFLO, after third party royalties, in excess of $1.95 million. Following the commercial launch of zileuton CR through December 31, 2010, the Company has agreed to pay DEY 35% of quarterly net sales, after third-party royalties, in excess of $1.95 million. From January 1, 2011 through December 31, 2013, the Company has agreed to pay DEY 20% of quarterly net sales, 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 upon mutual agreement by the parties.

The co-promotion agreement has a term expiring on December 31, 2013, which may be extended upon mutual agreement by the parties. Beginning three years after the commercial launch of zileuton CR, either party may terminate the co-promotion agreement with six-months advance written notice. If the commercial launch of zileuton CR is delayed beyond May 31, 2008, DEY has the right to terminate the co-promotion agreement on or before July 1, 2008 by providing written notice, which will be effective 60 days after receipt by the Company. If DEY exercises this termination right, the Company will be obligated to pay DEY $2.0 million if DEY has paid the Company the $4.0 million milestone related to the approval of the NDA for zileuton CR. In addition, DEY has the right to terminate the co-promotion agreement with two-months prior written notice if zileuton CR cumulative net sales for any four consecutive calendar quarters after commercial launch of zileuton CR are less than $25 million.

Under the co-promotion agreement, the Company granted DEY the exclusive right to negotiate with the Company for the development and commercialization, including co-promotion, of additional zileuton products in the United States for the treatment of asthma and, subject to FDA approval, other respiratory conditions. These exclusive negotiation rights are effective until September 1, 2007 with respect to zileuton injection and December 31, 2007 with respect to other zileuton products.

Binding Letter Agreement for COPD Co-Promotion

As contemplated by the terms of the zileuton co-promotion agreement with DEY, the Company and DEY entered into a separate binding letter agreement on March 13, 2007 providing for the Company to co-promote DEY's product candidate for chronic obstructive pulmonary disease ("COPD"), if approved by the FDA. Under the binding letter agreement, DEY agreed to pay the Company a co-promotion fee based on a percentage of net retail sales of DEY's product candidate for the number of units in excess of a specified level of unit sales. Under the binding letter agreement, the term of the co-promotion arrangement for DEY's COPD product candidate will expire upon termination of the zileuton co-promotion agreement.

Although the Company intends to enter into a more detailed written agreement relating to the co-promotion of DEY's product candidate, the terms of the binding letter agreement will govern the co-promotion of DEY's product candidate if the Company and DEY fail to agree upon a more detailed written agreement. The binding letter agreement provides that the Company and DEY anticipate that they will negotiate and execute a more detailed written agreement within 90 days of signing the binding letter agreement.

(15) Unaudited Quarterly Financial Data

The following table summarizes selected unaudited condensed quarterly financial information for 2006 and 2005. The Company believes that all adjustments, consisting of normal recurring adjustments

considered necessary for a fair presentation, have been included in the selected quarterly information (in thousands, except per share data).

	Quarter Ended December 31,	Quarter Ended September 30,	Quarter Ended June 30,	Quarter Ended March 31,
	(Unaudited) (In thousands except per share data)			
2006				
Revenues:				
Net product sales	$ 1,937	$ 1,879	$ 1,809	$ 1,022
Revenue under collaboration agreements	985	2,499	1,696	1,251
Total revenues	2,922	4,378	3,505	2,273
Cost of goods sold	(561)	(267)	(890)	(504)
Gross profit	2,361	4,111	2,615	1,769
Total operating expenses	(11,694)	(13,549)	(17,679)	(19,228)
Operating loss	(9,333)	(9,438)	(15,064)	(17,459)
Other income, net	581	558	661	712
Net loss	$ (8,752)	$ (8,880)	$(14,403)	$(16,747)
Net loss per share — basic and diluted	$ (0.22)	$ (0.26)	$ (0.42)	$ (0.49)
2005				
Revenues:				
Net product sales	$ 387	$ —	$ —	$ —
Revenue under collaboration agreements	1,712	1,335	1,431	1,359
Total revenues	2,099	1,335	1,431	1,359
Cost of goods sold	(514)	—	—	—
Gross profit	1,585	1,335	1,431	1,359
Total operating expenses	(17,030)	(16,025)	(11,148)	(10,833)
Operating loss	(15,445)	(14,690)	(9,717)	(9,474)
Other income, net	758	733	390	355
Net loss	$(14,687)	$(13,957)	$ (9,327)	$ (9,119)
Net loss per share — basic and diluted	$ (0.43)	$ (0.41)	$ (0.37)	$ (0.38)

Because of the method used in calculating per share data, the quarterly per share data will not necessarily add to the per share data as computed for the year.

deemed "soliciting material" or "filed" with the Securities and Exchange Commission or otherwise subject to the liabilities of Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that we specifically request that such information be treated as soliciting material or specifically incorporate such information by reference into a document filed under the Securities Act or the Exchange Act.

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 2007 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 2007 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 — Registered Public Accounting Firm's Fees" and "Corporate Governance — Pre-Approval Policy and Procedures" in the Proxy Statement for our 2007 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 80 of this annual report on Form 10-K.

(a)(2) *Financial Statement Schedules.*

All schedules are omitted because they are not applicable or the required information is included in the 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.

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.

CRITICAL THERAPEUTICS, INC.

By: /s/ FRANK E. THOMAS
Frank E. Thomas
President and Chief Executive Officer
Date: March 16, 2007

We, the undersigned officers and directors of Critical Therapeutics, Inc., hereby severally constitute and appoint Frank E. Thomas, Jeffrey E. Young 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 Critical 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 Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ FRANK E. THOMAS Frank E. Thomas	President and Chief Executive Officer and Director (Principal Executive Officer and Principal Financial Officer)	March 16, 2007
/s/ JEFFREY E. YOUNG Jeffrey E. Young	Vice President of Finance, Chief Accounting Officer and Treasurer (Principal Accounting Officer)	March 16, 2007
/s/ RICHARD W. DUGAN Richard W. Dugan	Director	March 16, 2007
/s/ NICHOLAS GALAKATOS Nicholas Galakatos, Ph.D.	Director	March 16, 2007
/s/ JEAN GEORGE Jean George	Director	March 16, 2007
/s/ CHRISTOPHER MIRABELLI Christopher Mirabelli, Ph.D.	Director	March 16, 2007
/s/ JAMES B. TANANBAUM James B. Tananbaum, M.D.	Director	March 16, 2007

Signature	Title	Date
/s/ CHRISTOPHER WALSH Christopher Walsh, Ph.D.	Director	March 16, 2007
/s/ ROBERT H. ZEIGER Robert H. Zeiger	Director	March 16, 2007
/s/ M. CORY ZWERLING M. Cory Zwerling	Director	March 16, 2007

Exhibit Index

Exhibit No.	Description
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	Second Amended and Restated Bylaws of the Registrant dated October 22, 2006 (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K dated October 25, 2006 (SEC File No. 000-50767)).
10.1*	2000 Equity Incentive Plan, as amended, of the Registrant (Incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.2*	2003 Stock Incentive Plan, as amended, of the Registrant (Incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.3*	2004 Stock Incentive Plan of the Registrant (Incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.4*	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)).
10.5*	2006 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K dated April 27, 2006 (SEC File No. 000-50767)).
10.6	Amended and Restated Investor Rights Agreement by and among the Registrant and the Investors named therein dated as of October 3, 2003 (Incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.7+	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)).
10.8++	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) dated January 1, 2003.
10.9+	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)).
10.10+	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 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)).
10.11+	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)).
10.12	Amendment No. 1, dated December 7, 2005, to the Registrant's Exclusive License and Collaboration Agreement with MedImmune, Inc. dated July 30, 2003 (Incorporated by reference to Exhibit 10.50 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005 (SEC File No. 000-50767)).
10.13+	License Agreement between the Registrant and Abbott Laboratories dated December 18, 2003 (Incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.14	Amendment No. 1, dated April 13, 2005, to License Agreement between the Registrant and Abbott Laboratories dated December 18, 2003.

Exhibit No.	Description
10.15+	License Agreement between the Registrant and Abbott Laboratories dated March 19, 2004 (Incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.16	Amendment No. 1, dated September 15, 2004, to License Agreement between the Registrant and Abbott Laboratories dated March 19, 2004.
10.17+	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)).
10.18+	Development and Scale-Up Agreement between the Registrant and Jagotec AG dated May 6, 2004 (Incorporated by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.19	Lease Agreement between ARE — 60 Westview Street, LLC and the Registrant dated as of November 18, 2003 (Incorporated by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.20+	Agreement for Manufacturing and Supply of ZILEUTON by and between Rhodia Pharma Solutions Ltd. and the Registrant dated February 8, 2005 (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)).
10.21	Loan and Security Agreement dated June 28, 2002, as modified by the Loan Modification Agreement dated as of December 11, 2002, the Second Loan Modification Agreement dated as of April 10, 2003, and the Third Loan Modification Agreement dated as of June 30, 2004 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004 (SEC File No. 000-50767)).
10.22	The Fourth Loan Modification Agreement dated as of January 6, 2006 to the Loan and Security Agreement by and between the Registrant and Silicon Valley Bank dated June 28, 2002 (Incorporated by reference to Exhibit 10.24 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005 (SEC File No. 000-50767)).
10.23+	Feasibility Study Agreement between Baxter Healthcare Corporation and the Registrant effective 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)).
10.24*	Form of Incentive Stock Option Agreement granted under 2004 Stock Incentive Plan (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)).
10.25*	Form of Nonstatutory Stock Option Agreement granted under 2004 Stock Incentive Plan (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)).
10.26*	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 26, 2006 ((SEC File No. 000-50767)).
10.27*	Form of Nonstatutory Stock Option Agreement for a Non-Employee Director granted under the 2004 Stock Incentive Plan (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)).
10.28*	Employment Agreement, dated April 26, 2006 by and between the Registrant and Dana Hilt, M.D. (Incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K dated May 1, 2006 (SEC File No. 000-50767)).
10.29*	Employment Agreement dated June 26, 2006 by and between the Registrant and Jeffrey E. Young (Incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K dated June 27, 2006 (SEC File No. 000-50767)).
10.30*	Employment Agreement dated December 21, 2004 by and between the Registrant and Trevor Phillips, Ph.D. (Incorporated by reference to Exhibit 99.3 to the Registrant's Current Report on Form 8-K dated December 21, 2004 (SEC File No. 000-50767)).
10.31*	Employment Agreement dated December 21, 2004 by and between the Registrant and Frank E. Thomas (Incorporated by reference to Exhibit 99.5 to the Registrant's Current Report on Form 8-K dated December 21, 2004 (SEC File No. 000-50767)).

Exhibit No.	Description
10.32*	Employment Agreement dated December 21, 2004 by and between the Registrant and Scott B. Townsend (Incorporated by reference to Exhibit 99.6 to the Registrant's Current Report on Form 8-K dated December 21, 2004 (SEC File No. 000-50767)).
10.33+	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, 2004 ((SEC File No. 000-50767)).
10.34	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 filed on June 23, 2005 (SEC File No. 000-50767)).
10.35	Form of Warrant (Included in Exhibit 10.34).
10.36	Form of Securities Purchase Agreement between the Registrant and certain Purchasers, dated June 6, 2005 (Incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K filed on June 7, 2005 (SEC File No. 000-50767)).
10.37++	Manufacturing Services Agreement between Patheon Pharmaceuticals Inc. and the Registrant, dated June 28, 2005 (Incorporated by Reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005 ((SEC File No. 000-50767)).
10.38*	Critical Therapeutics, Inc. Non-Employee Director Compensation and Reimbursement Policy.
10.39++	Exclusive License Agreement, dated as of January 29, 2007, between the Registrant and Innovative Metabolics, Inc. (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)).
10.40	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)).
10.41*	Consulting Agreement by and between the Registrant and M. Cory Zwerling, dated as of October 25, 2006 (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated October 25, 2006 (SEC File No. 000-50767)).
10.42*	Critical Therapeutics, Inc. 2007 Company Goals.
10.43*	Critical Therapeutics, Inc. 2006 Cash Bonuses for Executive Officers.
10.44*	Critical Therapeutics, Inc. 2007 Salaries for Executive Officers.
10.45*	Critical Therapeutics, Inc. Maximum Annual Cash Bonuses for Executive Officers.
10.46	Consulting Agreement by and between the Registrant and Kevin J. Tracey, M.D. dated January 31, 2001, as amended on January 16, 2003 (Incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.47	Approval Agreement dated March 7, 2006 by and between the Registrant and Kevin J. Tracey, M.D. (Incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005 (SEC File No. 000-50767)).
10.48	Amendment No. 2 to Consulting Agreement, Amendment No. 1 to Approval Agreement, and Mutual Release dated January 29, 2007 to the Consulting Agreement dated January 31, 2001 between the Registrant and Kevin J. Tracey, M.D., as amended, and the Approval Agreement dated March 7, 2006 by and between the Registrant and Kevin J. Tracey, M.D.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Deloitte & Touche LLP.
31.1	Certification of Principal Executive Officer and 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 and 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.

++ Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

stockholder information

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This annual report 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 expected timing and outcome of the New Drug Application, or NDA, submission for the controlled-release formulation of zileuton, or zileuton CR, possible therapeutic benefits and market acceptance of ZYFLO® (zileuton tablets) and, if approved, zileuton CR, the progress and timing of our drug development programs and related trials, the efficacy of our drug candidates, our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, may be forward-looking statements under the provisions 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," "will," "would" or 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" and risks relating to: the expected timing and outcome of the NDA for zileuton CR and related discussions with the U.S. Food and Drug Administration, or FDA; our ability to rely on historical data in seeking marketing approval for zileuton CR, including the sufficiency and acceptability of the results of the pharmacokinetic studies of zileuton CR for FDA purposes; our ability to successfully market and sell ZYFLO and, if approved, zileuton CR, including the success of our co-promotion arrangement with DEY, L.P.; our ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize ZYFLO and, if approved, zileuton CR; patient, physician and third-party payor acceptance of ZYFLO and, if approved, zileuton CR, as a safe and effective therapeutic product; adverse side effects experienced by patients taking ZYFLO and, if approved, zileuton CR; our ability to successfully enter into additional strategic co-promotion, collaboration or licensing transactions on favorable terms, if at all; conducting 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 heavy dependence on the commercial success of ZYFLO and, if approved, zileuton CR; our ability to obtain the substantial additional funding required to conduct our research, development and commercialization activities; our dependence on our strategic collaboration with MedImmune, Inc; and our ability to obtain, maintain and enforce patent and other intellectual property protection for ZYFLO, our discoveries and drug candidates. These and other risks are described in greater detail in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2006 and in other filings that we make with the Securities and Exchange Commission from time to time. 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 represent our views only as of the date of this annual report 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.

CORPORATE HEADQUARTERS

Critical Therapeutics, Inc.
60 Westview Street
Lexington, MA 02421
Phone: (781) 402-5700
Fax: (781) 402-5729
www.crtx.com

REGISTRAR AND TRANSFER AGENT

Questions regarding accounts, address changes, stock transfers and lost certificates should be directed to:

Mellon Investor Services LLC
480 Washington Boulevard
Jersey City, NJ 07310-1900

Domestic shareholders should call:
Phone: 1-800-288-9541
TTD for hearing impaired (domestic):
1-800-231-5469

Foreign shareholders should call:
Phone: 1-201-680-6578
TTD for hearing impaired (foreign):
1-201-680-6610

E-mail: www.melloninvestor.com

ANNUAL STOCKHOLDERS' MEETING

The Annual Meeting of Stockholders is scheduled to be held on Wednesday, May 2, 2007, at 10:00 a.m. local time at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, MA.

SEC FORM 10-K AND REQUESTS FOR INFORMATION

A copy of the Company's Annual Report on Form 10-K for the year ended December 31, 2006 as filed with the Securities and Exchange Commission is available without exhibits and free of charge upon request to:

Investor Relations
Critical Therapeutics, Inc.
60 Westview Street
Lexington, MA 02421
Phone: (781) 402-5700
E-mail: investor.relations@crtx.com

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Deloitte & Touche LLP
200 Berkeley Street
Boston, MA 02116

PRIMARY OUTSIDE LEGAL COUNSEL

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

HOLDERS

As of March 5, 2007, there were approximately 106 stockholders of record of our common stock. This may not be an accurate indication of the total number of beneficial owners of our common stock as of March 5, 2007 because many shares are held by nominees in street name for beneficial owners.

COMMON STOCK AND DIVIDEND INFORMATION

Critical Therapeutics, Inc. common stock is listed on the NASDAQ Global Market and is traded under the symbol "CRTX." The Company has never declared or paid cash dividends on its capital stock and anticipates that, for the foreseeable future, it will continue to retain any earnings for use in the operation of its business. The reported price range per share of Critical Therapeutics' common stock for each of the quarters in 2006 was as follows:

	Price Range		
Year Ended December 31, 2006	High	Low	Close
Fourth Quarter	$3.28	$1.45	$2.04
Third Quarter	$4.50	$2.08	$2.40
Second Quarter	$6.25	$3.28	$3.60
First Quarter	$7.41	$4.72	$5.09

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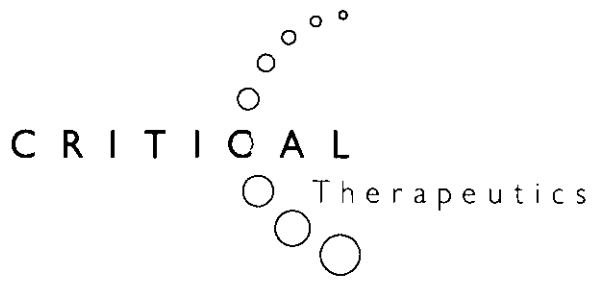

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END