

ALEXION PHARMACEUTICALS INC  
Form 10-K  
February 23, 2007  
Table of Contents

---

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-K**

---

**FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(D) OF  
THE SECURITIES AND EXCHANGE ACT OF 1934**

**x 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: 0-27756

---

**ALEXION PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

---

**Delaware** **13-3648318**  
(State or Other Jurisdiction of Incorporation or Organization) (I.R.S. Employer Identification No.)  
**352 Knotter Drive, Cheshire Connecticut 06410**  
(Address of Principal Executive Offices) (Zip Code)

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

203-272-2596

(Registrant's telephone number, including area code)

---

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

Common Stock, par value \$0.0001

Rights to Purchase Junior Participating

Cumulative Preferred Stock, par value \$.0001

Name of each exchange on which registered: 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 shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. Please see definition of accelerated and large accelerated filer in Rule 12b-2 of the Exchange Act. Check One:

Large Accelerated Filer:

Accelerated Filer:

Non-Accelerated Filer:

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based upon the last sale price of the Common Stock reported on the The Nasdaq Stock Market LLC on June 30, 2006, was approximately \$1.063 Billion.

The number of shares of Common Stock outstanding as of February 21, 2007 was 35,740,970.

Portions of the registrant's Definitive Proxy Statement to be used in connection with its Annual Meeting of Stockholders to be held on May 3, 2007, are incorporated by reference into Part III of this report.

---

**Table of Contents**

**PART I**

On December 9, 2005, our Board of Directors unanimously approved a change to our fiscal year end from July 31 to December 31. In view of this change, this Form 10-K includes financial information (i) for the five month transition period from August 1, 2005 to December 31, 2005, which we refer to as the transition period throughout this report and (ii) for the years ended December 31, 2006, July 31, 2005, 2004 and 2003. We identify each fiscal year in this transition report according to the calendar year in which such fiscal year ends. For example, we refer to the fiscal year ended July 31, 2004, as fiscal 2004 or 2004.

Unless the context requires otherwise, references in this report to we, our, us, Company and Alexion refer to Alexion Pharmaceuticals, Inc. and its subsidiaries.

**Note Regarding Forward-Looking Statements**

This annual report on Form 10-K contains forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management's beliefs and certain assumptions made by our management and may include, but are not limited to, statements regarding the status of our ongoing clinical trials and prospects for regulatory approval, timing for completion of our ongoing clinical trials, evaluation of our clinical trial results by regulatory agencies, the need for additional research and testing, the uncertainties involved in the drug development process, the safety and efficacy of our product candidates, our future research and development activities, estimates of the potential markets for our products, assessment of competitors and potential competitors, estimates of the capacity of manufacturing and other facilities to support our products, the sufficiency of our existing capital resources and projected cash needs, sales and marketing plans, assessment of impact of recent accounting pronouncements as well as assumptions relating to the foregoing. Words such as anticipates, expects, intends, plans, believes, seeks, estimates, variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this report under the section entitled Risk Factors. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in other reports or documents we file from time to time with the Securities and Exchange Commission.

**Item 1. BUSINESS.**

**Overview**

We are a biotechnology company working to develop and deliver life-changing drug therapies for patients with serious and life-threatening medical conditions. We are engaged in the discovery and development of therapeutic products aimed at treating patients with a wide array of severe disease states, including hematologic diseases, cancer, and autoimmune disorders. Since our incorporation in January 1992, we have devoted substantially all of our resources to drug discovery, research, and product and clinical development. Since September 2005, we have formed a number of wholly-owned subsidiaries to support commercial and regulatory

**Table of Contents**

operations. In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island for the future commercial production of our products.

In September 2006, we filed a Biologics License Application, or BLA, with the U.S. Food and Drug Administration, or FDA, and a European Marketing Authorization Application, or MAA, in Europe, for Soliris (eculizumab) for the treatment of a rare, life-threatening blood disorder known as Paroxysmal Nocturnal Hemoglobinuria, or PNH. The Phase III clinical development program for Soliris (eculizumab) in PNH is comprised of two Phase III clinical trials, known as TRIUMPH and SHEPHERD. The FDA agreed to the design of the protocols for these two trials under the Special Protocol Assessment, or SPA, process. TRIUMPH is a placebo-controlled pivotal efficacy trial and SHEPHERD is an open-label, non-placebo controlled safety trial with efficacy secondary endpoints. In January 2006, we reported positive results from TRIUMPH, and the results were later published in the September 2006 issue of the New England Journal of Medicine. All pre-specified, primary and secondary endpoints in the TRIUMPH trial were achieved with statistical significance. In December 2006, we reported positive results from SHEPHERD. Soliris (eculizumab) appeared to be safe and well tolerated during the twelve month SHEPHERD trial, and all pre-specified primary and secondary efficacy endpoints in the SHEPHERD trial were achieved with statistical significance. Data from TRIUMPH and SHEPHERD served as the primary basis for the BLA and MAA submitted in the United States and Europe, respectively.

In November 2006, we received priority review designation for the Soliris (eculizumab) BLA from the FDA. Priority review status is granted by the FDA to products that, if approved, would be a significant improvement over existing therapies. Similarly, in August 2006, we announced that our Soliris (eculizumab) MAA was granted accelerated assessment by the European Medicines Agency, or EMEA, in Europe. Review under the Accelerated Assessment Procedure is provided by the EMEA for medicinal products of major therapeutic interest and shortens the timeframe for review by that agency. The granting of priority review for our BLA and accelerated assessment for our MAA does not ensure or increase the likelihood that our applications for regulatory approval of Soliris (eculizumab) will be approved. In November 2006, we also announced that the EMEA had validated the Soliris MAA allowing for commencement of the review process.

In addition to our Phase III PNH clinical program, we are conducting the following activities: (1) the EMBRACE Expanded Access Trial, (2) the EXPLORE diagnostics trial and (3) a global Patient Registry for PNH patients. The EMBRACE trial (The Paroxysmal Nocturnal Hemoglobinuria Early Access Treatment Protocol) was initiated in December 2006 to provide the investigational agent eculizumab in the United States to PNH patients in accordance with a Treatment Protocol authorized by the FDA. Treatment Protocols are designed to make promising investigational agents available for patients with serious or life-threatening diseases for which there are no comparable or satisfactory alternative therapies, before general marketing is authorized. We initiated the EXPLORE trial in August 2006 to investigate the frequency and clinical characteristics of undiagnosed PNH patients who have been diagnosed with other bone marrow failure diseases such as aplastic anemia and myelodysplasia. The global PNH Patient Registry involves the study of the natural history of PNH.

In addition to PNH, we are considering the evaluation of other potential indications for Soliris (eculizumab) as well as other formulations of eculizumab for additional clinical indications, and we are actively pursuing development of other antibody product candidates in early stages of development. During 2006, we completed a final Phase III trial of another product candidate known as pexelizumab with our partner for this product, Procter & Gamble Pharmaceuticals. After reviewing results from that trial, we along with Procter & Gamble Pharmaceuticals, have determined not to pursue further development of pexelizumab.

## **Table of Contents**

To date, we have not received any revenues from the sale of our products. We have incurred operating losses since our inception. As of December 31, 2006, we had an accumulated deficit of approximately \$638 million. We expect to incur substantial operating losses for the next several years due to expenses associated with product research and development, pre-clinical studies and clinical testing, regulatory activities, manufacturing development, scale-up and commercial-scale manufacturing, pre-commercialization activities, developing a sales and marketing force, and other infrastructure support costs. We may need to obtain additional financing to cover these costs.

In November 2006, we sold 3.45 million shares of our common stock in a registered offering at a price to the public of \$43 per share resulting in proceeds of approximately \$140 million, net of underwriting discount, fees and other expenses. We intend to use the net proceeds from this offering for general corporate purposes.

### ***The Immune System***

The human immune system defends the body from attack or invasion by infectious agents or pathogens. This is accomplished through a complex system of proteins and cells, primarily complement proteins, antibodies and white blood cells, each with a specialized function. Under normal circumstances, complement proteins, together with antibodies and white blood cells, act to protect the body by removing:

harmful micro-organisms;

cells containing foreign proteins known as antigens; and

disease-causing combinations of antigens and antibodies known as immune complexes.

When activated by stimuli, the immune system triggers a series of enzymatic and biochemical reactions called the complement cascade that results in an inflammatory response. This inflammatory response is one of the immune system's weapons against foreign pathogens or otherwise diseased tissue. However, under certain circumstances, the complement cascade may be activated inappropriately to direct an inflammatory response at healthy tissue, which may result in acute and chronic inflammatory conditions.

Hematologic, autoimmune, or inflammatory diseases in which the complement cascade is activated include:

PNH;

transplantation;

Myasthenia Gravis;

autoimmune hemolytic anemias;

Guillain-Barre syndrome;

rheumatoid arthritis;

autoimmune kidney disease;

lupus;

inflammatory skin and muscle disorders;

multiple sclerosis;

antiphospholipid syndrome; and

asthma

**Table of Contents****Product Development Programs**

We have focused our product development programs on anti-inflammatory therapeutics for diseases for which we believe current treatments are either non-existent or inadequate. Our lead product candidate, eculizumab, is a genetically altered antibody known as a C5 complement inhibitor, or a C5 Inhibitor, which is designed to selectively block the production of inflammation-causing proteins in the complement cascade. We believe that selective suppression of this immune response may provide a significant therapeutic advantage relative to existing therapies. Although we believe C5 Inhibitors may be useful in the treatment of a variety of diseases and conditions resulting from aberrant complement response, we are currently focusing our efforts on the development of our lead product candidate, Soliris (eculizumab), for the treatment of PNH.

Our pipeline programs are as follows:

<b>Product Candidate</b>	<b>Indication</b>	<b>Clinical Trial</b>	<b>Status (a)</b>
Soliris (eculizumab)	Paroxysmal Nocturnal Hemoglobinuria (PNH)	TRIUMPH (Phase III)	Statistically significant positive results announced January 2006
		SHEPHERD (Phase III)	Statistically significant positive results announced December, 2006
		Phase III Extension study	Enrollment ongoing
Eculizumab (nebulized)	Renal Transplantation		Pre-clinical research
	Autoimmune diseases		Pre-clinical research
	Asthma		Pre-clinical research
Eculizumab (Intravitreal)	Age-Related Macular Degeneration		Pre-clinical research
CD200 Mab	CLL, Multiple Myeloma		Pre-clinical research
DC-SIGN Mab	Cancer Vaccine		Pre-clinical research

***C5 Inhibitors***

Complement proteins are a series of inactive proteins circulating in the blood. When activated by stimuli, including those associated with both acute and chronic inflammatory disorders, these inactive complement proteins are split by enzymes known as convertases into activated byproducts through the complement cascade.

Some of these byproducts, notably C3b, are helpful in fighting infections and inhibiting autoimmune disorders. However, the byproducts generated by the cleavage of C5, known as C5a and C5b-9, generally cause harmful inflammation if inappropriately or over-activated. The inflammatory byproducts of C5 cause:

lysis, or destruction, of red blood cells that are deficient in complement inhibitors;

activation and destruction of muscle and other tissue cells;

**Table of Contents**

activation of white blood cells;

attraction of white blood cells;

production of inflammatory chemicals including tumor necrosis factor-alpha;

activation of blood vessel-lining cells called endothelial cells, allowing leakage of white blood cells into tissue;

activation of kidney cells; and

initiation of cell suicide programs in heart cells

The following diagram illustrates the complement cascade:

Because of the generally beneficial effects of the components of the complement cascade prior to C5 and the greater inflammatory, destructive and disease-promoting effects of the cleavage products of C5, we have identified C5 as a potentially effective anti-inflammatory drug target. Our C5 Inhibitor, eculizumab, specifically and tightly binds to C5 blocking its cleavage into harmful byproducts, which we believe may inhibit subsequent damage from the inflammatory response.

In laboratory and animal models of human disease, we have shown that the administration of a C5 Inhibitor, as compared to placebo, has demonstrated the following:

prevention of lysis of red blood cells;

prevention of inflammation during cardiopulmonary bypass;

reduction of heart tissue damage during myocardial infarction;

reduction of brain damage in cerebral ischemia, or reduced blood flow to brain tissue;

enhancement of survival in a model of lupus;

preservation of kidney function in nephritis, or inflammation of kidney tissue;

prevention and amelioration of asthmatic attacks; and

enhancement of survival in organ transplantation models.





## **Table of Contents**

In addition, in human clinical trials, we have shown that C5 Inhibitors may be associated with:

reduction of red blood cell destruction, improvement in anemia, amelioration of fatigue and reduction of blood clots in PNH patients;

reduction of an objective measure of disease activity in rheumatoid arthritis patients; and

reduction of the incidence of proteinuria in lupus patients.

### ***C5 Inhibitor Immunotherapeutic Product Candidates***

We are developing our lead C5 Inhibitor product candidate, Soliris (eculizumab), for the treatment of inflammation related to chronic hematologic disorders and autoimmune disorders. The initial indication for which we are pursuing development of Soliris (eculizumab) is PNH.

To date, eculizumab has been observed to be reasonably well tolerated in completed clinical trials in which over 900 individuals were treated with eculizumab; 195 of these individuals were PNH patients enrolled in trials studying PNH. Our other C5 Inhibitor, pexelizumab, has been observed to be reasonably well tolerated in completed clinical trials in which over 10,000 individuals were treated with either pexelizumab or placebo.

### ***Lead Eculizumab Indication***

Eculizumab is a humanized antibody that blocks complement activity for one to two weeks after a single dose at the doses currently tested, and is designed for the chronic treatment of hematologic disorders such as PNH and autoimmune diseases. Results of the two Phase III clinical trials for Soliris (eculizumab) in PNH showed statistically significant achievement of all primary and secondary endpoints. We have filed for authorization to market Soliris (eculizumab) for PNH patients with the FDA and the EMEA in the United States and Europe, respectively. We have retained full commercial rights to Soliris (eculizumab) worldwide.

### ***About Paroxysmal Nocturnal Hemoglobinuria or PNH***

We are developing eculizumab for treatment of patients afflicted with the chronic hematologic disorder, Paroxysmal Nocturnal Hemoglobinuria, or PNH. PNH is a life-threatening, rare acquired genetic deficiency blood disorder characterized by severe anemia and risk of blood clotting, or thrombosis. Patients with PNH have an acquired genetic deficiency in certain protective proteins on the surface of their blood cells, allowing their own complement system to attack and destroy these blood cells. Patients with PNH may suffer from chronic hemolysis, or destruction of red blood cells caused by the C5 cleavage product C5b-9. This hemolysis is believed to lead to further clinical complications including frequent bouts of hemoglobinuria or release of blood cell hemoglobin into the urine, abdominal pain, painful swallowing, high blood pressure in the lungs, disabling fatigue, and a poor quality of life. The red blood cell destruction may be sufficiently large that recurrent blood transfusions are necessary to support normal red blood cell function. The hemolysis in patients with PNH may be associated with severe, life-threatening blood clots. The prevalence, or number of affected patients at any one time, has not been definitively determined but can be estimated at approximately 8,000-10,000 total patients in North America and Western Europe. Approximately one-half of the patients with PNH die from the disease within 10-15 years of diagnosis. Currently there is no U.S. Food and Drug Administration approved therapy for PNH. In 2003, the FDA and the European Medicines Agency, or EMEA, each granted Orphan Drug Status for the development of eculizumab in PNH.

---

**Table of Contents*****Clinical Trials PNH***

In September 2006, we submitted a Biologics License Application, or BLA, with the U.S. Food and Drug Administration, or FDA, and a European Marketing Authorization Application, or MAA, in Europe, for Soliris (eculizumab) for the treatment of PNH. Data from two clinical trials that comprised the pivotal Phase III program, known as the TRIUMPH and SHEPHERD trials, served as the primary basis for the BLA and MAA. In July 2004, we received written confirmation from the FDA indicating agreement with the protocol designs for the TRIUMPH and SHEPHERD trials. The agreement for the Phase III program was reached under the FDA's Special Protocol Assessment, or SPA, process, a procedure by which the FDA provides official evaluation and guidance on proposed protocols for pivotal Phase III clinical trials. Similarly, we have obtained protocol assistance from the EMEA with respect to the pivotal Phase III PNH program in Europe. Prior to submission of the BLA and MAA for Soliris (eculizumab) in PNH, we also presented and discussed available Phase III results with the FDA and EMEA. In 2003, the FDA and the EMEA granted Orphan Drug designation for the development of Soliris (eculizumab) in PNH. We retain all rights to eculizumab in all indications worldwide.

On January 26, 2006, we reported positive results with Soliris (eculizumab) in the pivotal Phase III TRIUMPH trial in PNH patients and published the trial results in the September 20, 2006 issue of the New England Journal of Medicine. TRIUMPH is a double-blind, randomized, placebo-controlled multi-center pivotal Phase III trial, examining the effects of eculizumab on the co-primary endpoints of hemoglobin stabilization and blood transfusion requirement in hemolytic, transfusion-dependent PNH patients during six months of therapy. The pre-specified co-primary endpoints in the TRIUMPH trial (median transfusion rate and hemoglobin stabilization) were each achieved with statistical significance. The median transfusion rate was reduced from 10 units/patient with placebo to 0 units/patient with eculizumab ( $p < 0.00000001$ ). Hemoglobin stabilization was achieved by 49% of eculizumab patients as compared to 0% for placebo ( $p < 0.0000001$ ). Soliris (eculizumab) reduced intravascular hemolysis, as shown by the 85.8% lower median area under the curve for lactate dehydrogenase in the eculizumab group, as compared with the placebo group (58,587 vs. 411,822 U per liter  $\times$  day;  $P < 0.001$ ). Clinically and statistically significant improvements in fatigue were observed as measured by scores on the Functional Assessment of Chronic Illness Therapy-Fatigue instrument ( $P < 0.001$ ) and the fatigue subscale of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) ( $P < 0.001$ ). Treatment with Soliris (eculizumab) also significantly improved overall health and patient functioning as measured by the EORTC QLQ-C30 instrument including global health status ( $P < 0.001$ ) and all five aspects of patient functioning: role ( $P < 0.001$ ), social ( $P = 0.003$ ), cognitive ( $P = 0.002$ ), physical ( $P < 0.001$ ) and emotional ( $P = 0.008$ ). Treatment also significantly reduced EORTC QLQ-C30 disease-related symptoms including pain ( $P = 0.002$ ), dyspnea ( $P < 0.001$ ), appetite loss ( $P < 0.001$ ), and insomnia ( $P = 0.014$ ). Additionally, Soliris (eculizumab) appeared to be well tolerated with an adverse event profile comparable to placebo. The most frequent adverse events with Soliris (eculizumab) were headache, nasopharyngitis (or cold symptoms) and back pain. The study enrolled patients in the U.S., Canada, Europe, and Australia.

In December 2006, we reported positive results with Soliris (eculizumab) in the Phase III SHEPHERD trial in PNH Patients. SHEPHERD trial was an open-label, twelve-month non-placebo controlled trial primarily aimed at generating additional safety data with eculizumab in 97 PNH patients in the United States, Canada, Europe, and Australia, and included a primary surrogate of efficacy and additional efficacy endpoints. Results from the SHEPHERD trial showed that Soliris (eculizumab) appeared to be safe and well tolerated and provided clinically and statistically significant improvements in intravascular hemolysis, anemia, fatigue and quality of life. Results from the SHEPHERD trial were presented in December 2006 at the 48th Annual Proceedings of the American Society of Hematology. Soliris (eculizumab) therapy in SHEPHERD improved

---

**Table of Contents**

the intravascular hemolysis, as shown by a reduction in the median LDH area under the curve (-632,264 U/L W day;  $P < 0.001$ ). LDH levels during the study were reduced 87% from a median of 2051 U/L at baseline to 269 U/L after 12 months of treatment ( $P < 0.001$ ). Clinically and statistically significant improvements in fatigue were observed as measured by change from baseline using the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) instrument ( $P < 0.001$ ) and the fatigue scale of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) instrument, a standard questionnaire developed to assess quality of life in cancer patients particularly suffering from severe fatigue and anemia ( $P < 0.001$ ). Treatment with Soliris (eculizumab) also significantly improved overall health and patient functioning as measured by the EORTC QLQ-C30 instrument including the global health status scale ( $P < 0.001$ ) and all five aspects of patient functioning: role ( $P < 0.001$ ), social ( $P < 0.001$ ), cognitive ( $P < 0.001$ ), physical ( $P < 0.001$ ) and emotional ( $P < 0.001$ ). Treatment also significantly improved 7 of 9 EORTC QLQ-C30 symptom scales and single item measures including pain ( $P < 0.001$ ), dyspnea ( $P < 0.001$ ), appetite loss ( $P < 0.001$ ), and insomnia ( $P < 0.001$ ). Clinically and statistically significant improvements in anemia were also observed with eculizumab therapy as evidenced by the reduction in transfusion requirements from a median of 8.0 packed red cells in the 12 month pre-treatment period to 0.0 units during the 12 months of treatment ( $P < 0.001$ ). Additionally, 51% of patients in SHEPHERD were transfusion independent for the entire 12 month treatment period ( $P < 0.001$ ). Other improvements in anemia included a 44% increase in the endogenous PNH red blood cell mass ( $P < 0.001$ ) and an increase in hemoglobin levels from 9.2g/dl at baseline to 10.2g/dl after 12 months of treatment ( $P < 0.001$ ).

Prior to SHEPHERD and TRIUMPH, we conducted a three-month, open-label study in 11 PNH patients, results of which were reported in the February 5, 2004 issue of the *New England Journal of Medicine*. Patients treated with Soliris (eculizumab) experienced a substantial decrease in the destruction of PNH red blood cells, with the mean percentage of these cells increasing from 36.7 percent of the total population found in the body to 59.2 percent ( $P = 0.005$ ), and lactate dehydrogenase levels, a biochemical marker of red blood cell destruction, falling from a mean of 3,111 IU per liter to a mean of 594 IU per liter ( $P = 0.002$ ). This reduction in PNH red blood cell destruction helped reduce the median patient transfusion rates from 1.8 units per patient, per month, to 0.0 units per patient, per month ( $P = 0.003$ ). Episodes of hemoglobinuria were reduced by an average of 96 percent ( $P < 0.001$ ) and quality of life measurements, using EORTC QLQ C-30, substantially improved during treatment. Soliris (eculizumab) appeared reasonably well tolerated in this trial. Adverse events reported for Soliris (eculizumab) or placebo were similar in type and frequency to those reported in other controlled trials of eculizumab. The most common adverse events were headache, upper respiratory infection, muscle/joint aches, and influenza-like symptoms, and the severe adverse events were viral chest infection, dizziness and shivering. In the June 2005 issue of the journal *Blood*, we reported on the safety and sustained effects of Soliris (eculizumab) in a 52-week extension of our pilot open-label PNH trial in 11 patients. In this study, patients who received Soliris (eculizumab) continued to tolerate the drug reasonably well and experienced reduced hemolysis resulting in an increase in PNH red blood cells, a reduction in the need for transfusion, and improvements in multiple quality of life measures. Reported adverse events occurring in three or more patients were flu-like symptoms, sore throat, pain, nausea, bruising, cough, and upper respiratory infection. The adverse event profile for eculizumab-treated patients in this study was similar to that of placebo-treated patients in other patient population trials of eculizumab.

Patients who have completed the TRIUMPH and SHEPHERD trials, as well as patients that have completed the initial, open-label clinical trial, have been enrolled in an open-label extension trial to further evaluate safety data in PNH patients treated with Soliris (eculizumab).

## **Table of Contents**

### **Eculizumab in Pre-Clinical Research Programs**

#### ***Renal Transplantation***

Solid-organ transplantation is an effective form of therapy for the management of patients with end-stage kidney, heart, lung, or liver failure. The rejection of the donor organ is usually managed by treatment of the recipient with immunosuppressive drugs that block the action of white blood cells to reject the donor organ. However, some potential transplant recipients have highly sensitized immune systems due to previous transplants, transfusions or pregnancies, or incompatibility with the blood type of the donor. In these presensitized graft recipients, antibody-mediated rejection, or AMR, is a major impediment to successful transplantation.

In collaboration with investigators at the Multi-Organ Transplant Program, London Health Sciences Centre, London, Ontario, Canada, we reported in the May 2005 issue of the journal *Transplantation* that inhibition of terminal complement using an anti-C5 complement-blocking antibody successfully prevented AMR in a rodent model of transplantation. Furthermore, addition of anti-C5 antibody to standard anti-cellular therapy resulted in a marked and significant increase in graft survival as compared to graft survival in animals treated with anti-cellular therapy alone. Importantly, AMR was prevented by anti-C5 antibody even in the presence of high levels of circulating anti-donor antibodies.

These data are supported by other studies that demonstrate an important role for terminal complement in antibody-mediated transplant rejection and suggest that complement blockade at C5 may be an effective therapy in patients who are either presensitized or who have received a blood type mismatched transplant organ. We are currently in pre-clinical studies to evaluate solid-transplantation as an indication for eculizumab.

#### ***Asthma***

Asthma is a chronic respiratory disease that results in bronchial inflammation and airway constriction that prompts asthma's hallmark symptoms: shortness of breath, chest tightness and wheezing.

In May 2005, we announced the results of a new animal model study that showed that treatment with an anti-C5 complement blocking antibody significantly reduced bronchial inflammation and airway constriction. The study, conducted by our researchers, the Yale University School of Medicine, and the Brigham and Women's Hospital, was published in the June 2005 issue of the *Journal of Clinical Investigation*.

The study suggested that both C5a and C5b-9 contribute to the initiation of airway inflammation and in immediate and sustained airway hyperreactivity. Importantly, the researchers found that animals given an anti-C5 blocking antibody—either systemically or when inhaled through a nebulizer (a common asthma inhalation device)—showed substantial reductions in airway reactivity even in the face of airway challenges with methacholine, a drug administered to confirm an asthma diagnosis.

The anti-C5 blocking antibody, unlike existing asthma therapies—high-dose inhaled and oral corticosteroids—blocked a wide range of inflammatory mediators known to contribute to the severity and persistence of asthma, including white blood cells and inflammatory mediators from eosinophils and neutrophils. These data suggest a direct role for complement-mediated inflammation in the pathogenesis of severe asthma. We are currently in pre-clinical studies to evaluate asthma as an indication for eculizumab.

## **Table of Contents**

### **Antibody Discovery Technology Platform**

#### ***Combinatorial Human Antibody Library Technologies***

In order to expand our pipeline of potential antibody therapeutics, in September 2000, we acquired Prolifaron, Inc., a privately held biopharmaceutical company and integrated this entity into Alexion as a wholly-owned subsidiary, Alexion Antibody Technologies, Inc. or AAT. The AAT technology includes extensive research expertise and methodologies that we call Combinatorial Human Antibody Library Technologies or CoALT, in the area of creating fully human antibodies from libraries containing billions of human antibody genes. During 2006, we decided to relocate CoALT and other AAT technologies to our expanded research and discovery groups in our Cheshire, Connecticut headquarters. As a result, we initiated an integration plan with AAT to consolidate certain functions and operations, including the termination of all AAT personnel and possible disposal of equipment in that facility.

Our goal, through CoALT and related technologies, is to develop new fully human therapeutic antibodies addressing multiple disease areas, including autoimmune and inflammatory disorders, cancer and infectious disease. These technologies involve, in part, the generation of diverse libraries of human antibodies derived from patients' blood samples, and the screening of these libraries against a wide array of potential drug targets. We believe that these technologies may be optimally suited to the rapid generation of novel, fully human and humanized, therapeutic antibodies directed at validated clinical targets. To date, we have focused on identifying antibodies that may be therapeutically effective in different cancers, autoimmune or inflammatory disorders, and infectious diseases. In addition, we believe that these technologies could permit the pre-clinical validation of new gene targets that are being identified by numerous groups from recent access to the human genome. We also believe that these technologies might identify therapeutic antibodies when the libraries are screened against certain of these new gene targets.

#### **Pre-Clinical Programs**

##### ***Anti-CD200 Antibody***

We are developing an antibody for the treatment of B-Chronic Lymphocytic Leukemia (B-CLL), an incurable chronic cancer that results from expansion of B-lymphocytes and other myeloid tumors such as multiple myeloma (MM). Our antibody binds to CD200, a molecule that is upregulated on the surface of B-CLL and MM tumor cells. CD200 normally acts as a potent immunosuppressant by interacting with the CD200 Receptor on macrophages and thereby sending an inhibitory signal to the macrophage. We believe upregulation of CD200 on the CLL and MM cell surface allows the tumor to inhibit the body's immune response to the tumor. Our antibody targets CLL and MM cells and blocks the interaction of CD200 with the CD200 Receptor with the objective of enhancing the body's immune response to these tumors. We have recently demonstrated the potent anti-tumor activity of our anti-CD200 antibody in a model of CLL, which was published in the January 2006 issue of the Proceedings of the National Academy of Sciences and presented at the 2006 meeting of the American Society for Clinical Oncology. Our anti-CD200 antibody drug candidates may have therapeutic application in patients suffering from B-CLL, MM and other blood and solid tumors with elevated CD200 expression.

##### ***Dendritic Cell Antibodies***

We are developing humanized antibodies to newly discovered cell surface proteins, DC-SIGN, found exclusively on human dendritic cells, a type of human immune cell, and a related receptor, L-SIGN. Under the

## **Table of Contents**

exclusive worldwide license agreement and research alliance with the University Medical Center of Nijmegen, The Netherlands, we received rights related to these molecules and any associated therapeutic product candidates, including already identified monoclonal antibodies. These products may have broad therapeutic application in several clinical settings including different cancers and infectious diseases, and in certain inflammatory disorders. This alliance broadens our interest in immune system modulation to also include human dendritic cells.

Dendritic cells have recently come to be appreciated as critical controllers of the immune system. In order for an immune response against foreign antigens to occur, these antigens must be displayed by so-called antigen-presenting cells. While dendritic cells are an extremely rare immune cell type, they are the most potent of all the antigen presenting cells. Dendritic cells capture antigens in the peripheral tissues, process and display the antigen fragments on their cell surface, and then migrate from the periphery to the T-cell areas of the lymphoid organs. There they attract resting T-cells and present their antigen load, thus activating the T-cells to begin an immune response. This process appears to be controlled in part by the newly identified molecule DC-SIGN. We have recently demonstrated that our DC-SIGN antibody potentially activates the immune system and exhibits significant anti-tumor activity in a model system. These results were recently presented at the 2006 meeting of the American Society for Clinical Oncology

### ***Anti-MBL Antibody***

We are developing an antibody that blocks complement activation via the Lectin Pathway. This inflammatory pathway is initiated by the binding of a specific protein, known as MBL, to targets on the surface of activated endothelial cells and may represent a major cause of inflammation and heart damage. Under a license agreement with The Brigham and Women's Hospital, Inc., we received exclusive worldwide rights to novel anti-inflammatory technologies and to associated therapeutic products, including a potent monoclonal antibody against MBL. The anti-MBL approach may have broad therapeutic application in patients suffering from various vascular disorders as well as some chronic inflammatory conditions.

### ***The CuraGen Corporation Agreement for Target Discovery***

We completed a drug target discovery and validation program with CuraGen Corporation focused on oncology, the study of tumors and/or cancers. This agreement enabled us and CuraGen to leverage our respective areas of expertise to discover and validate novel biologic and small molecule targets for use in developing pharmaceutical products.

Under the agreement, CuraGen applied its integrated functional genomic technologies to identify potential drug targets derived from our supplied research materials, and will retain the rights to potential non-antibody protein therapeutics across all disease areas. We are using our CoALT antibody discovery platform to determine the therapeutic utility of the targets. We own preferential rights to develop and commercialize some antibody and small molecule therapeutics against drug targets across all disease areas. CuraGen is eligible to receive licensing fees, development milestone payments and sales royalties from pharmaceutical products stemming from this alliance. CuraGen retains the right to develop or out license some candidates from the program.

---

**Table of Contents**

**Other Pre-Clinical Programs**

***Anti-TPO Receptor Antibody***

In December 2003, we and XOMA entered into a collaborative agreement for the development and commercialization of a rationally designed human c-MPL agonist antibody to treat chemotherapy-induced thrombocytopenia. Thrombocytopenia is an abnormal blood condition in which the number of platelets is reduced, potentially leading to bleeding complications. In November 2004, we and XOMA determined that the lead molecule in this c-MPL agonist antibody collaboration did not meet the criteria established in the program for continued development. We and XOMA agreed not to continue with this joint development program and terminated the collaboration in April 2005. Under the terms of the agreement, we received a \$1.5 million upfront non-refundable payment upon initiation of the collaboration. We recorded the payment as a deferred research and development payment. During the quarter ended April 30, 2005, we recognized the remaining balance of approximately \$1.3 million of the deferred payment as a reduction of research and development expense.

**Strategic Alliance with Procter & Gamble**

In January 1999, we entered into collaboration with P&G with respect to the joint development of pexelizumab in cardiovascular indications. In December 2001, we and P&G entered into a binding memorandum of understanding, or MOU, pursuant to which we and P&G revised our January 1999 collaboration. During 2006, we announced that results from the final Phase III clinical trial of pexelizumab did not achieve its primary endpoint, and that this trial and prior Phase III trials of pexelizumab will not be sufficient for filing for licensing approval. We have held discussions with P&G regarding the pexelizumab program, and we do not expect to continue development of pexelizumab with P&G or in the indications studied with P&G.

Under the revised structure per the MOU, we and P&G share decision-making and responsibility for all U.S. development and commercialization costs for pexelizumab, including clinical, manufacturing, marketing, and sales efforts. Prior to December 2001, P&G was generally funding all clinical development and manufacturing costs for pexelizumab. The revised collaboration per the MOU provides that we and P&G each incur approximately 50% of all Phase III clinical trial, product development and manufacturing, and commercialization costs necessary for the potential approval and marketing of pexelizumab in the U.S. and that we would receive approximately 50% of the gross margin on U.S. sales, if any. Under the MOU, P&G agreed to retain responsibility for future development and commercialization costs outside the U.S. and we would receive royalties on sales outside the U.S., if any. We would be responsible for paying royalties and licensing fees on certain third party intellectual property worldwide, if such intellectual property were necessary in order to commercialize pexelizumab. Additionally, as part of the MOU, we would receive milestone payments for achieving specified development steps, regulatory filings and approvals, but not for previously agreed sales milestones and we would generally forego further research and development support payments from P&G.

Reimbursements received by us from P&G in connection with P&G's share of our services and related personnel are recorded as a reduction of research and development and market research expense. As part of the revised collaboration per the MOU, P&G funded 100% of the costs for the two acute myocardial infarction, or AMI, Phase II clinical trials. We and P&G agreed, as per the MOU, that we share concurrently 50% of the ongoing U.S. pre-production and development manufacturing costs for pexelizumab as well as any future AMI or CABG Phase III clinical trial costs.

P&G has the right to terminate the collaboration or sublicense its collaboration rights at any time. If P&G terminates the collaboration, P&G is required to contribute its share of agreed to obligations and costs incurred



## **Table of Contents**

prior to termination, but may not be required to contribute towards costs incurred after termination. In the event that P&G were to terminate the collaboration, all rights and the exclusive license to our intellectual property related to pexelizumab would revert to us. The MOU does not contemplate any payments to P&G in the event P&G were to terminate the collaboration; however, P&G might seek to negotiate such a payment or might seek to sublicense its collaboration rights rather than terminate the collaboration.

## **Manufacturing**

We obtain drug product to meet our requirements for clinical studies using both internal and third-party contract manufacturing capabilities. We currently rely on a third-party contract manufacturer for our anticipated eculizumab commercial needs, and intend to equip and qualify our own manufacturing facility for anticipated eculizumab commercial needs in the future. For both clinical requirements and anticipated commercial requirements, we have contracted and expect to continue contracting for product finishing, vial filling, and packaging through third parties.

In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island. We intend to equip and develop the plant in accordance with FDA and other regulatory requirements to manufacture Soliris (eculizumab) and other product candidates. We have a pilot manufacturing plant suitable for the production and purification of certain of our product candidates for clinical studies. The pilot manufacturing plant is currently being decommissioned and transferred to the Smithfield, Rhode Island plant.

Our most significant agreement with a third party manufacturer is the Large-Scale Product Supply Agreement, or the Lonza Agreement, dated December 18, 2002 with Lonza Biologics PLC, or Lonza, relating to the manufacture of our product candidate eculizumab. The Lonza Agreement was amended, or the Lonza Amendment, on April 9, 2004. Per the Lonza Agreement, we have remitted cash advances aggregating \$13.5 million through December 31, 2006. If we terminate the Lonza Agreement we may be required to pay for batches of product scheduled for manufacture up to 12 months following termination.

The amounts paid to Lonza in consideration of the Lonza Agreement are accounted for as prepaid manufacturing costs within the accompanying balance sheet and are recognized as additional manufacturing costs as the batches are manufactured. On a quarterly basis, we evaluate our plans to proceed with production under the Lonza Agreement, considering our commercialization plans for Soliris (eculizumab). In addition, we evaluate the prepaid manufacturing costs against estimated net realizable value, or NRV. If estimated NRV is not positive, then all or a portion of the prepaid manufacturing cost may be recognized as an expense.

## **Sales and Marketing**

We currently have established core marketing capabilities and have begun to establish sales and distribution capabilities. We are developing our own specialized sales force and marketing organization to market Soliris (eculizumab) in the United States and in Europe. We will need to continue developing or will have to contract with others to obtain these capabilities to commercialize Soliris (eculizumab) successfully. We may promote Soliris (eculizumab) in collaboration with marketing partners or rely on relationships with one or more companies with established distribution systems and direct sales forces, either in the United States or in other countries.

## **Table of Contents**

### **Patents and Proprietary Rights**

Patents and other proprietary rights are important to our business. Our policy is to file patent applications to protect technology, inventions and improvements to our technologies that are considered important to the development of our business. We also rely upon our trade secrets, know-how, and continuing technological innovations to develop and maintain our competitive position, as well as patents that we have licensed or may license from other parties.

We have filed several U.S. patent applications and international counterparts of certain of these applications. In addition, we have in-licensed several additional U.S. and international patents and patent applications. As of January 31, 2007, we own or in-license over 77 U.S. patents and 61 U.S. patent applications. These patents and patent applications relate to technologies or products in the C5 Inhibitor program, high throughput screening, vectors, cancer, the MBL program, recombinant antibodies, the dendritic cell program, and other technologies. We own or in-license 58 foreign patents and 167 pending foreign patent applications. We will owe royalties and other fees to the licensors of some of those patents and patent applications in connection with any future commercial manufacture and sale of our product candidates, including eculizumab.

Our success will depend in part on our ability to obtain and maintain U.S. and international patent protection for our products and development programs, to preserve our trade secrets and proprietary rights, and to operate without infringing on the proprietary rights of third parties or having third parties circumvent our rights. Because of the length of time and expense associated with bringing new products through development and regulatory approval to the marketplace, the health care industry has traditionally placed considerable importance on obtaining patent and trade secret protection for significant new technologies, products and processes. Significant legal issues remain to be resolved as to the extent and scope of patent protection for biotechnology products and processes in the United States and other important markets outside of the United States. Accordingly, there can be no assurance that patent applications owned or licensed by us will issue as patents, or that any issued patents will afford meaningful protection against competitors. Moreover, once issued, patents are subject to challenge through both administrative and judicial proceedings in the United States and in foreign jurisdictions. Such proceedings include interference proceedings before the U.S. Patent and Trademark Office and opposition proceedings before the European Patent Office. Litigation may be required to enforce our intellectual property rights. Any litigation or administrative proceeding may result in a significant commitment of our resources and, depending on outcome, may adversely affect the validity and scope of certain of our patent or other proprietary rights.

We are aware of broad patents owned by third parties relating to the manufacture, use, and sale of recombinant humanized antibodies, recombinant humanized single-chain antibodies, recombinant human antibodies and recombinant human single-chain antibodies. Many of our product candidates are genetically engineered antibodies, including recombinant humanized antibodies, recombinant humanized single chain antibodies, recombinant human antibodies, or recombinant human single chain antibodies. We have received notices from the owners of some of these patents in which the owners claim that some of these patents may be infringed by the development and commercialization of some of our drug candidates, including eculizumab. We are also aware of other patents owned by third parties that might be claimed to be infringed by the development and commercialization of some of our drug candidates, including eculizumab. We have acquired licenses to certain of these patents which we believe are relevant for the expeditious development and commercialization of eculizumab and certain of our other products as currently contemplated. With regard to certain other patents, we have either determined in our judgment that the patents are invalid, that our products do not infringe the patents, or that we can license such patents on commercially reasonable terms, or we have identified and are testing

## **Table of Contents**

various approaches which we believe should not infringe the patents and which should permit commercialization of our products. If our judgment is incorrect, and we are unable to acquire a license to a necessary patent on commercially reasonable terms, our ability to commercialize our products, including eculizumab, could be significantly adversely affected or could be prevented.

It is our policy to require our employees, consultants and parties to collaborative agreements to execute confidentiality agreements upon the commencement of employment or consulting relationships or collaborations with us. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us is to be kept confidential and not to be disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law.

## **Government Regulation**

The pre-clinical studies and clinical testing, manufacture, labeling, storage, record keeping, advertising, promotion, export, and marketing, among other things, of our proposed products, including Soliris (eculizumab), are subject to extensive regulation by governmental authorities in the U.S. and other countries. In the U.S., pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. We believe that Soliris (eculizumab) will be regulated by the FDA as a biologic. Biologics require the submission of a Biologics License Application, or BLA, and approval by FDA prior to being marketed in the United States. Manufacturers of biologics may also be subject to state regulation. Failure to comply with FDA requirements, both before and after product approval, may subject us and/or our partners, contract manufacturers, and suppliers to administrative or judicial sanctions, including FDA refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, fines and/or criminal prosecution.

The steps required before a biologic may be approved for marketing in the U.S. generally include:

- (1) pre-clinical laboratory tests and animal tests;
- (2) submission to the FDA of an Investigational New Drug Application for human clinical testing, which must become effective before human clinical trials may commence;
- (3) adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;
- (4) submission to the FDA of a BLA;
- (5) FDA pre-approval inspection of product manufacturers; and
- (6) FDA review and approval of BLA.

The testing and approval process requires substantial time, effort and financial resources, and we cannot assure you that any approval will be granted on a timely basis or at all, for Soliris (eculizumab) or any other product.

Pre-clinical studies include laboratory evaluation, as well as animal studies to assess the potential safety and efficacy of the product candidate. Pre-clinical safety tests must be conducted in compliance with FDA

## **Table of Contents**

regulations regarding good laboratory practices. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an Investigational New Drug Application, or IND, which must become effective before human clinical trials may be commenced. The IND will automatically become effective 30 days after receipt by the FDA, unless the FDA before that time raises concerns about the drug candidate or the conduct of the trials as outlined in the IND. The IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. We cannot assure you that submission of an IND will result in FDA authorization to commence clinical trials or that once commenced, other concerns will not arise.

Clinical trials involve the administration of the investigational product to healthy volunteers or to patients, under the supervision of qualified principal investigators. Each clinical study at each clinical site must be reviewed and approved by an independent institutional review board, prior to the recruitment of subjects.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap and different trials may be initiated with the same drug candidate within the same phase of development in similar or differing patient populations.

Phase I studies are closely monitored and may be conducted in a limited number of patients, but are usually conducted in healthy volunteer subjects. The drug is usually tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmacodynamics and pharmacokinetics.

Phase II usually involves studies in a larger, but still limited patient population to evaluate preliminarily the efficacy of the drug candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible short-term adverse effects and safety risks.

Phase III trials are undertaken to further evaluate clinical efficacy of a specific endpoint and to test further for safety within an expanded patient population at geographically dispersed clinical study sites. Phase I, Phase II or Phase III testing might not be completed successfully within any specific time period, if at all, with respect to any of our product candidates. Results from one trial are not necessarily predictive of results from later trials. Furthermore, the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Under the Special Protocol Assessment procedure, a sponsor may seek the FDA's agreement on the design and size of a clinical trial intended to form the primary basis of an effectiveness claim. If the FDA agrees in writing, its agreement may not be changed after the trial begins, except in limited circumstances. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on it as the primary basis for approval with respect to effectiveness. The Phase III clinical program for Soliris (eculizumab) for the PNH indication was conducted pursuant to an SPA. There can be no assurance that the FDA will agree to the design and size of future clinical trials, and there can be no assurance that any trial will have a successful outcome.

The results of the pre-clinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA as part of a BLA requesting approval to market the product candidate. Under the Prescription Drug User Fee Act, as amended, the fees payable to FDA for reviewing a BLA, as well as annual fees for commercial manufacturing establishments and for approved products, can be substantial. The BLA review fee alone can exceed \$500,000, subject to certain limited deferrals, waivers and reductions that may be available. Each BLA submitted to FDA for approval is typically reviewed for administrative completeness and reviewability within 45 to 60 days following submission

## Table of Contents

of the application. If found complete, the FDA will file the BLA, thus triggering substantive review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable. In November 2006, we announced that the FDA has accepted our BLA for filing, thereby triggering the substantive review. The FDA's established goals for the review of BLAs is six months for priority applications and 10 months for regular applications. Also in November 2006, we announced that FDA has granted Priority Review for the Soliris (eculizumab) BLA. The FDA is not legally obligated, however, to complete its review within these established goals and its review goals are subject to change from time to time. Further, the outcome of the review, even if generally favorable, typically is not an actual approval but an action letter that describes additional work that must be done before the application can be approved. Before approving a BLA, the FDA may inspect the facilities at which the product is manufactured and will not approve the product unless current Good Manufacturing Practices, or cGMP, compliance is satisfactory. The FDA may deny approval of a BLA if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can delay the approval process. FDA approval of any application may include many delays or never be granted. If a product is approved, the approval will impose limitations on the indicated uses for which the product may be marketed, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. To market for other indicated uses, or to make certain manufacturing or other changes requires FDA review and approval. Further post-marketing testing and surveillance to monitor the safety or efficacy of a product may be required. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. Finally, new government requirements may be established that could delay or prevent regulatory approval of Soliris (eculizumab) and our other products under development.

The U.S. Congress and regulatory authorities, including the FDA, are considering whether an abbreviated approval process for so-called generic or follow-on biological products should be adopted. An abbreviated approval process is currently available for generic versions of conventional chemical drug compounds, sometimes referred to as small molecule compounds, but not for biological products approved under the Public Health Service Act through a BLA. Currently, an applicant for a generic version of a small molecule compound only has to reference in its application an approved product for which full clinical data demonstrating safety and effectiveness exist for the approved conditions of use; demonstrate that its product has the same active ingredients, dosage form, strength, route of administration and conditions of use and is absorbed in the body at the same rate and to the same extent as the referenced approved drug; include certifications to patents listed with the FDA for the referenced approved drug; and await the expiration of any non-patent exclusivity. Various proposals have been made to establish an abbreviated approval process to permit approval of generic or follow-on versions of biological products. It is unclear as to when, or if, any such proposals may be adopted but any such abbreviated approval process could have a material impact on our business as follow-on products would be significantly less costly to bring to market and may be priced significantly lower than our products would be.

Both before and after the FDA approves a product, the manufacturer and the holder or holders of the BLA for the product are subject to comprehensive regulatory oversight. For example, quality control and manufacturing procedures must conform to cGMP requirements after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to spend time, monies, and effort to maintain cGMP compliance.

## **Table of Contents**

### **Orphan Drug Designation**

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances. Soliris (eculizumab) was granted Orphan Drug designation for the PNH indication by the FDA in 2003.

### **Foreign Regulation**

In addition to regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials and marketing approval for drugs. The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above as well as additional country-specific regulations. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

For example, under European Union regulatory systems, we may submit marketing authorizations either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

During November 2006, we announced that the European Medicines Agency, or EMEA, has validated our submission of a Marketing Authorization Application, or MAA, for Soliris (eculizumab) that we had submitted in September 2006. This step commences the review process of the MAA. In addition, the EMEA has notified us that they will utilize their Accelerated Assessment Procedure for review of the Soliris (eculizumab) MAA. Accelerated Assessment is given for medicinal products of major therapeutic interest and shortens the timeframe for review by the EMEA.

### **Reimbursement**

Sales of pharmaceutical products depend in significant part on the availability of coverage and the amount of reimbursement from government programs, including Medicare and Medicaid in the United States, and other third-party payers. These health insurance programs may restrict coverage of some products. Many third-party payers use formularies, under which only selected drugs are covered, variable co-payments that make drugs that are not preferred by the payor more expensive for patients, and utilization management controls, such as requirements for prior authorization or failure on another type of treatment, before the payer will cover a

## **Table of Contents**

particular drug. Payers may especially impose these obstacles to coverage for higher-priced drugs, as Soliris (eculizumab) is likely to be.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

Since Soliris (eculizumab) will likely be too expensive for most patients to afford without health insurance coverage, adequate coverage and reimbursement by third-party payers is essential to our ability to successfully commercialize Soliris (eculizumab).

## **Competition**

Currently, many companies, including major pharmaceutical and chemical companies as well as specialized biotechnology companies, are engaged in activities similar to our activities. Universities, governmental agencies and other public and private research organizations also conduct research and may market commercial products on their own or through joint ventures. These companies and organizations are in the U.S., Europe and elsewhere. Many of these entities may have:

substantially greater financial and other resources;

larger research and development staffs;

lower labor costs; and/or

more extensive marketing and manufacturing organizations.

Many of these companies and organizations have significant experience in pre-clinical testing, human clinical trials, product manufacturing, marketing, sales and distribution and other regulatory approval and commercial procedures. They may also have a greater number of significant patents and greater legal resources to seek remedies for cases of alleged infringement of their patents by us to block, delay, or compromise our own drug development process.

We compete with large pharmaceutical companies that produce and market synthetic compounds and with specialized biotechnology firms in the U.S., Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biotechnology companies have focused their developmental efforts in the human therapeutics area, and many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or have made commercial arrangements with other biotechnology companies. A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us; in some instances, these products have already entered clinical trials or are already being marketed. Other companies are engaged in research and development based on complement proteins.

Each of Adprotech Ltd., Avant Immunotherapeutics, Inc., Baxter International Inc., Tanox, Inc., XOMA Ltd., Novo Nordisk A/S, and Archemix Corporation has publicly announced intentions to develop complement

## **Table of Contents**

inhibitors to treat diseases related to trauma, inflammation or certain brain or nervous system disorders. We are also aware that Abbott Laboratories Inc., Baxter International, Inc., Millenium Pharmaceuticals, Inc. and Neurogen Corporation have had programs to develop complement inhibitor therapies. We believe that our potential C5 Inhibitors differ substantially from those of our competitors due to our compounds' demonstrated ability to specifically intervene in the complement cascade, for potentially prolonged periods of time, at what we believe to be the optimal point so that the disease-causing actions of complement proteins generally are inhibited while the normal disease-preventing functions of complement proteins generally remain intact as do other aspects of immune function.

Each of Cambridge Antibody Technology Group (a subsidiary of AstraZeneca PLC), Medarex, Amgen, Dyax Corporation, and MorphoSys AG has publicly announced intentions to develop therapeutic genetically altered human antibodies from libraries of human antibody genes. Additionally, each of Amgen, Inc., and Medarex, Inc. has publicly announced intentions to develop therapeutic genetically altered human antibodies from mice that have been bred to include some human antibody genes.

## **Employees**

As of December 31, 2006, we had 296 full-time employees, of which 188 were engaged in research, development, manufacturing, and clinical development, and 108 in administration, commercial and business development and finance. Doctorates are held by 73 of our employees. Each of our employees is required to sign a confidentiality agreement. Our employees are not represented by any collective bargaining unit, and we regard the relationships with our employees as satisfactory.

## **Available Information**

Our Web site address is [www.alexionpharm.com](http://www.alexionpharm.com). On our Web site, we make available, free of charge, our annual and transition reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practical after we electronically file such material with or furnish it to the SEC. The information found on our Web site is not part of this or any other report we file with or furnish to the SEC.



---

**Table of Contents**

**Item 1A. RISK FACTORS.**

You should carefully consider the following risk factors before you decide to invest in our Company and our business because these risk factors may have a significant impact on our business, operating results, financial condition, and cash flows. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected.

**Risks Related to Our Financial Position and Need for Additional Capital**

*If we continue to incur operating losses, we may be unable to continue our operations.*

We have incurred losses since we started our company in January 1992. As of December 31, 2006, we had an accumulated deficit of approximately \$638 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. Since we began our business, we have focused on research and development of product candidates. Although we have submitted for filing a BLA with the FDA in the United States and an MAA in Europe for Soliris (eculizumab), we have no products that are available for sale and do not know when we will have products available for sale, if ever. We expect to continue to operate at a net loss for at least the next several years as we continue our research and development efforts, continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. Our future profitability depends on our receiving regulatory approval of our product candidates and our ability to successfully manufacture and market approved drugs. The extent and the timing of our future losses and our profitability, if we are ever profitable, are highly uncertain.

*If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development.*

We believe that our existing cash, cash equivalents and marketable securities will provide sufficient capital to fund our operations and product development for at least twelve months. We may need to raise additional capital before or after that time to complete the development and continue the commercialization of our product candidates. We are currently preparing for the commercialization of Soliris (eculizumab) and conducting or evaluating several clinical trials. Funding needs may shift between projects and potentially accelerate and increase as we get closer to commercialization of Soliris (eculizumab) or if we initiate new clinical trials for our product candidates.

Additional financing could take the form of public or private debt or equity offerings, equity line facilities, bank loans, collaborative research and development arrangements with corporate partners and/or the sale or licensing of some of our property. The amount of capital we may need depends on many factors, including:

the time and cost necessary to obtain regulatory approvals;

the time and cost necessary to develop sales, marketing and distribution capabilities;

the cost necessary to sell, market and distribute our products, if any are approved;

the time and cost necessary to purchase or to further develop manufacturing processes, arrange for contract manufacturing or build manufacturing facilities and obtain the necessary regulatory approvals for those facilities;

## Table of Contents

changes in applicable governmental regulatory policies or requests by regulatory agencies for additional information or data;

the existence, terms, maintenance, termination and status of collaborative arrangements and strategic partnerships, such as our collaboration with Procter & Gamble, or P&G;

the progress, timing and scope of our research and development programs;

the progress, timing and scope of our preclinical studies and clinical trials;

any new collaborative, licensing or other commercial relationships that we may establish.

We may not get funding when we need it or funding may only be available on unfavorable terms. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back or eliminate our research and development activities or future operations. We might have to license our technology to others. This could result in sharing revenues that we might otherwise retain for ourselves. Any of these actions would harm our business.

*We are significantly leveraged.*

On December 31, 2006, we had outstanding \$150,000,000 principal amount of 1.375% convertible senior notes. On July 11, 2006, our subsidiary Alexion Manufacturing borrowed \$26,000,000 to finance the purchase and construction of our Smithfield, Rhode Island manufacturing facility which may not be prepaid in whole or in part prior to July 11, 2009. The loan is guaranteed by us and bears a fixed annual rate of 9.17%. Our 1.375% convertible senior notes and the mortgage loan remain outstanding, and the degree to which we are leveraged could, among other things:

make it difficult for us to make payments on our notes and our loan;

make it difficult for us to obtain financing for working capital, acquisitions or other purposes on favorable terms, if at all;

make us more vulnerable to industry downturns and competitive pressures; and

limit our flexibility in planning for, or reacting to changes in, our business.

Our ability to meet our debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

### **Risks Related to Our Business**

*We depend heavily on the success of our lead product candidate, Soliris (eculizumab), which is still under development. If we do not obtain FDA approval of Soliris (eculizumab), or if the FDA delays approval or narrows the indications for which we may market Soliris (eculizumab), our business will be materially harmed.*

We recently submitted for filing a BLA to the FDA in the United States and an MAA in Europe for Soliris (eculizumab) for the treatment of PNH. In the near term, our ability to generate revenues will depend on approval and successful commercialization of Soliris (eculizumab). The commercial success of Soliris (eculizumab) will depend on several factors, including the following:

receipt of marketing approvals from the FDA and similar foreign regulatory authorities;

**Table of Contents**

establishing commercial manufacturing capabilities ourselves or through third-party manufacturers;

successfully launching commercial sales of the product;

the number of patients with PNH that may be treated with the product;

acceptance of the product in the medical community; and

acceptance of the product's price by third-party payers.

We may not receive required regulatory approvals on a timely basis or at all. The approval process can involve additional lengthy clinical testing and other costly and time-consuming procedures.

Several biotechnology companies have failed to obtain regulatory approvals because regulatory agencies were not satisfied with the structure or conduct of clinical trials or the formatting or content of regulatory submissions. Similar problems could delay or prevent us from obtaining approvals. Furthermore, regulatory authorities, including the FDA, may not agree with our interpretations of our clinical trial data, which could delay, limit or prevent regulatory approvals. In addition, before a product candidate is approved for marketing, we, or any third-party manufacturing our product, are subject to inspection of the manufacturing facilities and the FDA will not approve the product for marketing if we or our third-party manufacturers are not in compliance with current good manufacturing practices.

Even if the FDA and similar foreign regulatory authorities do grant marketing approval for Soliris (eculizumab), they may narrow the indications for which we are permitted to market the product, may pose other restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. A narrowed indication or other restrictions may limit the market potential for the product and obligation to conduct additional clinical trials would likely result in increased expenditures and lower revenues. Even where the FDA or similar foreign regulatory agencies indicate they are prepared to grant marketing approval for Soliris (eculizumab), we may choose to continue negotiating for broader indications with fewer restrictions, and such negotiations could cause a delay in marketing approval or could jeopardize the receipt of any marketing approval. If we are not successful in commercializing Soliris (eculizumab), or are significantly delayed or limited in doing so, our business will be materially harmed and we may need to curtail or cease operations.

*Inability to contract with third-party manufacturers on commercially reasonable terms, or failure or delay by us or our third-party manufacturers, in manufacturing our drug products in the volumes and quality required, would have a material adverse effect on our business.*

We have no experience or capacity for manufacturing drug products in volumes that would be necessary to support commercial sales and we can provide no assurance that we will be able to do so successfully. We depend on a few outside suppliers for manufacturing. Our small, clinical-scale manufacturing plant cannot manufacture enough of our product candidates for later stage clinical development or commercial supply. We do not have the capacity to produce more than one product candidate at a time in that plant. We acquired a commercial-scale manufacturing plant in Smithfield, Rhode Island in July 2006. However, that plant is not currently equipped or approved by the FDA or other regulatory agencies to manufacture Soliris (eculizumab) or our other drug candidates. We expect that it will be at least two years before the plant is capable of making product for commercial sale. We have no experience in developing commercial-scale manufacturing of the sort anticipated in Smithfield, Rhode Island. We can provide no assurance that we will be able to develop the Smithfield, Rhode Island site into a plant capable of manufacturing our drug products under conditions required by the FDA or

## **Table of Contents**

foreign regulatory agencies on a timely basis, if at all. Our plant in Smithfield, Rhode Island will be subject to FDA inspection and approval before we can begin manufacturing Soliris (eculizumab) there and will continue to be subject to ongoing FDA inspections thereafter. Our Smithfield, Rhode Island plant will also be subject to European regulatory inspection and approval before we can begin manufacturing Soliris (eculizumab) there for European sales and will continue to be subject to ongoing European regulatory inspection thereafter.

We have executed a commercial-scale product supply agreement with Lonza for the long-term manufacture of eculizumab. The failure of Lonza to manufacture appropriate supplies of eculizumab on a timely basis, or at all, may prevent or impede the commercialization of Soliris (eculizumab). If eculizumab is approved for sale, we expect that Lonza or we would be required to manufacture substantially more material than we have required for clinical and preclinical trials. We and our outside manufacturers may experience higher manufacturing failure rates than in the past if and when we attempt to substantially increase production volume. If we experience interruptions in the manufacture of our products, our drug development and commercialization efforts will be delayed. If any of our outside manufacturers stops manufacturing our products or reduces the amount manufactured, or is otherwise unable to manufacture our required amounts at our required quality, we will need to find other alternatives, which is likely to be expensive and time consuming, and even if we are able to find alternatives they may ultimately be insufficient for our needs. As a result, our ability to conduct testing and drug trials and our plans for commercialization would be materially adversely affected. Submission of products and new development programs for regulatory approval, as well as our plans for commercialization, would be delayed. Our competitive position and our prospects for achieving profitability would be materially and adversely affected.

Manufacture of drug products, including the need to develop and utilize manufacturing processes that consistently produce our drug products to their required quality specifications, is highly regulated by the FDA and other domestic and foreign authorities. Regulatory authorities must approve the facilities in which our products are manufactured prior to granting market approval for any product candidate. Manufacturing facilities are also subject to ongoing inspections, and minor changes in manufacturing processes may require additional regulatory approvals. We cannot assure you that we or our third-party collaborators will successfully comply with all of those requirements and regulations, which failure would have a materially adverse effect on our business.

Manufacture of our drug products is highly technical and only a few third-parties have the ability and capacity to manufacture our drug products for our development and commercialization needs. We cannot assure you that these potential third-party collaborators will agree to manufacture our products on our behalf on commercially reasonable terms, if at all. If we do achieve agreement from one or more third parties to manufacture our drug products, we cannot assure you that they will be able or willing to honor the terms of the agreements, including any obligations to manufacture the drug products in accordance with regulatory requirements and to our quality specifications and volume requirements. Due to the highly technical requirements of manufacturing our drug products, our third-party collaborators and we may be unable to manufacture our drug products despite their and our efforts.

Due to the nature of the current market for third-party commercial manufacturing, many arrangements require substantial penalty payments by the customer for failure to use the manufacturing capacity for which it contracted. We could owe substantial penalty payments to Lonza if we were not to use the manufacturing capacity for which we contracted. Penalty payments under these agreements typically decrease over the life of

---

**Table of Contents**

the agreement, and may be substantial initially and de minimis or non-existent in the final period. The payment of a substantial penalty would harm our financial condition.

*If we are unable to establish sales, marketing and distribution capabilities, or to enter into agreements with third parties to do so, we will be unable to successfully market and sell future drug products.*

We have no experience with marketing, sales and distribution of drug products and have only recently established pre-commercial capability in those areas. If we are unable to establish capabilities to sell, market and distribute our products, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully sell Soliris (eculizumab) or our future drug products. In that event, we will not be able to generate significant revenues. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need. We may not be able to enter into any marketing or distribution agreements with third-party providers on acceptable terms, if at all.

*If we are unable to obtain reimbursement for our future products from government health administration authorities, private health insurers and other organizations, our products may be too costly for regular use and our ability to generate revenues would be harmed.*

Soliris (eculizumab), if commercialized, is likely to be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if we cannot depend on governmental, private third-party payers and other third-party payers, including Medicare and Medicaid, to defray the cost of Soliris (eculizumab) to the consumer. If these entities refuse to provide coverage and reimbursement with respect to Soliris (eculizumab) or determine to provide an insufficient level of coverage and reimbursement, Soliris (eculizumab) may be too costly for general use, and physicians may not prescribe it. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Third-party payers may be especially likely to impose these obstacles to coverage for higher-priced drugs, which we anticipate Soliris (eculizumab) to be.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability and worsen our financial condition. In the United States and elsewhere, there have been, and we expect there will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs.

Since Soliris (eculizumab) will likely be too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers is not available, our ability to successfully commercialize Soliris (eculizumab) may be adversely impacted. Any limitation on the use of Soliris (eculizumab) or any decrease in the price of Soliris (eculizumab) will have a material adverse effect on our ability to achieve profitability.

Even where patients have access to insurance, their insurance co-payment amounts may be too expensive for them to afford. We anticipate that Alexion will financially support charitable organizations whose mission is to assist patients in acquiring drugs such as Soliris (eculizumab). Those charitable organizations may assist patients who have no insurance coverage for drugs or whose insurance coverage leaves them with prohibitive co-payment amounts or other expensive financial obligations. In addition, we anticipate that Alexion will provide

## **Table of Contents**

Soliris (eculizumab) without charge for related charitable purposes. We are not able to predict the financial impact of the support we may provide for these and other charitable purposes; however, substantial support could have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operation may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

*If the testing or use of our products harms people, or is perceived to harm patients even when such harm is unrelated to our products, our clinical trials may be adversely affected, our regulatory approval process could be delayed, negatively impacted or abandoned, any regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.*

The testing, manufacturing, marketing and sale of drugs for use in humans exposes us to product liability risks. Side effects and other problems from using our products could cause serious adverse events and give rise to product liability claims against us. We might have to withdraw or recall our products from the marketplace. Some of these risks are unknown at this time.

We have tested Soliris (eculizumab) in only a small number of patients. If our applications for marketing Soliris (eculizumab) are approved and more patients begin to use our product, new risks and side effects associated with Soliris (eculizumab) may be discovered, and risks previously viewed as inconsequential could be determined to be significant. As a result, regulatory authorities may delay or revoke their approvals; we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers' manufacturing facilities. We may also experience a significant drop in the potential sales of our product if and when regulatory approvals for Soliris (eculizumab) are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of Soliris (eculizumab) or substantially increase the costs and expenses of commercializing and marketing Soliris (eculizumab).

We may be sued by people who participate in our trials or who use our products. Many patients who participate in our trials or use our products are already very ill. Any informed consents or waivers obtained from people who enroll in our trials or use our products may not protect us from liability or litigation. Our product liability insurance may not cover all potential types of liabilities or may not cover covered types of liabilities completely. Moreover, we may not be able to maintain our insurance on acceptable terms. In addition, negative publicity relating to the use of our product or to a product liability claim may make it more difficult, or impossible, for us to recruit patients for our clinical trials or to market and sell our products. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

## **Table of Contents**

Our clinical trials are often conducted with patients who have severe and advanced stages of disease when they enter our trials. Patients involved in clinical trials such as ours often have known as well as unknown significant pre-existing health risks. During the course of a trial, patients may suffer adverse events, including death, for reasons that may or may not be related to our products. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients or delay, negatively impact or end our opportunity to receive regulatory approval to market our products. Even in a circumstance in which we do not believe that an adverse event is related to our product, the investigation into the circumstance may be time consuming or may be inconclusive. These investigations may delay our regulatory approval process, impact and limit the type of regulatory approvals our products receive, or end our opportunity to receive regulatory approval. PNH patients in our trials sometimes have additional, pre-existing, potentially life-threatening disease, including for example bone marrow failure.

Some patients who have participated in our PNH trials have died or suffered potentially life-threatening diseases either during or after ending study-specified treatments. In particular, use of C5 Inhibitors, such as eculizumab, is associated with an increased risk for infection with Neisseria bacteria. Serious cases of Neisseria infection can result in severe illness, including but not limited to brain damage, loss of limbs or parts of limbs, kidney failure, or death. PNH patients in our TRIUMPH and SHEPHERD trials all received vaccination against the Neisseria bacteria prior to first administration of eculizumab; however, vaccination does not eliminate all risk of becoming infected with Neisseria bacteria. Some patients in our trials of eculizumab for the treatment of PNH and other diseases have become infected with Neisseria bacteria, including PNH patients in the open-label extension trial E05-001 who had been vaccinated against Neisseria bacteria. Each such incident has been reported to appropriate regulatory agencies in accordance with relevant regulations.

We are also aware of a potential risk for PNH patients who delay a dose of Soliris (eculizumab) or discontinue their treatment of Soliris (eculizumab). Treatment with Soliris (eculizumab) blocks complement and allows complement-sensitive PNH red blood cells to increase in number. If treatment with Soliris (eculizumab) is thereafter delayed or discontinued, a greater number of red blood cells therefore would become susceptible to destruction when the patient's complement system is no longer blocked. The rapid destruction of a larger number of a patient's red blood cells may lead to numerous complications, including death. Several PNH patients in our studies of Soliris (eculizumab) have received delayed doses or discontinued their treatment. In none of those circumstances were complications from rapid destruction of a larger number of PNH red blood cells observed to be significant; however, we have not studied the delay or termination of treatment in enough patients to determine that complications in the future are unlikely to occur. Determination of significant complications associated with the delay or discontinuation of Soliris (eculizumab) could have a material adverse effect on our ability to sell eculizumab for PNH.

*If we are unable to engage and retain third-party collaborators, our research and development efforts may be delayed.*

We depend upon third-party collaborators to assist us in the development of our product candidates. If any of our existing collaborators breaches or terminates its agreement with us or does not perform its development work under an agreement in a timely manner, or at all, we would experience significant delays in the development or commercialization of our product candidates. We would also experience significant delays if we could not engage additional collaborators when required. In either event, we would be required to devote additional funds or other resources to these activities or to terminate them. Either of these events would divert funds or other resources from other parts of our business.



## Table of Contents

We cannot assure you that:

our current collaboration arrangements will continue in their current form;

we will be able to negotiate acceptable collaborative agreements to develop or commercialize our product candidates;

any arrangements with third parties will be successful; or

current or potential collaborators will not pursue treatments for other diseases or seek other ways of developing treatments for our disease targets.

*If our competitors get to the marketplace before we do with better or cheaper drugs, our drugs may not be profitable to sell or to continue to develop.*

Each of Adprotech Ltd., Avant Immunotherapeutics, Inc., Tanox, Inc., XOMA, Ltd., Novo Nordisk A/S and Archemix Corporation have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. We are also aware that Abbott Laboratories, Inc., Baxter International, Inc., Millennium Pharmaceuticals, Inc. and Neurogen Corporation, have had programs develop complement inhibitor therapies. Each of AstraZeneca, MorphoSys AG and Dyax Corporation has publicly announced intentions to develop therapeutic human antibodies from libraries of human antibody genes. Additionally, each of Amgen, Inc. and Medarex, Inc. has publicly announced intentions to develop therapeutic human antibodies from mice that have been bred to include some human antibody genes. These and other pharmaceutical companies, many of which have significantly greater resources than we, may develop, manufacture, and market better or cheaper drugs than our product candidates. They may establish themselves in the marketplace even before we are able to finish our clinical trials. Other pharmaceutical companies also compete with us to attract academic research institutions as drug development partners, including for licensing these institutions' proprietary technology. If our competitors successfully enter into such arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may not be able to find equivalent opportunities elsewhere.

*If we fail to recruit and retain personnel, our research and product development programs may be delayed.*

We are highly dependent upon the efforts of our senior management and scientific personnel, particularly Dr. Leonard Bell, M.D., our Chief Executive Officer and a member of our Board of Directors, David W. Keiser, our President, Chief Operating Officer and a member of our Board of Directors, and Stephen P. Squinto, Ph.D., our Executive Vice President and Head of Research. There is intense competition in the biotechnology industry for qualified scientific and technical personnel. Since our business is very science-oriented and specialized, we need to continue to attract and retain such people. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. We have employment agreements with Dr. Bell, Mr. Keiser, and Dr. Squinto. None of our key personnel is nearing retirement age or to our knowledge, planning to retire. To our knowledge, there is no tension between any of our key personnel and the Board of Directors. If we lose the services of our management and scientific personnel and fail to recruit other scientific and technical personnel, our research and product development programs will be materially and adversely affected.

In particular, we highly value the services of Dr. Bell, our Chief Executive Officer. The loss of his services could materially and adversely affect our ability to achieve our objectives.

## Table of Contents

*We are subject to environmental laws and potential exposure to environmental liabilities.*

We are subject to various federal, state and local environmental laws and regulations that govern our operations, including the handling and disposal of non-hazardous and hazardous wastes, including medical and biological wastes, and emissions and discharges into the environment, including air, soils and water sources. Failure to comply with such laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We also are subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs of remediating its property or locations to which wastes were sent from its facilities, without regard to whether the owner or operator knew of, or necessarily caused, the contamination. Such obligations and liabilities, which to date have not been material, could have a material impact on our business and financial condition.

*We may expand our business through acquisitions that could disrupt our business and harm our financial condition.*

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions to do so. Acquisitions involve numerous risks, including:

substantial cash expenditures;

potentially dilutive issuance of equity securities;

incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;

difficulties in assimilating the operations of the acquired companies;

diverting our management's attention away from other business concerns;

risks of entering markets in which we have limited or no direct experience; and

the potential loss of our key employees or key employees of the acquired companies.

We cannot assure you that any acquisition will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions. We cannot assure you that we will be able to make the combination of our business with that of acquired businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired business or companies may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our capital stock, which could dilute current stockholders' ownership interest in our company, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest in our company upon conversion.

*Our ability to use net operating loss carry forwards to reduce future tax payments may be limited if there is a change in ownership of Alexion.*

As of December 31, 2006, we had approximately \$618 million of net operating loss carry forwards, or NOLs, available to reduce taxable income in future years. We believe that some of these NOLs are currently subject to an annual limitation under section 382 of the Internal Revenue Code of 1986, as amended.



## **Table of Contents**

Our ability to utilize our NOLs may be further limited if we undergo an ownership change, as defined in section 382, as a result of subsequent changes in the ownership of our outstanding stock. We would undergo an ownership change if, among other things, the stockholders, or group of stockholders, who own or have owned, directly or indirectly, 5% or more of the value of our stock, or are otherwise treated as 5% stockholders under section 382 and the regulations promulgated there under, increase their aggregate percentage ownership of our stock by more than 50 percentage points over the lowest percentage of our stock owned by these stockholders at any time during the testing period, which is generally the three-year period preceding the potential ownership change. In the event of an ownership change, section 382 imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change NOLs. The limitation imposed by section 382 for any post-change year would be determined by multiplying the value of our stock immediately before the ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Any unused limitation may be carried over to later years, and the limitation may under certain circumstances be increased by built-in gains which may be present with respect to assets held by us at the time of the ownership change that are recognized in the five-year period after the ownership change. Our use of NOLs arising after the date of an ownership change would not be affected.

### **Risks Related to Our Industry**

*We are subject to extensive government regulation, and, if we do not obtain and maintain regulatory approvals, we will not be able to sell our drug products.*

We and our partners cannot sell or market our products without regulatory approval. If we or our partners do not obtain and maintain regulatory approval for our products, the value of our company and our results of operations will be harmed. In the United States, we or our partners must obtain and maintain approval from the FDA for each indication for each drug that we intend to sell and for each facility where such drug is manufactured. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed outside the United States and facilities outside the United States where such drugs are manufactured, and obtaining their approvals can also be lengthy, expensive and highly uncertain. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. In certain foreign jurisdictions we would be required to obtain pricing approvals prior to marketing our products. None of our product candidates has received regulatory approval to be marketed and sold in the United States or any other country. We may not receive regulatory approval for any of our product candidates for at least the next several years, if ever.

We and our partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by the FDA, other federal and state agencies, and governmental authorities in other countries. These regulations apply both before and after approval of our product candidates, if our product candidates are ever approved, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, and export of biologics. As a condition of approval for marketing our product, FDA, or governmental authorities in other countries may require us to conduct additional clinical trials. Our manufacturing and other facilities and those of any third parties manufacturing our products will be subject to inspection prior to grant of marketing approval and subject to continued review and periodic inspections by the regulatory authorities. Any third party we would use to manufacture our products for sale must also be licensed by applicable regulatory authorities. Failure to

**Table of Contents**

comply with the laws, including statutes and regulations, administered by the FDA or other agencies could result in:

administrative and judicial sanctions, including, warning letters;

fines and other civil penalties;

delays in approving or refusal to approve a product candidate;

withdrawal of a previously granted approval;

product recall or seizure;

interruption of production;

operating restrictions;

injunctions; and

criminal prosecution.

The discovery of previously unknown problems with a product or the facility used to produce the product could result in a regulatory authority imposing restrictions on us, or could cause us to voluntarily adopt such restrictions, including withdrawal of one or more of our products or services from the market.

We may be unable to obtain necessary regulatory approvals in the United States and foreign countries on a timely basis, if at all, for any of our product candidates or maintain such approvals if obtained. Any delays in obtaining necessary regulatory approvals or failure to maintain them could prevent us from marketing our products.

The FDA has granted orphan drug designation for eculizumab in the treatment of PNH and membranous nephritis. Orphan drug designation does not convey any advantage in, or shorten the duration of, the FDA review and approval process. If a product which has an orphan drug designation is the first drug of its type to receive FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances.

*If our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our products.*

We must conduct extensive testing of our product candidates before we can obtain regulatory approval for our products. We need to conduct both preclinical animal testing and clinical human trials. These tests and trials may not achieve favorable results. The FDA typically requires two well controlled clinical trials that demonstrate efficacy in order to obtain FDA approval to market a product candidate. The special protocol assessment for our development of Soliris (eculizumab) for PNH provides for only a single efficacy trial and the FDA has indicated that the trials should provide compelling evidence of clinically meaningful benefit in order to warrant consideration for marketing approval. The FDA has noted that a study that is merely statistically positive may not provide the evidence necessary to support filing or approval of a product candidate.

## Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

The FDA and other regulatory agencies may require additional information or data prior to and after acceptance of our BLA and MAA for Soliris (eculizumab) for PNH. We may have to conduct additional lengthy clinical testing and other costly and time-consuming procedures. Inconclusive or negative final data from

---

**Table of Contents**

our 12 month Phase III SHEPHERD trial would have a significant negative impact on our prospects. Even if we view the data as positive, the FDA may not agree with our interpretations of our clinical trial data for Soliris (eculizumab) and may decide that our results are not adequate to support approval for marketing of Soliris (eculizumab). In those circumstances, we would not be able to obtain regulatory approval on a timely basis, if ever. Even if approval is granted, the approval may require limitations on the indicated uses for which the drug may be marketed. In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries.

*Completion of clinical trials does not guarantee advancement to the next phase of development.*

Completion of clinical trials does not guarantee that we will initiate additional trials for our product candidates, that if the trials are initiated what the scope and phase of the trial will be or that they will be completed, or that if the trials are completed, that the results will provide a sufficient basis to proceed with further trials or to apply for or receive regulatory approvals or to commercialize products. Results of trials could be inconclusive, requiring additional or repeat trials. If the results achieved in our clinical trials are insufficient to proceed to further trials or to regulatory approval of our product candidates, our company could be materially adversely affected. Failure of a trial to achieve its pre-specified primary endpoint generally increases the likelihood that additional studies will be required if we determine to continue development of the product candidate, reduces the likelihood of timely development of and regulatory approval to market the product candidate, and may decrease the chances for successfully achieving the primary endpoint in scientifically similar indications.

*There are many reasons why drug testing could be delayed or terminated.*

For human trials, patients must be recruited and each product candidate must be tested at various doses and formulations for each clinical indication. In addition, to ensure safety and effectiveness, the effect of drugs often must be studied over a long period of time, especially for the chronic diseases that we are studying. Unfavorable results or insufficient patient enrollment in our clinical trials could delay or cause us to abandon a product development program. We may decide to abandon development of a product candidate at any time, or we may have to spend considerable resources repeating clinical trials or conducting additional trials, either of which would increase costs and delay any revenue from those product candidates, if any.

Additional factors that can cause delay, impairment or termination of our clinical trials or our product development efforts include:

slow patient enrollment, including for example due to the rarity of the disease being studied;

long treatment time required to demonstrate effectiveness;

lack of sufficient supplies of the product candidate;

disruption of operations at the clinical trial sites;

adverse medical events or side effects in treated patients;

**Table of Contents**

the failure of patients taking the placebo to continue to participate in our clinical trials;

insufficient clinical trial data to support effectiveness of the product candidates;

lack of effectiveness of the product candidate being tested;

lack of sufficient funds;

inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner; or

failure to obtain the necessary regulatory approvals for the product candidate or the approvals for the facilities in which such product candidate is manufactured.

**Risks Related to Intellectual Property**

*If we cannot protect the confidentiality and proprietary nature of our trade secrets, our business and competitive position will be harmed.*

Our business requires using sensitive technology, techniques and proprietary compounds that we protect as trade secrets. However, since we are a small company, we also rely heavily on collaboration with suppliers, outside scientists and other drug companies. Collaboration presents a strong risk of exposing our trade secrets. If our trade secrets were exposed, it would help our competitors and adversely affect our business prospects.

In order to protect our drugs and technology more effectively, we need to obtain and maintain patents covering the drugs and technologies we develop. We may obtain patents through ownership or license. Our drugs are expensive and time-consuming to test and develop. Without patent protection, competitors may copy our methods, or the chemical structure or other aspects of our drugs. Even if we obtain and maintain patents, the patents may not be broad enough to protect our drugs from copycat products.

*If we are found to be infringing on patents owned by others, we may be forced to pay damages to the patent owner and obtain a license to continue the manufacture, sale or development of our drugs and/or pay damages. If we cannot obtain a license, we may be prevented from the manufacture, sale or development of our drugs.*

Parts of our technology, techniques and proprietary compounds and potential drug candidates, including those which are in-licensed, may be found to infringe patents owned by or granted to others. If we cannot resolve these conflicts, we may be liable for damages, be required to obtain costly licenses or be stopped from manufacturing, using or selling our products or conducting other activities. For example, we are aware of broad patents owned by others relating to the manufacture, use and sale of recombinant humanized antibodies, recombinant humanized single chain antibodies, recombinant human antibodies, and recombinant human single chain antibodies. Many of our product candidates, including our lead product candidate, eculizumab, are either genetically engineered antibodies, including recombinant humanized antibodies, recombinant humanized single chain antibodies, recombinant human antibodies, or recombinant human single chain antibodies.

We have received notices from the owners of some of these patents claiming that their patents may be infringed by the development, manufacture or sale of some of our drug candidates, including eculizumab. We are also aware of other patents owned by third parties that might be claimed to be infringed by the development and commercialization of some of our drug candidates, including eculizumab. In respect to some of these patents, we



## **Table of Contents**

have obtained licenses, or expect to obtain licenses. However, with regard to other patents, we have either determined in our judgment that:

we believe our products do not infringe the patents;

we do not believe the patents are valid; or

we have identified and are testing various modifications that we believe should not infringe the patents and which should permit commercialization of our product candidates.

Any holder of these patents or other patents covering similar technology could sue us for damages and seek to prevent us from manufacturing, selling or developing our drugs. Legal disputes can be costly and time consuming to defend. If any patent holder successfully challenges our judgment that our products do not infringe their patents or that their patents are invalid, we could be required to pay costly damages or to obtain a license to sell or develop our drugs. A required license may be costly or may not be available on acceptable terms, if at all. A costly license, or inability to obtain a necessary license, could have a material adverse effect on our business.

There can be no assurance that we would prevail in a patent infringement action; will be able to obtain a license to any third-party patent on commercially reasonable terms; successfully develop non-infringing alternatives on a timely basis; or license alternative non-infringing technology, if any exists, on commercially reasonable terms. Any impediment to our ability to manufacture or sell approved forms of our product candidates could have a material adverse effect on our business and prospects.

### **Risks Related to Our Common Stock**

*If the trading price of our common stock continues to fluctuate in a wide range, our stockholders will suffer considerable uncertainty with respect to an investment in our common stock.*

The trading price of our common stock has been volatile and may continue to be volatile in the future. Factors such as announcements of fluctuations in our or our competitors' operating results or clinical or scientific results, fluctuations in the trading prices or business prospects of our competitors and collaborators, changes in our prospects, particularly with respect to regulatory approval of Soliris (eculizumab), and market conditions for biotechnology stocks in general could have a significant impact on the future trading prices of our common stock and our convertible senior notes. In particular, the trading price of the common stock of many biotechnology companies, including ours, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of the companies whose stocks were affected. This is due to several factors, including general market conditions, the announcement of the results of our clinical trials or product development and the results of our attempts to obtain FDA approval for our products. In particular, since August 1, 1999, the sales price of our common stock has ranged from a low of \$9.05 per share to a high of \$119.88 per share. While we cannot predict our future performance, if our stock price continues to fluctuate in a wide range, an investment in our common stock may result in considerable uncertainty for an investor.

*Anti-takeover provisions of Delaware law, provisions in our charter and bylaws and our stockholders' rights plan, or poison pill, could make a third-party acquisition of us difficult and may frustrate any attempt to remove or replace our current management.*

Because we are a Delaware corporation, the anti-takeover provisions of Delaware law could make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to

## **Table of Contents**

stockholders. We are subject to the provisions of Section 203 of the Delaware General Laws, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our corporate charter and by-law provisions and stockholder rights plan may discourage certain types of transactions involving an actual or potential change of control that might be beneficial to Alexion or its stockholders. Our bylaws provide that special meetings of our stockholders may be called only by the Chairman of the Board, the President, the Secretary, or a majority of the Board of Directors, or upon the written request of stockholders who together own of record 50% of the outstanding stock of all classes entitled to vote at such meeting. Our bylaws also specify that the authorized number of directors may be changed only by resolution of the board of directors. Our certificate does not include a provision for cumulative voting for directors, which may have enabled a minority stockholder holding a sufficient percentage of a class of shares to elect one or more directors. Under our certificate of incorporation, our board of directors has the authority, without further action by stockholders, to designate up to 5,000,000 shares of preferred stock in one or more series. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any class or series of preferred stock that may be issued in the future.

Pursuant to our stockholder rights plan, each share of common stock has an associated preferred stock purchase right. The rights will not trade separately from the common stock until, and are exercisable only upon, the acquisition or the potential acquisition through tender offer by a person or group of 20% or more of the outstanding common stock. The rights are designed to make it more likely that all of our stockholders receive fair and equal treatment in the event of any proposed takeover of us and to guard against the use of partial tender offers or other coercive tactics to gain control of us.

These provisions could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices. These provisions could also limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and could adversely affect the price of our common stock.

### **Item 1B. UNRESOLVED STAFF COMMENTS.**

None

### **Item 2. PROPERTIES.**

#### **Facilities**

We lease our headquarters and research and development facilities in Cheshire, Connecticut. The lease, which had an initial term of ten years and six months, expiring in December 2010, was extended in August 2006 to expire in July 2017. At this site, we lease a total of approximately 129,000 square feet of space. Our pilot manufacturing plant, which may be used for producing compounds for some of our current and anticipated clinical trials, is located in New Haven, Connecticut, encompassing approximately 33,000 square feet of labs and offices. The lease for our facility in New Haven has an initial term of approximately 5 years, expiring in October 2007 with three renewal options to extend for periods of one year each. Alexion Antibody Technologies, Inc.

**Table of Contents**

leases approximately 17,000 square feet of labs, office and unimproved storage space in San Diego, California. The lease has an initial term of ten years, expiring in August 2012. Alexion Manufacturing, LLC owns a manufacturing facility in Smithfield, Rhode Island, which it purchased in July 2006. The facility is approximately 56,500 square feet in total, with approximately 25,000 square feet of manufacturing space and 31,500 square feet of clinical and office space. Alexion Europe SAS rents approximately 350 square meters of office space in Paris, France. The agreement has automatic renewal features built in until the agreement is terminated by either party or December 2008, whichever is earlier. We believe our research and development facilities, our pilot manufacturing facility, and our manufacturing facility, together with third party manufacturing facilities, will be adequate for our on-going activities.

**Item 3.      *LEGAL PROCEEDINGS.***

We are not a party to any material legal proceeding.

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

There were no matters voted on.

**Table of Contents****EXECUTIVE OFFICERS AND KEY EMPLOYEES OF THE COMPANY**

The executive officers and key employees of the Company and their respective ages and positions with the Company as of February 23, 2007 are as follows:

<b>Name</b>	<b>Age</b>	<b>Position with Alexion</b>
* Leonard Bell, M.D.	48	Chief Executive Officer, Secretary, Treasurer, Director
* David W. Keiser	55	President and Chief Operating Officer
* Stephen P. Squinto, Ph.D.	50	Executive Vice President and Head of Research
* Patrice Coissac	58	Senior Vice President General Manager and President of Alexion Europe SAS
* Thomas I.H. Dubin, J.D.	44	Senior Vice President and General Counsel
* Christopher F. Mojcik, M.D., Ph.D.	47	Senior Vice President, Clinical Development
NancyC. Motola, Ph.D.	54	Senior Vice President, Regulatory Affairs and Quality
Scott A. Rollins, Ph.D.	43	Senior Vice President, Drug Development and Project Management
Russell P. Rother, Ph. D.	46	Senior Vice President, Research
* Vikas Sinha, M.B.A., C.A.	43	Senior Vice President and Chief Financial Officer
Paul W. Finnegan, M.D, M.B.A.	46	Vice President, Global Commercial Operations and Development
David Hallal	40	Vice President, United States Commercial Operations
M. Stacy Hooks, Ph.D.	39	Vice President, Manufacturing and Technical Services
Barry P. Luke, M.B.A.	48	Vice President, Finance, Assistant Secretary
Daniel N. Caron	43	Executive Director, Operations and Engineering

\* These employees are officers for purposes of Section 16 of the Securities Exchange Act of 1934.

**Leonard Bell, M.D.** is the principal founder of Alexion, and has been a director of Alexion since February 1992 and the Company's President and Chief Executive Officer, Secretary and Treasurer from January 1992. In April 2002, the title of President was transferred to David Keiser. From 1991 to 1992, Dr. Bell was an Assistant Professor of Medicine and Pathology and co-Director of the program in Vascular Biology at the Yale University School of Medicine. From 1990 to 1992, Dr. Bell was an attending physician at the Yale-New Haven Hospital and an Assistant Professor in the Department of Internal Medicine at the Yale University School of Medicine. Dr. Bell was a recipient of the Physician Scientist Award from the National Institutes of Health and Grant-in-Aid from the American Heart Association as well as various honors and awards from academic and professional organizations. His work has resulted in more than 20 scientific publications and 9 patent applications. Dr. Bell was also a director of The Medicines Company from May 2000 until April 2005. He also served as a director of the Biotechnology Research and Development Corporation from 1993 to 1997. Dr. Bell received his A.B. from Brown University and M.D. from Yale University School of Medicine. Dr. Bell is currently an Adjunct Assistant Professor of Medicine and Pathology at Yale University School of Medicine.

**David W. Keiser** became President in addition to Chief Operating Officer, and joined the board as a director in April 2002. From July 1992 to April 2002, Mr. Keiser was Executive Vice President and Chief Operating Officer of Alexion. From 1990 to 1992, Mr. Keiser was Senior Director of Asia Pacific Operations for G.D. Searle & Company Limited, a manufacturer of pharmaceutical products. From 1986 to 1990, Mr. Keiser was successively Licensing Manager, Director of Product Licensing and Senior Director of Product Licensing for

## Table of Contents

Searle. From 1984 to 1985, Mr. Keiser was New Business Opportunities Manager for Mundipharma AG, a manufacturer of pharmaceutical products, in Basel, Switzerland where he headed pharmaceutical licensing and business development activities in Europe and the Far East. From 1978 to 1983, he was Area Manager for F. Hoffmann La Roche Ltd., a manufacturer of pharmaceutical products, in Basel, Switzerland. Mr. Keiser received his B.A. from Gettysburg College.

**Stephen P. Squinto, Ph.D.** is a founder of Alexion and has been Executive Vice President and Head of Research since August 2000. He held the positions of Senior Vice President and Chief Technical Officer from March 1998 to July 2000, Vice President of Research, Molecular Sciences, from August 1994 to March 1998, Senior Director of Molecular Sciences from July 1993 to July 1994, and Director of Molecular Development from 1992 to July 1993. From 1989 to 1992, Dr. Squinto held various positions at Regeneron Pharmaceuticals, Inc. most recently serving as Senior Scientist and Assistant Head of the Discovery Group. From 1986 to 1989, Dr. Squinto was an Assistant Professor of Biochemistry and Molecular Biology at Louisiana State University Medical Center. Dr. Squinto's work has led to over 70 scientific papers in the fields of gene regulation, growth factor biology and gene transfer. Dr. Squinto's work is primarily in the fields of regulation of eukaryotic gene expression, mammalian gene expression systems and growth receptor and signal transduction biology. Dr. Squinto served as a Director of the Biotechnology Research and Development Corporation, a biotechnology consortium, from 1997 to 2003. Dr. Squinto received his B.A. in Chemistry and Ph.D. in Biochemistry and Biophysics from Loyola University of Chicago.

**Patrice Coissac**, joined Alexion as Senior Vice President, General Manager and President of Alexion Europe SAS in November 2005. Mr. Coissac has a broad international background in the pharmaceutical industry. Most recently since mid 2004, he founded and ran his own consulting firm to serve the bio pharmaceutical companies in their strategic development. Previously he was President of Pharmacia SAS in France, a position he held from 1999 to mid 2003 when Pharmacia was acquired by Pfizer. While at Pharmacia, Mr. Coissac was responsible for the integration of Monsanto (Searle) with Pharmacia & Upjohn in France. During his tenure, sales grew almost three fold to 615 millions in 2002. Prior to joining Pharmacia, Mr. Coissac held several managerial positions at leading pharmaceutical companies including Head of Operations for Novartis, Belgium; and President of Boehringer Mannheim Therapeutics in France. Mr. Coissac also served as Senior Vice President, Marketing for global pharmaceutical operations at Corange International. And previously, he held several global marketing positions in Sandoz Pharmaceuticals: in Tokyo where he was posted during several years, in Switzerland in Sandoz World Headquarters and in France at the beginning of his career.

**Thomas I.H. Dubin, J.D.** has been Senior Vice President and General Counsel since August 2005. He was Vice President and General Counsel from January 2001 to July 2005. From February 1999 to September 2000 he served as Vice President, General Counsel and Secretary for ChiRex Inc., a NASDAQ-traded international corporation providing advanced process development services and specialty manufacturing to the pharmaceutical industry, which in September 2000 was acquired by and merged into Rhodia. From 1992 to 1999, Mr. Dubin held various positions with Warner-Lambert Company, including Assistant General Counsel, Pharmaceuticals. Prior to his tenure with Warner-Lambert, Mr. Dubin was a corporate attorney for five years with Cravath, Swaine & Moore in New York. Mr. Dubin received his J.D. from New York University and his B.A., cum laude, from Amherst College.

---

**Table of Contents**

**Christopher F. Mojcik, M.D., Ph.D.** has been Senior Vice President, Clinical Development since February 2004. Dr. Mojcik was Vice President, Clinical Development from August 2000 to January 2004. From the time he joined Alexion in July 1998, until July 2000, Dr. Mojcik was Senior Director of Clinical Development. From 1996 until July 1998, he was an Associate Director in the Metabolics/Rheumatics Department at Bayer Corporation's Pharmaceuticals Division. Dr. Mojcik was responsible for Phase II and III development of certain arthritis programs and certain Phase IV programs in cardiopulmonary bypass. From 1993 to 1996, he was a Senior Staff Fellow in the Cellular Immunology Section of the Laboratory of Immunology in the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. From 1991 to 1993, he completed his Fellowship in Rheumatology in the National Institute of Arthritis and Musculoskeletal and Skin Diseases at the NIH. He received his B.A. from Washington University in St. Louis, Missouri, and his M.D. and Ph.D. from the University of Connecticut.

**Nancy C. Motola, Ph.D., RAC** has been the Senior Vice President, Regulatory Affairs and Quality since February 2004. Dr. Motola was Vice President, Regulatory and Quality from 1998 to January 2004. From 1991 to 1998, she served as Assistant, Associate and then Deputy Director, Regulatory Affairs for the Bayer Corporation Pharmaceuticals Division where she was responsible for regulatory aspects of product development and U.S. life-cycle management programs for cardiovascular, neuroscience, metabolic and oncology drugs. These programs included drugs targeting arthritis, cardiac disorders, stroke and cognitive dysfunction. Prior to Bayer, Dr. Motola held regulatory affairs positions of increasing responsibility at Abbott Laboratories from 1989 to 1991 and at E.R. Squibb and Sons, Inc. from 1987 to 1989. From 1983 to 1987, she was Research Investigator, Chemical Process Technologies at Squibb. Dr. Motola has been responsible for the filing of numerous Investigational New Drug Applications (INDs) and has filed New and Supplemental Drug Applications for marketing approval, resulting in marketed drugs. She also served as Chairperson of the Regulatory Sciences Section of the American Association of Pharmaceuticals Scientists (AAPS). Dr. Motola is Regulatory Affairs (RAC) certified and received her B.A. in Chemistry from Central Connecticut State University and M.S. and Ph.D. degrees in medicinal chemistry from the University of Rhode Island, College of Pharmacy.

**Scott A. Rollins, Ph.D.** is a co-founder of Alexion and has been Senior Vice President, Drug Development and Project Management since September 2002. From August 2000 to September 2002, Dr. Rollins was Vice President, Drug Development and Project Management. Dr. Rollins was Senior Director of Project Management and Drug Development from August 1999 to July 2000, Senior Director of Complement Biology from 1997 to 1999, Director of Complement Biology from 1996 to 1997, Principal Scientist from 1994 to 1996, and Staff Scientist from 1992 to 1994. Over the past 15 years at Alexion, Dr. Rollins has played a key role in the discovery, characterization and development of eculizumab and pexelizumab. Prior to 1992, Dr. Rollins was a postdoctoral research fellow in the Department of Immunobiology at Yale University School of Medicine. Dr. Rollins is recognized as a leader in the field of Complement Biology and his work has led to over 50 scientific papers and patents. He received his B.S. in Cytotechnology and Ph.D. in Microbiology and Immunology from the University of Oklahoma Health Sciences Center.

**Russell P. Rother, Ph.D.** has been Senior Vice President, Research since August 2005, Vice President, Discovery Research from 2001 to 2005, Senior Director of Discovery Research from 1999 to 2001, Director of Gene Technologies from 1996 to 1999, Senior Staff Scientist from 1994 to 1996 and Staff Scientist from 1992 to 1994. As one of the original scientists at Alexion, Dr. Rother played a critical role in the engineering and development of Alexion's current antibody therapeutics and continues to lead discovery efforts in the identification of new indications and targets. Dr. Rother was also primarily responsible for the initiation of the paroxysmal nocturnal hemoglobinuria (PNH) program and played a major role in its development to date. Prior

---

**Table of Contents**

to 1992, Dr. Rother was a Postdoctoral Research Fellow in the Department of Immunobiology at Yale University School of Medicine. Dr. Rother's work has led to over 50 scientific papers and patents in the fields of hematology, complement biology, transplantation, autoimmunity, and gene therapy. Dr. Rother received a B.S. in Biology from Southwestern Oklahoma State University and a Ph.D. in Microbiology and Immunology from the University of Oklahoma Health Sciences Center in conjunction with the Oklahoma Medical Research Foundation.

**Vikas Sinha, M.B.A., C.A.** joined Alexion as Senior Vice President and Chief Financial Officer in September 2005. From June 1994 to August 2005, Mr. Sinha held various positions with Bayer AG in the United States, Japan, Germany, and Canada, most recently serving since February 2001 as Vice President and Chief Financial Officer of Bayer Pharmaceuticals Corporation, USA. Mr. Sinha has been responsible for financial and business risk management, strategic planning, contracting, customer services, information systems, and supply chain and site administration in North America. Mr. Sinha was also a member of the Pharmaceutical Management Committee for North America. Prior to his appointment in the United States, Mr. Sinha was Vice President and Chief Financial Officer of Bayer Yakuhin Ltd., in Japan and Manager, Mergers and Acquisitions with Bayer AG in Germany. He began his career at Bayer in Toronto as part of an executive development program in the healthcare division. Prior to Bayer, Mr. Sinha held several positions of increasing responsibilities with ANZ Bank and Citibank in South Asia. Mr. Sinha holds a Masters of Business Administration from the Asian Institute of Management which included an exchange program with the University of Western Ontario (Richard Ivey School of Business). He is also a qualified Chartered Accountant from the Institute of Chartered Accountants of India.

**Paul W. Finnegan, M.D., M.B.A.** has been Vice President, Global Commercial Operations and Development since August 2006 and is responsible for global marketing, commercial development and partnerships, distribution, reimbursement and policy, business analytics, pharmacoeconomics, and professional and advocacy communications and relations. In addition, he is responsible for building Alexion subsidiaries in country markets outside of the U.S. and Europe. From July 2006 to February 2002, Dr. Finnegan was responsible for worldwide marketing and sales, business development, external relations, distribution, pricing and reimbursement, pharmaco-economics, strategic planning and corporate development. He joined Alexion in April 2001 as Executive Director of Commercial Operations. From 1999 to 2000, Dr. Finnegan was Senior Director, Global Medical Marketing at Pharmacia Corporation, formerly Searle. He joined Searle, a Monsanto company, as Director, Global Medical Marketing in 1998. At Searle, he was responsible for various pre-launch and launch initiatives in Japan, Asia-Pacific, Latin America and Canada for all therapeutic areas as well as contributing to the scale up of international operations and partnership management. From 1993 to 1997, Dr. Finnegan was Director and Partner of Toronto East General & Orthopedic Radiology Associates, LLC. Dr. Finnegan earned his M.B.A. with Honors, in Finance and Strategy, from the University of Chicago, Graduate School of Business. He also holds the degrees of M.D., C.M. from McGill University in Montreal and is a Fellow of the Royal College of Physicians, Canada.

**David Hallal** has been Vice President of US Commercial Operations since June 2006. Mr. Hallal is responsible for all Commercial Functions in the U.S. Market, including marketing, sales, and reimbursement/access. Prior to Alexion, from April 2004 to June 2006, Mr. Hallal was Vice President of Sales at OSI Eyetech where he led the U.S. launch of the first-in-class anti-VEGF therapy, Macugen for age-related macular degeneration. From August 2002 to February 2004, Mr. Hallal was Senior Director of Sales for Biogen Idec's Immunology Sales Team, where he built a sales organization dedicated to the launch of the first-in-class biologic Amevive for psoriasis. For more than ten years starting in 1992, Mr. Hallal held various leadership positions at

**Table of Contents**

Amgen, focusing on the blockbuster brands Epogen, Neupogen, Neulasta and Aranesp in the hematology and oncology marketplace. More specifically from April 1999 to August 2002, he served as the Southeast Oncology Sales Director and Oncology Health Systems Sales Director. From 1998 to 1999, Mr. Hallal served as Amgen's Director of Oncology National Accounts. From 1992 to 1998, Mr. Hallal served in roles of escalating responsibility for the promotion of Epogen and Neupogen, including National Account Manager where he was responsible for forging relationships with many of the largest managed care organizations in the U.S. He holds a B.A. from the University of New Hampshire.

**M. Stacy Hooks, Ph.D.** has been Vice President Manufacturing and Technical Services since July 2006, Executive Director, Manufacturing and Technical Services from August 2004 to July 2006, Senior Director, Manufacturing and Technical Services from January 2004 to August 2004, and Director of Quality Control from December 2002 to January 2004. Dr. Hooks is responsible for managing the development, manufacturing, process validation, and testing of products. From 2001 to 2002, Dr. Hooks was a Director of Quality Assurance at Pharmacia, Inc. From 2000 to 2001, Dr. Hooks was the Director of Quality at QIAGEN, Inc., a multinational life sciences company. From 1996 to 2000 Dr. Hooks was employed at MedImmune, Inc., a biopharmaceutical firm, in increasing roles of responsibility, most recently as the Associate Director of Quality Control. Prior to MedImmune Dr. Hooks was employed at Biogen-IDEC. Dr. Hooks received his B.S. in Chemistry from Murray State University and a Ph.D. in Chemistry from Emory University.

**Barry P. Luke, M.B.A.** has been Vice President, Finance since September 1998 and Senior Director of Finance and Administration of Alexion from August 1995 to September 1998. Prior thereto he was Director of Finance and Accounting of the Company from May 1993 to August 1995. From 1989 to 1993, Mr. Luke was Chief Financial Officer, Secretary and Vice President-Finance and Administration at Comtex Scientific Corporation, a publicly held distributor of electronic news and business information. From 1985 to 1989, he was Controller and Treasurer of Softstrip, Inc., a manufacturer of computer peripherals and software. From 1980 to 1985, Mr. Luke was employed by General Electric Company where he held positions at GE's Corporate Audit Staff after completing GE's Financial Management Program. Mr. Luke received a B.A. in Economics from Yale University and an M.B.A. in management and marketing from the University of Connecticut.

**Daniel N. Caron** has been Executive Director, Operations and Engineering since August 2004. After joining the Company in 1992, Mr. Caron was Operations Manager from 1992 to 1993, Senior Operations Manager from 1993 to 1996, Director of Operations from 1996 to 1998, and Senior Director, Operations and Engineering from 1998 to 2004. Mr. Caron has been responsible for managing the engineering, build-out, and operations of the Company's research, manufacturing, and administrative facilities. Prior to 1992, Mr. Caron was a research scientist at Imclone Systems, Inc., a biopharmaceutical firm. Mr. Caron received his B.A. in Biology, cum laude, from Adelphi University and M.S. in Biomedical Engineering from Polytechnic University of New York.



**Table of Contents****PART II****Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES.**

Our common stock is quoted on The Nasdaq Stock Market, LLC under the symbol ALXN. The following table sets forth the range of high and low sales prices for our common stock on The Nasdaq Stock Market, LLC for the periods indicated since August 1, 2004.

	High	Low
<b>Fiscal 2005</b>		
First Quarter		
(August 1, 2004 to October 31, 2004)	\$ 19.20	\$ 13.30
Second Quarter		
(November 1, 2004 to January 31, 2005)	\$ 26.03	\$ 17.27
Third Quarter		
(February 1, 2005 to April 30, 2005)	\$ 26.96	\$ 19.79
Fourth Quarter		
(May 1, 2005 to July 31, 2005)	\$ 26.93	\$ 20.28
<b>2005 Transition Period</b>		
Five-Month Transition Period		
(August 1, 2005 to December 31, 2005)	\$ 30.00	\$ 18.37
<b>Fiscal 2006</b>		
First Quarter		
(January 1, 2006 to March 31, 2006)	\$ 38.40	\$ 20.06
Second Quarter		
(April 1, 2006 to June 30, 2006)	\$ 36.12	\$ 30.10
Third Quarter		
(July 1, 2006 to August 31, 2006)	\$ 38.68	\$ 31.46
Fourth Quarter		
(September 1, 2006 to December 31, 2006)	\$ 45.40	\$ 34.84

As of February 15, 2007, we had 188 stockholders of record of our common stock and an estimated 5,000 beneficial owners. The closing sale price of our common stock on February 15, 2007 was \$39.58 per share.

In November 2006, we sold 3,450,000 shares of common stock in a public offering at \$43.00 per share, resulting in gross proceeds from the sale of approximately \$148.3 million. We incurred underwriting discounts and commissions of approximately \$8.1 million or \$2.42 per share as well as other expenses, resulting in net proceeds of approximately \$140.2 million. We will utilize the proceeds from this offering to fund general corporate obligations.

In August 2005, we sold 2,500,000 shares of our common stock in a registered offering at a price to the public of \$26.75 per share resulting in net proceeds of approximately \$64.5 million, net of underwriting discount, fees and other expenses of approximately \$2.4 million related to the transaction. We used the proceeds from this offering to fund general corporate obligations.

## Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

In January 2005, we sold \$150.0 million principal amount of 1.375% Convertible Senior Notes due February 1, 2012, or the 1.375% Notes, in a private placement to qualified institutional buyers pursuant to Rule

**Table of Contents**

144A under the Securities Act of 1933, as amended. The interest rate on the notes is 1.375% per annum on the principal amount from January 25, 2005, payable semi-annually in arrears in cash on February 1 and August 1 of each year, beginning August 1, 2005. The 1.375% Notes is convertible into our common stock at an initial conversion rate of 31.7914 shares of common stock (equivalent to a conversion price of approximately \$31.46 per share) per \$1,000 principal amount of the 1.375% Notes, subject to adjustment, at any time prior to the close of business on the final maturity date of the notes. We do not have the right to redeem any of the 1.375% Notes prior to maturity.

If a holder elects to convert its 1.375% Notes upon the occurrence of a transaction or event such as a liquidation, tender offer, consolidation, merger, recapitalization, or otherwise, in connection with which 50% or more of our common stock is exchanged for consideration which is not at least 90% common stock that is listed on a U.S. national exchange or market (such as NASDAQ), the holder will be entitled to receive an additional number of shares of common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option, are set according to a table within the offering document, and are capped (in no event will the shares issuable upon conversion of a note exceed 42.9100 shares per \$1,000 principal amount). We incurred deferred financing costs related to this offering of approximately \$4.8 million, which are recorded in the condensed consolidated balance sheet and are being amortized as a component of interest expense over the seven-year term of the notes.

In March 2000, we completed a \$120 million private placement of our 5.75% Convertible Subordinated Notes, or 5.75% Notes, due March 15, 2007. We incurred issuance costs related to this offering of approximately \$4.0 million, including discounts to J.P. Morgan & Co., U.S. Bancorp Piper Jaffray, Chase H&Q and Warburg Dillon Read LLC, the initial purchasers of the notes. The costs were being amortized into interest expense over the seven-year term of the notes.

The net proceeds of approximately \$145.2 million from the sale of the 1.375% Notes were used to redeem our entire outstanding \$120.0 million principal amount of 5.75% Notes and for general corporate purposes. On March 15, 2005, we redeemed all of the 5.75% Notes outstanding at the redemption price of 101.643% for each \$1,000 principal amount of 5.75% Notes. We paid a redemption premium related to these notes of approximately \$2.0 million. The remaining balance of deferred financing costs related to the 5.75% Notes was approximately \$1.2 million at the redemption date. The difference between the amount paid, including the redemption premium, and the carrying value of the notes, including the remaining deferred financing costs, was recognized as a \$3.2 million loss from early extinguishment of convertible notes.

Except as provided below, we did not make any repurchases of common stock during the year ended December 31, 2006:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of shares Purchased as Part of Publicly Announced Program	Maximum Number of Shares that may yet be Purchased Under the Program
October 1 to October 31				
November 1 to November 30				
December 1 to December 31	6,919	40.39		
Total	6,919	40.39		

**Table of Contents**

The Company currently does not have a stock repurchase plan. All share exchanges made during the year ended December 31, 2006 were done through open-market transactions.

**DIVIDEND POLICY**

We have never paid cash dividends. We do not expect to declare or pay any dividends on our common stock in the near future. We intend to retain all earnings, if any, to invest in our operations. The payment of future dividends is within the discretion of our board of directors and will depend upon our future earnings, if any, our capital requirements, financial condition and other relevant factors.

**EQUITY COMPENSATION PLAN INFORMATION**

<b>Plan Category</b>	<b>Number of shares of common stock to be issued upon exercise of outstanding options (2)</b>	<b>Weighted-average exercise price of outstanding options</b>	<b>Weighted-average term to expiration of options outstanding</b>	<b>Number of shares of common stock remaining available for future issuance under equity compensation plans</b>
Equity compensation plans approved by stockholders <sup>(1)</sup>	5,337,252	\$ 26.69	6.2 years	1,054,177
Equity compensation plans not approved by stockholders				

- (1) Reflects number of shares of common stock to be issued upon exercise of outstanding options under all of our equity compensation plans, including our 2004 Incentive Plan. No shares of common stock are available for future issuance under any of our equity compensation plans, except the 2004 Incentive Plan.
- (2) Does not include 35,211 shares of common stock to be issued upon exercise of options granted under Prolifaron Inc. 1999 Long Term Incentive and Stock Option Plan with a weighted vested average exercise price of \$45.45 per share. The stock options granted under this plan were converted into options to acquire shares of our common stock in connection with our acquisition of Prolifaron in September 2000. No subsequent grants of options will be made under this plan. In addition, this does not include 133,500 restricted shares outstanding that were issued under the 2004 Incentive Plan.
- (3) The outstanding options and restricted shares are not transferable for consideration and do not have dividend equivalent rights attached.

**Table of Contents****THE COMPANY'S STOCK PERFORMANCE**

The following graph compares cumulative total return of the Company's Common Stock with the cumulative total return of (i) the NASDAQ Stock Market-United States, and (ii) the NASDAQ Biotechnology Index. The graph assumes (a) \$100 was invested on July 31, 2001 in each of the Company's Common Stock, the stocks comprising the NASDAQ Stock Market-United States and the stocks comprising the NASDAQ Biotechnology Index, and (b) the reinvestment of dividends.

**CUMULATIVE TOTAL RETURN**

	7/01	7/02	7/03	7/04	7/05	12/05	12/06
Alexion Pharmaceuticals, Inc.	100.00	83.79	90.82	86.01	140.68	109.40	218.21
NASDAQ Stock Market (U.S.)	100.00	68.03	87.94	97.38	113.04	115.92	131.81
NASDAQ Biotechnology	100.00	60.84	90.98	86.42	104.19	109.64	107.92



---

**Table of Contents**

**Item 7. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.***  
*(amounts in thousands, except per share data)*

This report contains forward-looking statements, which involve risks and uncertainties. Such statements are subject to certain factors, which may cause our plans and results to differ significantly from plans and results discussed in forward-looking statements. Factors that might cause or contribute to such differences include, but are not limited to, those discussed in the section entitled item 1A Risk Factors .

**Overview**

We are a biotechnology company working to develop and deliver life-changing drug therapies for patients with serious and life-threatening medical conditions. We are engaged in the discovery and development of therapeutic products aimed at treating patients with a wide array of severe disease states, including hematologic diseases, cancer, and autoimmune disorders. Since our incorporation in January 1992, we have devoted substantially all of our resources to drug discovery, research, and product and clinical development. Since September 2005, we have formed a number of wholly-owned foreign and domestic entities to support commercial and regulatory operations. In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island, for the future commercial production of our products.

In September 2006, we filed a Biologics License Application, or BLA, with the U.S. Food and Drug Administration, or FDA, and a European Marketing Authorization Application, or MAA, in Europe, for Soliris (eculizumab) for the treatment of a rare, life-threatening blood disorder known as Paroxysmal Nocturnal Hemoglobinuria, or PNH. The Phase III clinical development program for Soliris (eculizumab) in PNH is comprised of two Phase III clinical trials, known as TRIUMPH and SHEPHERD. The FDA agreed to the design of the protocols for these two trials under the Special Protocol Assessment, or SPA, process. TRIUMPH is a placebo-controlled efficacy trial and SHEPHERD is an open-label, non-placebo controlled safety trial with efficacy secondary endpoints. In January 2006, we reported positive results from TRIUMPH, which results were later published in the September 2006 issue of the New England Journal of Medicine. All pre-specified, primary and secondary endpoints in the TRIUMPH trial were achieved with statistical significance. In December 2006, we reported positive results from SHEPHERD. Soliris (eculizumab) appeared to be safe and well tolerated during the twelve month SHEPHERD trial, and all pre-specified primary and secondary efficacy endpoints in the SHEPHERD trial were achieved with statistical significance. Data from TRIUMPH and SHEPHERD served as the primary basis for the BLA and MAA submitted in the United States and Europe, respectively.

In November 2006, we received priority review designation for the Soliris (eculizumab) BLA from the FDA. Priority review status is granted by the FDA to products that, if approved, would be a significant improvement over existing therapies. Similarly, in August 2006, we announced that our Soliris (eculizumab) MAA was granted accelerated assessment by the European Medicines Agency, or EMEA, in Europe. Review under the Accelerated Assessment Procedure is provided by the EMEA for medicinal products of major therapeutic interest and shortens the timeframe for review by that agency. In November 2006, we also announced that the EMEA had validated the Soliris MAA allowing for commencement of the review process.

In addition to our Phase III PNH clinical program, we are conducting the following efforts: (1) the EMBRACE Expanded Access Trial, (2) the EXPLORE diagnostics trial and (3) a global Patient Registry for PNH patients. The EMBRACE trial (The Paroxysmal Nocturnal Hemoglobinuria Early Access Treatment Protocol) was initiated in December 2006 to provide the investigational agent eculizumab in the United States to

## **Table of Contents**

PNH patients in accordance with a Treatment Protocol authorized by the FDA. Treatment Protocols are designed to make promising investigational agents available for patients with serious or life-threatening diseases for which there are no comparable or satisfactory alternative therapies, before general marketing is authorized. We initiated the EXPLORE trial in August 2006 to investigate the frequency and clinical characteristics of undiagnosed PNH patients who have been diagnosed with other bone marrow failure diseases such as aplastic anemia and myelodysplasia. The global PNH Patient Registry involves the study of the natural history of PNH.

In addition to PNH, we are considering the evaluation of other potential indications for Soliris (eculizumab) as well as other formulations of eculizumab for additional clinical indications, and we are actively pursuing development of other antibody product candidates in early stages of development. During 2006, we completed a final Phase III trial of another product candidate known as pexelizumab with our partner for this product, Procter and Gamble Pharmaceuticals. After reviewing results from that trial, we along with Procter & Gamble Pharmaceuticals, have determined not to pursue further development of pexelizumab.

To date, we have not received any revenues from the sale of our products. We have incurred operating losses since our inception. As of December 31, 2006, we had an accumulated deficit of approximately \$637,723. We expect to incur substantial operating losses for the next several years due to expenses associated with product research and development, pre-clinical studies and clinical testing, regulatory activities, manufacturing development, scale-up and commercial-scale manufacturing, pre-commercialization activities, developing a sales and marketing force, and other infrastructure support costs. We may need to obtain additional financing to cover these costs.

In November 2006, we sold 3,450,000 shares of our common stock in a registered offering at a price to the public of \$43.00 per share resulting in proceeds of approximately \$140,229, net of underwriting discount, fees and other expenses. We intend to use the net proceeds from this offering for general corporate purposes.

## **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. We do indemnify certain third parties against liabilities they may incur in connection with the manufacturing, development, or sale of our drug candidates.

In January 2005, we sold \$150,000 principal amount of 1.375% Notes in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. If the holder elects to convert its 1.375% Notes upon the occurrence of a designated event, the holder will be entitled to receive an additional number of shares of common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option, are set according to a table within the offering document, and are capped (in no event will the shares issuable upon conversion of a note exceed 42.9100 per \$1 principal amount).

## **Critical Accounting Policies and the Use of Estimates**

In our preparation of consolidated financial statements, we use certain estimates and assumptions that affect reported amounts and disclosures. Our estimates are often based on judgments, probabilities and assumptions that we believe are reasonable, but that are inherently uncertain and unpredictable. All of these judgments and estimates can materially impact our result of operations.



---

**Table of Contents**

We believe the following critical accounting policies affect our significant judgments and estimates used in the preparation of our consolidated financial statements:

*Marketable Securities* We invest in marketable debt securities of highly rated financial institutions and investment-grade debt instruments and limit the amount of credit exposure with any one entity. Unrealized gains or losses are included in accumulated other comprehensive loss as a component of stockholders' equity. We believe that our conservative investment policy ensures reasonable assurance against impairment of marketable securities held, and also enables us to avoid incurring realized losses that could occur if securities were not held to maturity.

*Inventories* Inventories are stated at the lower of cost or estimated realizable value, with cost determined under the first-in, first-out, or FIFO, method. Our policy is to capitalize inventory costs associated with our products, subsequent to the filing of our Biologics License Application, or BLA, but prior to regulatory approval, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. We assess the regulatory approval process and where the particular product stands in relation to that approval process. Our assessment includes any known constraints and impediments to approval, including safety, efficacy and potential labeling restrictions. We evaluate our anticipated research and development initiatives and constraints relating to the product and the indication for which it will be used. We consider our manufacturing environment including our supply chain in determining logistical constraints that could possibly hamper approval or commercialization. We consider the shelf life of the product in relation to the expected timeline for approval and we consider patent related or contract issues that may prevent or cause delay in commercialization. We also base our judgment on the viability of commercialization, trends in the marketplace and market acceptance criteria. Finally, we consider the reimbursement strategies that may prevail with respect to the product and assess the economic benefit that we are likely to realize.

There is a risk inherent in these judgments, and we would be required to expense previously capitalized costs related to pre-approval inventory upon a change in such judgment, due to, among other potential factors, a denial or delay of approval by necessary regulatory bodies.

We periodically review our inventories for excess or obsolete inventory and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual realizable value is less than that estimated by us, or if there are any further determinations that inventory will not be marketable based on estimates of demand, additional inventory write-downs may be required. These reserves are determined based on significant estimates.

A substantial amount of our current Soliris (eculizumab) inventory was manufactured early enough in the regulatory process that we determined to expense the full manufacturing cost. Approximately 100 patient years of Soliris (eculizumab) inventory is sellable and fully expensed.

*Long-Lived Assets* We assess the potential impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that we consider important, and which could trigger an impairment review, include, among others, the following:

- a significant adverse change in the extent or manner in which a long-lived asset is being used;
- a significant adverse change in the business climate that could affect the value of a long-lived asset; and
- a significant decrease in market value of assets.

## **Table of Contents**

If we determine that the carrying value of long-lived assets may not be recoverable, based upon the existence of one or more of the above indicators of impairment, we will compare the carrying value of the asset group to the undiscounted cash flows expected to be generated by the group. If the carrying value exceeds the undiscounted cash flows, we will then compare the carrying value of the asset group to its fair value to determine whether an impairment charge is required. If the fair value is less than the carrying value, such amount is recognized as an impairment charge.

*Goodwill* Goodwill represents the difference between the purchase price of acquired businesses and the fair value of their net assets, and is not amortized. We test goodwill for impairment at least annually and whenever events or changes in circumstances indicate the carrying amount of goodwill might not be recoverable. No impairment charge resulted upon the adoption of this standard or as a result of our annual impairment assessment. The first step of the review is to compare the fair market capitalization of Alexion, annually in November, to our net stockholders equity. If fair market capitalization is greater than net stockholders equity, then no impairment charges are necessary. The analysis is impacted by the price of the stock on the date of the test. Impairment charges, if any, will be recorded as a component of operating expenses in the period in which the impairment is determined.

*Prepaid Manufacturing Costs* Cash advances paid by us to secure future long-term manufacturing production at third-party contract manufacturers are recorded as prepaid manufacturing costs. These costs are recognized over the period of manufacturing production on a unit of production method. The cash advances are subject to refund if the manufacturing facility is unavailable as scheduled or forfeiture if we terminate the scheduled production.

We evaluate the prepaid manufacturing costs against estimated net realizable value, or NRV. If estimated NRV were to be negative, all or a portion of the prepaid manufacturing cost may have to be recognized as an expense. Our calculation of NRV involves estimates of expected sales volume, sales price, and market penetration of the product in question.

*Revenue Recognition* We record contract research revenues from research and development support payments, license fees and milestone payments under collaborations with third parties, and amounts received from various government grants. We evaluate all deliverables in our collaborative agreement to determine whether it represents separate units of accounting. Deliverables qualify for separate accounting treatment if they have standalone value to the customer and if there is objective evidence of fair value for the undelivered items.

Up-front, non-refundable license fees received in connection with a collaboration agreement are deferred and amortized into revenue over the life of the agreement or underlying technologies.

Revenues derived from the achievement of milestones are recognized when the milestone is achieved, provided that the milestone is substantive and a culmination of the earnings process has occurred. Revenues derived from the achievement of milestones or recognition of related work when performed under terms of a contract may cause our operating results to vary considerably from period to period. Research and development support revenues are recognized as the related work is performed and expenses are incurred under the terms of the contracts for development activities.

Deferred revenue results from cash received or amounts receivable in advance of revenue recognition under research and development contracts.

*Research and Development Expenses* Research and development expenses are comprised of costs incurred in performing research and development activities including salaries and benefits, pre-clinical,

---

**Table of Contents**

clinical trial and related clinical manufacturing costs, manufacturing development and scale-up costs, contract services and other outside contractor costs, research license fees, depreciation and amortization of lab facilities, and lab supplies. These costs are expensed when incurred.

We have entered into a collaboration research agreement with P&G in which we share costs. We record these costs as research and development expenses as incurred. A portion of these costs are reimbursed by our collaborator and are recorded as a reduction of research and development expense.

Accrued research and development expenses are comprised of amounts owed to suppliers for research and development work performed on our behalf. At the end of each period, we evaluate the accrued expense balance related to these activities based upon information received from the supplier and estimated progress toward completion of the research or development objectives to ensure that the balance is appropriately stated. Such estimates are subject to change as additional information becomes available.

*Stock Based Compensation* We adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment ( SFAS 123R ), effective August 1, 2005. SFAS 123R requires the recognition of the fair value of stock-based compensation in net earnings. We have elected to utilize the modified prospective transition method for adopting SFAS 123R. Under this method, the provisions of SFAS 123R apply to all awards granted or modified after the date of adoption. In addition, the unrecognized expense of awards not yet vested at the date of adoption, determined under the original provisions of SFAS 123, shall be recognized in the periods after the date of adoption. Due to our net loss position, a windfall tax benefit was not realized during the period. As of December 31, 2006, there was \$30,713 of total unrecognized compensation expense related to non-vested share-based compensation arrangements granted under the Plan. The expense is expected to be recognized over a weighted-average period of 2 years.

Prior to August 1, 2005, we accounted for stock options and restricted stock utilizing the intrinsic value method in accordance with Accounting Principles Board Opinion, or APB, No. 25, Accounting for Stock Issued to Employees, and accordingly, recognize no compensation expense for the options when the option grants have an exercise price equal to the fair market value at the date of grant.

Our estimates of employee stock option values rely on estimates of factors we input into the Black-Scholes model. The key factors involve an estimate of future uncertain events.

Significant assumptions include the use of historical volatility to determine the expected stock price volatility. Also, of significance, is our expected term until exercise. We currently use historical exercise patterns as our best estimate of future exercise patterns. Once employee stock option values are determined, they may not be changed.

We continually seek to refine and improve our assumptions used to measure the value of employee stock options.

*Foreign Currency Translation* For our foreign subsidiary with a functional currency different from U.S. dollars, we translate its financial statements into U.S. dollars using the current exchange rate at each balance sheet date for assets and liabilities the average exchange rate prevailing during each period for revenues and expenses, and the historical exchange rate for our investments in our foreign subsidiary. Adjustments from translating these financial statements into U.S. dollars are included in Accumulated other comprehensive loss.

**Table of Contents****Results of Operations**

On December 9, 2005, our Board of Directors approved a change of our fiscal year end from July 31 to December 31. The five months results reported relate to the transition period ended December 31, 2005.

The following table sets forth consolidated statements of operations data for the periods indicated. This information has been derived from the consolidated financial statements included elsewhere in this annual report. (amounts in thousands, except per share data)

	Year Ended December 31,		Five Month Period Ended December 31,		Year Ended July 31,	
	2006	2005	2005	2004	2005	2004
	(Unaudited)		(Unaudited)			
Contract research revenues:						
P&G	\$ 588	\$ 588	\$ 245	\$ 245	\$ 588	\$ 4,588
U.S. government grants	870	894	419		476	21
Other revenue	100					
<b>Total revenues</b>	<b>1,558</b>	<b>1,482</b>	<b>664</b>	<b>245</b>	<b>1,064</b>	<b>4,609</b>
Research and development expenses:						
Clinical development	32,262	52,473	21,966	12,810	43,314	20,398
Manufacturing and manufacturing development	4,794	23,430	10,714	8,119	20,835	14,027
Product development	37,056	75,903	32,680	20,929	64,149	34,425
Payroll and benefits	30,061	21,202	10,481	6,662	17,397	14,749
Discovery research	8,214	2,572	1,620	1,479	2,431	3,592
Operating, occupancy, depreciation, and amortization	7,894	8,078	3,457	2,844	7,411	7,074
<b>Total research and development expenses</b>	<b>83,225</b>	<b>107,755</b>	<b>48,238</b>	<b>31,914</b>	<b>91,388</b>	<b>59,840</b>
General and administrative	54,879	25,509	12,763	6,160	18,951	14,459
Impairment of fixed assets	539					760
<b>Total operating expenses</b>	<b>138,643</b>	<b>133,264</b>	<b>61,001</b>	<b>38,074</b>	<b>110,339</b>	<b>75,059</b>
Operating loss	(137,085)	(131,782)	(60,337)	(37,829)	(109,275)	(70,450)
Other income (expense):						
Investment income	8,076	6,633	3,123	1,756	5,266	3,373
Interest expense	(2,837)	(4,164)	(1,192)	(3,153)	(6,125)	(7,709)
Gain from extinguishment of note payable				3,804	3,804	
Loss on early extinguishment of debt		(3,185)			(3,185)	
Other	(41)				0	
<b>Total other income (expense)</b>	<b>5,198</b>	<b>(716)</b>	<b>1,931</b>	<b>2,407</b>	<b>(240)</b>	<b>(4,336)</b>
State tax benefit	373	1,154	450	61	765	691
<b>Net loss</b>	<b>\$ (131,514)</b>	<b>\$ (131,344)</b>	<b>\$ (57,956)</b>	<b>\$ (35,361)</b>	<b>\$ (108,750)</b>	<b>\$ (74,095)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (4.15)</b>	<b>\$ (4.30)</b>	<b>\$ (1.90)</b>	<b>\$ (1.28)</b>	<b>\$ (3.90)</b>	<b>\$ (3.43)</b>

**Table of Contents**

***Comparison of the Years Ended December 31, 2006 and 2005***

*(amounts in thousands, except per share amounts)*

We earned revenues of approximately \$1,558 and \$1,482 for the years ended December 31, 2006 and 2005, respectively. Revenue reflects the amortization of deferred revenue resulting from cash received from P&G under our collaboration for the development and commercialization of pexelizumab, U.S. government funded research grant revenue related to our research programs, and a nonrefundable fee for exclusive access to our xenotransplantation technologies, a program that was terminated in October 2003.

During the year ended December 31, 2006, we incurred research and development expenses of \$83,225 compared to the same period in 2005 where we incurred research and development expenses of \$107,755. We report research and development costs by the category in which they are incurred, rather than by project. Our research and development costs consist primarily of payroll and benefits costs, product development costs, discovery research costs, depreciation and amortization expense, and occupancy related facility-operating costs. Product development costs consist of pre-clinical costs, clinical trial costs and other clinical-related development costs, manufacturing development and manufacturing costs.

The \$24,530 decrease in research and development expenses resulted primarily from a significant decrease in clinical development and manufacturing expenses costs, \$20,211 and \$18,636, respectively, related to the termination of the pexelizumab programs. These decreases in total research and development were partially offset by substantial increases in payroll and benefits costs of \$8,859, which were primarily impacted by the adoption of SFAS 123R and the resulting expensing of employee stock options grants as well as increased headcount to support our research and drug development activities. In addition, research and discovery expenses increased by approximately \$5,642, primarily related to development activities related to our PNH programs.

We anticipate that expenses for research and development will remain at a significant level in 2007 as critical and substantive clinical trials near their completion and as we may initiate development of other promising candidates.

During the year ended December 31, 2006, we incurred general and administrative expenses of \$55,418, which include impairment costs of \$539, compared to the same period in 2005 where we incurred general and administrative expenses of \$25,509. The increase in general and administrative expenses of \$29,909 from 2005 to 2006 was due principally to increased pre-commercial activities associated with Soliris in the U.S. as well as in Europe, increased headcount in support of our operations, and \$7,087 of expenses related to the closure of Alexion Antibody Technologies, Inc.

Excluding the effect of the closure of Alexion Antibody Technologies, we expect that general and administrative costs will increase in fiscal 2007 as we continue to put in place the commercial organization and infrastructure required to bring Soliris to market.

Total operating expenses were \$138,643 and \$133,264 for the years ended December 31, 2006 and 2005, respectively.

Investment income was \$8,076 for the year ended December 31, 2006 compared to \$6,633 for the same period in 2005, reflecting higher market interest rates and higher principal amounts. Interest expense decreased to \$2,799 from \$4,164, impacted by the lower coupon rate of the convertible debt of \$150,000 principal amount of

---

**Table of Contents**

1.375% convertible senior notes, or 1.375% Notes, following redemption of our \$120,000 principal amount of 5.75% convertible subordinated notes, or 5.75% Notes, in March 2005.

A state tax benefit of \$373 and \$450 was recognized for the years ended December 31, 2006 and 2005, respectively, resulting from our estimated exchange of our December 31, 2006 and 2005 incremental research and development tax credits.

As a result of the above factors, we incurred net losses of \$131,514 and \$131,344 or \$4.15 and \$4.30 basic and diluted net loss per share for the years ended December 31, 2006 and 2005, respectively.

***Comparison of the Five Months Ended December 31, 2005 to the Five Months Ended***

***December 31, 2004***

*(amounts in thousands, except per share amounts)*

We earned contract research revenues of \$664 and \$245 for the five months ended December 31, 2005 and 2004, respectively. Of the revenue earned for the five months ended December 31, 2005 and 2004, \$245 is a non-cash item representing the amortization of deferred revenue from a \$10,000 upfront fee paid to us by P&G in February 1999. Revenue from U.S. government grants totaled \$419 and \$0 for the five months ended December 31, 2005 and 2004, respectively. The increase in revenues associated with U.S. government grants obtained in the transition period ended December 31, 2005 resulted primarily from research under the anti-anthrax bio-defense program.

During the five months ended December 31, 2005, we incurred research and development expenses of \$48,238 compared to the five months ended December 31, 2004 where we incurred research and development expenses of \$31,914. We report our research and development costs by the category in which they are incurred rather than by project. Our research and development costs consist primarily of payroll and benefits costs, product development costs, discovery research costs, depreciation and amortization expense, and occupancy related facility operating costs. Product development costs consist of pre-clinical costs, clinical trial costs and other clinical-related development costs, manufacturing development and manufacturing costs.

The \$16,324 increase in research and development expenses resulted primarily from greater product development costs of \$11,751 from higher clinical development and higher manufacturing expenses costs related to the current Phase III clinical trials of our lead drug candidates, Soliris (eculizumab) and pexelizumab, for TRIUMPH, SHEPHERD, and the PNH extension trials and PRIMO-CABG2 and APEX-AMI trials, respectively. Payroll and benefits costs were impacted by the adoption of SFAS 123R and the resulting expensing of employee stock options grants as well as increased headcount to support our research and drug development activities.

Our collaboration with P&G resulted in pexelizumab-related product development costs, excluding payroll-related costs, of \$17,805 for the five months ended December 31, 2005 compared to \$11,121 for the five months ended December 31, 2004. This represented 54% and 53%, respectively, of our product development costs. The remaining balance of our product development costs was primarily for Soliris and other pre-clinical product candidates.

Our general and administrative expenses were \$12,763 for the period, compared with \$6,160 for the same period last year. The increase in general and administrative expenses of \$6,603 from 2004 to 2005 was principally from expensing of employee stock options, increased headcount dedicated to commercial

---

**Table of Contents**

development activities and higher professional fees principally for patent and compliance activities. The impact on payroll and benefits expenses from the adoption of SFAS 123R was material, but the overall increase in expenses was predominantly driven by our ongoing development of a commercial organization that will ultimately support sales and marketing of product candidates, if approved by regulatory agencies.

Total operating expenses were \$61,001 and \$38,074 for the five months ended December 31, 2005 and 2004, respectively.

Investment income was \$3,123 for the five months ended December 31, 2005 compared to \$1,756 for the same period in 2004, reflecting higher market interest rates and a higher principal balance. The higher principal balance is a result of the August 2005 issuance of 2,500,000 shares of common stock in a public offering at \$26.75 per share, resulting in net proceeds from the sale of \$64,530, as well as an increase in convertible debt due to the sale of \$150,000 principal amount of 1.375% convertible senior notes, or 1.375% Notes, in January 2005, which was partially offset by the redemption of our \$120,000 principal amount of 5.75% convertible subordinated notes, or 5.75% Notes, in March 2005. Interest expense decreased to \$1,192 from \$3,153, impacted by the lower coupon rate of the 1.375% Notes.

A state tax benefit of \$450 and \$61 was recognized for the five months ended December 31, 2005 and 2004, respectively, resulting from our estimated exchange of our December 31, 2005 and 2004 incremental research and development tax credits.

As a result of the above factors, we incurred net losses of \$57,956 and \$35,361 or \$1.90 and \$1.28 basic and diluted net loss per share for the five months ended December 31, 2005 and 2004, respectively.

***Comparison of the Fiscal Years Ended July 31, 2005 and 2004***

*(amounts in thousands, except per share amounts)*

We earned contract research revenues of \$1,064 and \$4,609 for the fiscal years ended July 31, 2005 and 2004, respectively. In the fourth quarter of 2004, we recognized a \$4,000 milestone payment from P&G concurrent with the dosing of our first patient in the APEX-AMI trial. Substantially all of the other revenue in fiscal years 2005 and 2004 is a non-cash item representing the amortization of deferred revenue from the \$10,000 upfront fee paid to us by P&G in February 1999. Revenue from U.S. government grants totaled \$476 in fiscal 2005 and \$21 in fiscal 2004. The \$455 increase in revenues associated with U.S. government grants obtained in fiscal 2005 resulted from research under the anti-anthrax bio-defense program.

During fiscal year 2005, we incurred research and development expenses of \$91,388 compared to fiscal year 2004 when we incurred research and development expenses of \$59,840. We report research and development costs by category incurred rather than by project. Our research and development costs consist primarily of payroll and benefits costs, pre-clinical costs, clinical trial costs and other clinical-related development costs, manufacturing development and manufacturing costs, discovery research costs, depreciation and amortization expense, and occupancy related facility operating costs.

The \$31,548 increase in research and development expenses from 2004 to 2005 resulted primarily from greater product development costs of \$29,724 from higher clinical development and higher manufacturing expenses for the cost of conducting our two Phase III clinical trials PRIMO-CABG2 and APEX-AMI in pexelizumab and the increased production of material used in our clinical trials involving Soliris and

**Table of Contents**

pexelizumab. The increase in payroll and benefits from 2004 to 2005 is primarily attributable to the increase in staff involved in clinical and manufacturing development as well as regulatory and quality assurance activities. The decrease in discovery research is due principally to recognition of the approximately \$1,300 balance of the non-refundable payment received from XOMA. In 2003, XOMA paid an upfront non-refundable fee of approximately \$1,500 pursuant to a collaborative agreement. We recorded the payment as a deferred research and development payment and amortized the payment as a reduction of research and development expense. Upon cancellation of the XOMA collaborative agreement in 2005, the remaining balance of \$1,300 was recognized as a reduction of research and development expenses.

Our collaboration with P&G resulted in pexelizumab-related product development costs, excluding payroll-related costs, of \$36,358 for the 2005 compared to \$15,902 for 2004 representing 57% and 46%, respectively, of our product development costs. The remaining balance of our product development costs was primarily for Soliris and other pre-clinical product candidates.

Our general and administrative expenses were \$18,951 and \$14,459 for fiscal years 2005 and 2004, respectively. The increase in general and administrative expenses of \$4,492 from 2004 to 2005 was due principally to increased pre-commercial activities associated with our two lead product candidates, as well as increased headcount in support of our operations.

Total operating expenses were \$110,339 and \$75,059 for the years ended July 31, 2005 and 2004, respectively.

Investment income was \$5,266 for the year ended July 31, 2005 compared to \$3,373 for the year ended July 31, 2004. The increase in investment income of \$1,893 in 2005 resulted primarily from higher interest rates and higher principal amounts. Interest expense was \$6,125 for the year ended July 31, 2005 compared to \$7,709 for the year ended July 31, 2004. The decrease in interest expense in fiscal 2005 is attributable to the lower interest rate for the 1.375% Notes issued in January 2005, which replaced the previous outstanding notes with a rate of 5.75%. We recorded a \$3,185 loss from early extinguishment of the 5.75% Notes, which consisted of the write-off of the remaining balance of non-refundable deferred financing costs of approximately \$1,200 and the redemption premium of approximately \$2,000.

During the first fiscal quarter of 2005, we recorded a net gain to other income of \$3,804 to complete the termination of the Unigraft xenotransplantation program at Columbus Farming Corporation, or CFC. This consisted of the extinguishment of the \$3,900 note payable used to purchase the xenotransplantation assets and the extinguishment of the accrued interest of \$300 on the note, partially offset by the transfer to Tyco International, Ltd., or Tyco, of the remaining assets of \$450 used to secure the note.

A state tax benefit of \$765 and \$691 was recognized for the year ended July 31, 2005 and 2004, respectively, resulting from our estimated exchange of our July 31, 2005 and actual exchange of our July 31, 2004 incremental research and development tax credits.

As a result of the above factors, we incurred net losses of \$108,750 and \$74,095 or \$3.90 and \$3.43 basic and diluted net loss per share for the years ended July 31, 2005 and 2004, respectively.



## **Table of Contents**

### ***Liquidity and Capital Resources***

*(amounts in thousands, except shares and per share amounts)*

Since our inception in 1992, our primary source of cash is through public offerings of our common stock and the sale of convertible notes. Other sources include debt financing, payments received under corporate collaborations and grants, and equipment and leasehold improvements financing. Our primary use of cash includes business development activities and research and development.

As of December 31, 2006, cash, cash equivalents, and marketable securities were \$250,148 compared with \$212,456 at December 31, 2005. The increase was primarily due to the issuance of 3,450,000 shares of common stock in a public offering at \$43.00 per share, resulting in gross proceeds from the sale of \$148,350. We incurred underwriting discounts and commissions of \$7,788, or \$2.26 per share as well as other expenses, resulting in net proceeds of \$140,229, which was *substantially* offset by cash used to fund operating activities.

### ***Operating Activities***

Net cash used in operating activities for the year ended December 31, 2006 was \$109,914. The decrease compared to the balance as of December 31, 2005 is primarily due to working capital fluctuations driven by increased prepaid expenses and inventory balances and decreased accrued expense balance, offset partly by increased accounts payable balance.

### ***Investing Activities***

Net cash provided by investing activities for the year ended December 31, 2006 was \$53,907. This included \$119,357 of proceeds from the maturity or sale of marketable securities, net of purchases of marketable securities, offset by property, plant and equipment additions of \$31,856 and increases in restricted cash of \$33,594.

### ***Financing Activities***

Net cash provided by financing activities for the year ended December 31, 2006 was \$179,324, consisting of proceeds from the sale of common stock of \$140,229, proceeds from the mortgage loan of \$26,000 and the exercise of stock options of \$13,598, offset by the acquisition of 6,919 treasury shares at a cost of \$279 and payment on capital leases of \$224.

### ***Sufficiency of Cash Resources***

We anticipate that our existing capital resources as of December 31, 2006, as well as cash from investment income earned on available cash and marketable securities should provide us *with* adequate resources to fund our operating expenses and capital requirements as currently expected for the next eighteen months. We may pursue additional stock offerings, debt or other sources of *funding* to finance our operations.

### ***Contractual Obligations***

Our contractual obligations include our \$150,000 1.375% Convertible Senior Notes due February 2012, or 1.375% Notes, our \$26,000 mortgage loan due August 2016 with a fixed annual interest rate of 9.17%, our annual payments of approximately \$4,000 for operating and capital leases, principally for facilities and

**Table of Contents**

equipment, and an open letter of credit of \$200 which serves as a security deposit on our facility in Cheshire, Connecticut.

The following table summarizes our contractual obligations at December 31, 2006 and the effect such obligations and commercial commitments are expected to have on our liquidity and cash flow in future fiscal years. These do not include milestones and assume non-termination of agreements. These obligations, commitments and supporting arrangements represent payments based on current operating forecasts, which are subject to change:

	(in millions)				
	Total	Less than 1 Year	1 3 Years	3 5 Years	More than 5 Years
<b>Contractual obligations:</b>					
Convertible notes payable	\$ 150.0	\$	\$	\$	\$ 150.0
Mortgage loan	26.0		2.9	6.9	16.2
Interest expense	25.7	4.5	8.9	7.7	4.6
Capital and operating leases	26.4	3.8	6.3	5.1	11.2
 Total contractual obligations	 \$ 228.1	 \$ 8.3	 \$ 18.1	 \$ 19.7	 \$ 182.0
<b>Commercial commitments:</b>					
Clinical and manufacturing development	\$ 55.1	\$ 27.8	\$ 27.3	\$	\$
Licenses	3.5	1.2	1.1	0.8	0.4
Research and development	0.1	0.1			
 Total commercial commitments	 \$ 58.7	 \$ 29.1	 \$ 28.4	 \$ 0.8	 \$ 0.4

**Convertible Senior Notes**

In January 2005, we sold \$150,000 principal amount of 1.375% Notes in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 1.375% per annum on the principal amount from January 25, 2005, payable semi-annually in arrears in cash on February 1 and August 1 of each year, beginning August 1, 2005. The 1.375% Notes is convertible into our common stock at an initial conversion rate of 31.7914 shares of common stock per \$1 principal amount of 1.375% Notes, subject to adjustment (equivalent to a conversion price of approximately \$31.46 per share). We do not have the right to redeem any of the 1.375% Notes prior to maturity.

We do not have financial covenants related to our 1.375% Notes. However, there are certain designated events which could occur such as a liquidation, tender offer, consolidation, merger, recapitalization, or otherwise, in connection with which 50% or more of our common stock is exchanged for, converted into, acquired for or constitutes solely the right to receive, consideration which is not at least 90% common stock that is listed on a U.S. national exchange or market. If the holder elects to convert its 1.375% Notes upon the occurrence of a designated event, the holder will be entitled to receive an additional number of shares of common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option, are set according to a table within the offering document, and are capped (in no event will the shares issuable upon conversion of a note exceed 42.9100 shares per \$1 principal amount).

## **Table of Contents**

We incurred deferred financing costs related to this offering of the 1.375% Notes of approximately \$4,800, which are recorded in the consolidated balance sheet and are being amortized as a component of interest expense over the seven-year term of the notes.

### *Purchase of Manufacturing Facility*

On July 13, 2006, our wholly owned affiliate, Alexion Manufacturing LLC purchased a manufacturing facility in Smithfield, Rhode Island from Dow Chemical Company for \$13,000,000. The biopharmaceutical manufacturing facility will be used primarily to produce Soliris (eculizumab). Pursuant to the Purchase and Sale Agreement dated April 13, 2006, or the purchase agreement, we acquired rights to approximately a 55,000 square foot facility, certain equipment located at, or used in connection with, the facility and certain rights under service contracts related to the facility. We deposited into an escrow account \$500,000 upon execution of the purchase agreement on April 13, 2006 and an additional \$500,000 upon the completion of the due diligence period in July 2006. The deposits were held in escrow until the closing date at which time the escrowed amounts and the remaining balance, net of property taxes owed for the first part of the year, of \$11,926,289 was paid to Dow.

### *Mortgage Loan*

In July 2006, our wholly owned affiliate Alexion Manufacturing, LLC, entered into a mortgage loan agreement to borrow \$26,000 to finance the purchase and construction of our Smithfield, Rhode Island manufacturing facility. The mortgage loan bears interest at a fixed annual rate of 9.17% and all obligations under the loan agreement are guaranteed by Alexion Pharmaceuticals, Inc. The loan principal is required to be repaid in equal monthly instalments of \$289, starting March 2009 and until August 2016, at which time all outstanding balances are due. The loan may not be prepaid in whole or in part prior to July 2009. After that date the loan can be prepaid in whole, but not in part, and must include a prepayment premium as described in the loan agreement. Under the terms of the agreement, among other things, Alexion Manufacturing, LLC is restricted with respect to additional borrowings, leasing arrangements and mergers. In the event that approval to market Soliris (eculizumab) has not been obtained before December 31, 2007, Alexion Manufacturing LLC must deliver an acceptable letter of credit to the lender for the amount of \$13,000. Also, included in the loan agreement are certain provisions which, if satisfied, would allow for additional borrowings of up to \$9,000.

Under the terms of the agreement, among other things, Alexion Manufacturing is restricted with respect to additional borrowings, leasing arrangements and mergers. Alexion Manufacturing also may not modify, amend, or waive material obligations with respect to, or terminate, material agreements or proprietary rights, or engage in any business other than ownership and operation of facility. Alexion Pharmaceuticals, Inc. may not, among other things, liquidate wind-up or dissolve as long as the guarantee remains in effect.

As a condition of the loan, Alexion Manufacturing, LLC is required to maintain restricted cash accounts. These accounts must be used specifically for the purchase and construction of the manufacturing facility. The lender has a first priority security interest and the right to approve all disbursements from the accounts holding restricted cash. Under the agreement, we are required to, at all times, maintain a balance in the restricted cash accounts sufficient to complete the project.

### *Capital Leases*

We currently lease office equipment under capital lease agreements expiring in 2010. The assets and liabilities under capital lease are recorded at the lower of the present value of the minimum lease payments or the

## **Table of Contents**

fair value of the asset. The assets are amortized over the lower of their related lease terms or their estimated useful lives. The interest rate on the above capital lease is 22.1% and is imputed based on the lower of our incremental borrowing rate at the inception of each lease.

### *Operating Leases*

Our operating leases are principally for facilities and equipment. We lease our headquarters and research and development facility in Cheshire, Connecticut. The lease, which had an initial term of ten years and six months, expiring in December 2010, was extended in August 2006 to expire in July 2017. At this site, we lease a total of 129,000 square feet of space. We pay a pro rata percentage of real estate taxes and operating expenses. Our pilot manufacturing plant, which may be used for producing compounds for some of our current and anticipated clinical trials, is located in New Haven, Connecticut and encompasses approximately 33,000 square feet of labs and offices. The lease in New Haven has an initial term ending in October 2007 with three options to extend for one year each. Alexion Antibody Technologies, Inc., our wholly-owned subsidiary, leases approximately 17,000 square feet of labs, office space, and unimproved storage in San Diego, California. The lease in San Diego expires in August 2012. We believe our research and development facilities and pilot manufacturing facility, together with third party manufacturing facilities, will be adequate for our current ongoing activities.

### *Commercial Commitments*

Our commercial commitments consist of cancelable research and development, licenses, operations, clinical development including clinical trials, and manufacturing cost commitments along with anticipated supporting arrangements, subject to certain limitations and cancellation clauses. The timing and level of our commercial scale manufacturing costs (assuming we utilize our long-term commercial scale product manufacturing capacity), which may or may not be realized, are contingent upon our clinical development programs' progress as well as our commercialization plans. Our commercial commitments are represented principally by our agreement with Lonza Biologics, PLC and our collaboration with Procter & Gamble Pharmaceuticals.

### *Lonza Agreement*

The Large-Scale Product Supply Agreement dated December 18, 2002, or the Lonza Agreement, between Lonza Biologics PLC, or Lonza, and us, relating to the manufacture of our product candidate Soliris (eculizumab), was amended, or the Lonza Amendment, in April 2004. Under the Lonza Amendment, the facility in which Lonza will manufacture Soliris is changed; the manufacturing capacity we are required to purchase is reduced; and future potential payments of \$10,000 by us to Lonza relating to achievement of Soliris sales milestones and of up to \$15,000 payable by us relating to manufacturing yields achieved by Lonza are eliminated. In August 2004, we paid Lonza an additional \$3,500 as a non-refundable advance under the Lonza Amendment. In addition, the amounts we would be required to pay in connection with a voluntary termination of the Lonza Agreement by us have been changed. Under the current Agreement, if we terminate the Agreement after September 30, 2006, we may be required to pay for batches of product scheduled for manufacture up to 12 months following termination.

### *P&G Pharmaceuticals Collaboration*

In January 1999, we and Procter & Gamble Pharmaceuticals, or P&G, entered into an exclusive collaboration to develop and commercialize pexelizumab. We granted P&G an exclusive license to our intellectual property related to pexelizumab, with the right to sublicense.

## **Table of Contents**

In December 2001, we and P&G entered into a binding memorandum of understanding, or MOU, pursuant to which the January 1999 collaboration was revised. We and P&G have agreed, as per the MOU, that we will share concurrently 50% of the ongoing U.S. pre-production and development manufacturing costs for pexelizumab as well as any AMI or CABG Phase III clinical trial costs.

P&G has the right to terminate the collaboration or sublicense its rights at any time. If P&G terminates the collaboration, as per the MOU, P&G is required to contribute its share of agreed to obligations and costs incurred prior to the termination, but may not be required to contribute towards obligations incurred after termination. In such circumstance all rights and the exclusive license to our intellectual property related to pexelizumab would revert back to us and we would be entitled to all future pexelizumab revenues, if any, without any sharing of revenues, if any, with P&G. If P&G were to sublicense its rights, the sub-licensee would be required to assume all of P&G's obligations under the collaboration.

During 2006, we completed a final Phase III trial of pexelizumab. After reviewing results from that trial, we along with P&G, have determined not to pursue further development of pexelizumab.

Under terms of our MOU we may be obligated to reimburse P&G for 50% of cancellation costs under P&G's third-party pexelizumab manufacturing contract. Our portion of those cancellation costs amounts to approximately \$2,000.

### ***Additional Payments***

Additional payments, aggregating up to approximately \$8,243, would be required if we elect to continue development under our current pre-clinical development programs and if specified development milestones are reached (including achievement of commercialization). Approximately \$2,380 of these costs may be incurred in the next three years.

### ***Taxes***

At December 31, 2006, we have available for federal tax reporting purposes, net operating loss carry forwards of approximately \$618,061 which expire from 2007 through 2026. We also have federal and state research and development credit carry forwards of approximately \$21,891 which expire from 2008 through 2026. The Tax Reform Act of 1986 contains certain provisions that can limit a taxpayer's ability to utilize net operating loss and tax credit carry forwards in any given year resulting from cumulative changes in ownership interests in excess of 50 percent over a three-year period. We have determined that these limiting provisions were triggered. However, such limitation is not expected to result in the loss of the federal net operating loss and research and development credit carry forward.

### **Recently Issued Accounting Standards**

In July 2006, the FASB approved the issuance of FASB Interpretation FIN No. 48, Accounting for Uncertainty in Income Taxes (as amended). This Interpretation clarifies the accounting for uncertain income tax positions in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. Additionally, this Interpretation 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. This Interpretation also provides guidance on de-recognition, classification,

**Table of Contents**

interest and penalties, accounting in interim periods, disclosure, and transition. The Interpretation is effective for reporting periods beginning after December 15, 2006 with earlier application permitted. For Alexion, the effective date will be the first quarter of 2007. Management is evaluating the impact of adopting this accounting standard on our financial position and results of operations.

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

(amounts in thousands, except per share data)

As of December 31, 2006, we held approximately 77% of our cash and investments in financial instruments with original maturity dates of three months or less which includes restricted cash, 6% in financial instruments with original maturity dates of greater than three months and less than one year, and the remaining 17% in financial instruments with original maturity dates of equal to or greater than one year and less than two years. These financial instruments are subject to interest rate risk and will decline in value if interest rates increase. We estimate that a change of 100 basis points in interest rates would result in an increase or decrease of approximately \$257 in the fair value of our cash and investments, which had a weighted average duration of approximately 1 month at December 31, 2006.

Our outstanding long-term liabilities as of December 31, 2006 included our \$150,000, 1.375% Convertible Senior Notes due February 1, 2012. As the notes bear interest at a fixed rate, our results of operations would not be affected by interest rate changes. As of December 31, 2006, the market value of our \$150,000 1.375% convertible senior notes due February 1, 2012, based on quoted market prices, was estimated at \$217,125.

In July 2006, Alexion Manufacturing borrowed \$26,000 to purchase and finance construction of the Smithfield, Rhode Island manufacturing facility. The loan bears interest at a fixed rate. Accordingly, any changes in the interest rate will not affect our future payments on the loan.

Accordingly, we do not believe that there is any material market risk exposure with respect to derivative or other financial instruments that would require disclosure under this item.

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

The consolidated financial statements and supplementary data of the Company required in this item are set forth beginning on page F-1.

**Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**Item 9A. CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures.**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act,) as of December 31,

## **Table of Contents**

2006. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2006, our disclosure controls and procedures were effective to provide reasonable assurance that information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure, and ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

### **Management's Report on Internal Control over Financial Reporting.**

Management of Alexion Pharmaceuticals, Inc. is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management utilized the criteria set forth in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, to conduct an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006. Based on the assessment, management has concluded that, as of December 31, 2006, our internal control over financial reporting is effective.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

### **Changes in Internal Control over Financial Reporting.**

We have expended significant resources in achieving compliance with Section 404 of the Sarbanes-Oxley Act. Through internal resources and the assistance of outside consultants, we developed and executed a plan to evaluate, document, test and improve, where necessary, our internal control over financial reporting.

There has been no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### **Item 9B. OTHER INFORMATION**

On February 23, 2007, the Company entered into the Amendment No. 4 to the Rights Agreement, dated as of February 14, 1997 by and between the Company and Continental Stock Transfer & Trust Company, as amended, to, among other things, provide that (a) the term of the Rights Agreement expires on March 6, 2017 and (b) the purchase price for each one one-hundredth of a share of preferred stock to be issued pursuant to the exercise of a right to purchase junior participating cumulative preferred stock is \$300.

**Table of Contents**

**PART III**

**Item 10. *DIRECTORS AND EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE***

The information required by this item with respect to our executive officers is provided under the caption entitled *Executive Officers and Key Employees of the Company* in Part I of this Annual Report on Form 10-K and is incorporated by reference herein. The information required by this item with respect to our directors and our audit committee and audit committee financial expert will be set forth in our definitive Proxy Statement under the captions *General Information About the Board of Directors* and *Election of Directors*, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated herein by reference to our Proxy Statement.

**SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE**

The information concerning our directors regarding compliance with Section 16(a) of the Securities Exchange Act of 1934 required by this Item will be set forth in our definitive Proxy Statement under the caption *Section 16(a) Beneficial Ownership Reporting Compliance*, to be filed within 120 days after the end of the fiscal year covered by this annual report on Form 10-K, and is incorporated herein by reference to our Proxy Statement.

**CODE OF ETHICS**

We have adopted a Code of Ethics, or our Code of Ethics, that applies to directors, officers and employees and complies with the requirements of Item 406 of Regulation S-K and the listing standards of the Nasdaq Global Market. Our Code of Ethics is located on our website ([www.alexionpharm.com](http://www.alexionpharm.com)). Any amendments or waivers to our Code of Ethics will be promptly disclosed on our website and as required by applicable laws, rules and regulations of the Securities and Exchange Commission and Nasdaq.

**Item 11. *EXECUTIVE COMPENSATION.***

The information required by this Item will be set forth in our definitive Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated herein by reference to our Proxy Statement.

**Item 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.***

The information required by this Item will be set forth in our definitive Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated herein by reference to our Proxy Statement.

**Item 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.***

The information required by this Item will be set forth in our definitive Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated herein by reference to our Proxy Statement.



---

**Table of Contents**

**PART IV**

**Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.**

The information required by this Item will be set forth in our definitive Proxy Statement under the caption Independent Registered Public Accounting Firm, to be filed within 120 days after the end of the year ended December 31, 2006 covered by this Annual Report on Form 10-K, and is incorporated herein by reference to our Proxy Statement.

**Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.**

**(1) Financial Statements**

The financial statements required by this item are submitted in a separate section beginning on page F-1 of this report.

**(2) Financial Statement Schedules**

Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in the financial statements or notes thereto beginning on page F-1 of this report.

**(3) Exhibits:**

- 2.1 Agreement and Plan of Merger by and among Alexion Pharmaceuticals, Inc., PI Acquisition Company, Inc., and Prolifaron, Inc., dated September 22, 2000. (1)
- 3.1 Certificate of Incorporation, as amended. (13)
- 3.2 Bylaws, as amended. (12)
- 4.1 Specimen Common Stock Certificate. (2)
- 4.2 Form of Amended and Restated Senior Debt Indenture dated as of May 7, 2004 between Alexion Pharmaceuticals, Inc. and U.S. Bank National Association, as trustee. (16)
- 4.3 Form of Amended and Restated Subordinated Debt Indenture dated as of May 7, 2004 between Alexion Pharmaceuticals, Inc. and U.S. Bank National Association, as trustee. (16)
- 4.4 Rights Agreement between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer & Trust Company, Rights Agent, dated as of February 14, 1997. (17)
- 4.5 Amendment No. 1 to Rights Agreement, dated as of September 18, 2000, between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer and Trust Company. (18)
- 4.6 Amendment No. 2 to Rights Agreement, dated as of December 12, 2001, between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer and Trust Company, which includes as Exhibit B the form of Right Certificate. (19)
- 4.7 Amendment No. 3 to Rights Agreement, dated as of November 16, 2004, between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer and Trust Company. (20)

**Table of Contents**

4.8	Indenture between Alexion Pharmaceuticals, Inc. and U.S. Bank National Association relating to Alexion Pharmaceuticals, Inc. s 1.375% Convertible Senior Notes due 2012. (21)
4.9	Registration Rights Agreement between Alexion Pharmaceuticals, Inc., Morgan Stanley & Co. Incorporated, Bear, Stearns & Co. Inc., SG Cowen & Co., LLC and J.P. Morgan Securities Inc. (21)
4.10	Amendment No. 4 to Rights Agreement, dated February 23, 2007, between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer and Trust Company.
10.1	Employment Agreement, dated as of February 14, 2006, between the Company and Dr. Leonard Bell. (10)
10.2	Employment Agreement, dated as of February 14, 2006, between the Company and David W. Keiser. (10)
10.3	Employment Agreement, dated as of February 14, 2006, between the Company and Dr. Stephen P. Squinto. (10)
10.4	Employment Agreement, dated as of February 14, 2006, between the Company and Vikas Sinha. (10)
10.5	Employment Agreement, dated November 7, 2005, between the Company and Patrice Coissac. (24)
10.6	Form of Employment Agreement (Senior Vice Presidents). (10)
10.7	Severance Letter Agreement, dated as of November 7, 2005, by and between Alexion Europe SAS and Patrice Coissac. (24)
10.8	Administrative, Research and Development Facility Lease, dated May 9, 2000, between the Company and WE Knotter L.L.C. (3)
10.9	Company s 1992 Stock Option Plan, as amended. (9)
10.10	Company s 2000 Stock Option Plan, as amended. (12)
10.11	Company s 1992 Outside Directors Stock Option Plan, as amended. (5)
10.12	Company s 2004 Incentive Plan. (14)
10.13	Exclusive License Agreement dated as of June 19, 1992 among the Company, Yale University and Oklahoma Medical Research Foundation. (2)
10.14	License Agreement dated as of September 30, 1992 between the Company and Yale University, as amended July 2, 1993. (2)+
10.15	Exclusive Patent License Agreement dated April 21, 1994 between the Company and the National Institutes of Health (2)
10.16	License Agreement dated as of January 10, 1995 between the Company and Yale University. (2)
10.17	License Agreement dated as of May 27, 1992 between the Company and Yale University, as amended September 23, 1992. (2)+
10.18	License Agreement dated March 27, 1996 between the Company and Medical Research Council. (5)+
10.19	License Agreement dated May 8, 1996 between the Company and Enzon, Inc. (5)+

**Table of Contents**

10.20	Asset Purchase Agreement date as of February 9, 1999 between the Company and United States Surgical Corporation. (6)
10.21	Collaboration Agreement dated January 25, 1999 between the Company and the Procter & Gamble Company, as amended. (6)+
10.22	Binding Memorandum of Understanding dated December 11, 2001 between the Company and the Procter & Gamble Company. (7)+
10.23	Research and Development Facility lease, dated February 1, 2002, between the Company and PMSI SRF L.L.C. (8)
10.24	Large-Scale Product Supply Agreement, dated December 18, 2002, between the Company and Lonza Biologics plc., as amended. (13)+
10.25	Industrial Real Estate lease, dated January 1, 2003, between the Company and SP-K Development, LLC. (9)
10.26	Co-Development and Co-Commercialization Agreement between the Company and XOMA (US) LLC, dated December 17, 2003. (11)+
10.27	Form of Stock Option Agreement for Directors. (14)
10.28	Form of Stock Option Agreement for Executive Officers (Form A). (22)
10.29	Form of Stock Option Agreement for Executive Officers (Form B). (22)
10.30	Form of Restricted Stock Award Agreement for Executive Officers (Form A). (23)
10.31	Form of a Stock Option Agreement for named executive officer(s) of Alexion Europe SAS. (24)
10.32	Form of a Restricted Stock Agreement for named executive officer(s) of Alexion Europe SAS. (24)
10.33	Purchase and Sale Agreement by and between The Dow Chemical Company and Alexion Manufacturing LLC, dated as of April 13, 2006, as amended. (25)
10.34	Loan and Security Agreement between Alexion Manufacturing LLC and iStar Financial Inc., dated as of July 11, 2006. (25)
10.35	Completion, Payment, and Performance Guarantee by Alexion Pharmaceuticals, Inc. in favor of iStar Financial Inc., dated as of July 11, 2006. (25)
10.36	Construction Mortgage Deed, Assignment of Leases and Rents, Security Agreement and Fixture Filing, dated as of July 11, 2006 by Alexion Manufacturing LLC in favor of iStar Financial Inc. (25)
10.37	Environmental Indemnity Agreement by and among Alexion Manufacturing LLC, Alexion Pharmaceuticals, Inc. in favor of iStar Financial Inc., dated as of July 11, 2006. (25)
12.1	Statement Regarding Computation of Ratio of Earnings to Fixed Charges. (13)
21.1	Subsidiaries of Alexion Pharmaceuticals, Inc.
23.1	Consent of PricewaterhouseCoopers LLP.

---

**Table of Contents**

- 31.1 Certificate of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002.
- 31.2 Certificate of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
- 32.1 Certificate of Chief Executive Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.
- 32.2 Certificate of Chief Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.

- 
- (1) Incorporated by reference to our report on Form 8-K, filed on October 3, 2000.
  - (2) Incorporated by reference to our Registration Statement on Form S-1 (Reg. No. 333-00202).
  - (3) Incorporated by reference to our Registration Statement on Form S-3 (Reg. No. 333-36738) filed on May 10, 2000.
  - (4) Incorporated by reference to our Registration Statement on Form S-8 (Reg. No. 333-71985) filed on February 8, 1999.
  - (5) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended July 31, 1996.
  - (6) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended July 31, 1999.
  - (7) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended July 31, 2002.
  - (8) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2002.
  - (9) Incorporated by reference to our quarterly report on form 10-Q for the quarter ended January 31, 2003
  - (10) Incorporated by reference to our Report on Form 8-K filed on February 16, 2006.
  - (11) Incorporated by reference to our report on Form 8-K/A, filed on March 22, 2004.
  - (12) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2004.
  - (13) Incorporated by reference to our Registration Statement on Form S-3 (Reg. No. 333-128085), filed on September 2, 2005.
  - (14) Incorporated by reference to our report on Form 8-K, filed on December 16, 2004.
  - (15) Incorporated by reference to our report on Form 8-K, filed on September 2, 2005.
  - (16) Incorporated by reference to Amendment No. 1 to Form S-3 (Reg. No. 333-114449), filed on May 10, 2004.
  - (17) Incorporated by reference to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on February 21, 1997.
  - (18) Incorporated by reference to Amendment No. 1 to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on October 6, 2000.
  - (19) Incorporated by reference to Amendment No. 2 to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on February 12, 2002.
  - (20) Incorporated by reference to Amendment No. 3 to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on November 17, 2004.
  - (21) Incorporated by reference to our report on Form 8-K (Reg. No. 000-27756), filed on January 25, 2005.
  - (22) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2005.
  - (23) Incorporated by reference to our report on Form 8-K (Reg. No. 000-27756), filed on March 14, 2005.
  - (24) Incorporated by reference to our report on Form 8-K (Reg. No. 000-27756), filed on November 14, 2005.
  - (25) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2006.
  - + Confidential treatment was granted for portions of such document.

**Table of Contents**

**Item 15(b) Exhibits**

See (a) (3) above.

**Item 15(c) Financial Statement Schedules**

See (a) (2) above.

Table of Contents

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALEXION PHARMACEUTICALS, INC.

By: /s/ LEONARD BELL  
**Leonard Bell, M.D.**  
*Chief Executive Officer,  
 Secretary and Treasurer*  
**Dated: February 23, 2007**

By: /s/ DAVID W. KEISER  
**David W. Keiser**  
*President and Chief Operating Officer*  
**Dated February 23, 2007**

Pursuant to the requirements of the Securities Exchange 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.

/s/ LEONARD BELL  <b>Leonard Bell, M.D.</b>	Chief Executive Officer, Secretary, Treasurer and Director (principal executive officer)	February 23, 2007
/s/ DAVID W. KEISER  <b>David W. Keiser</b>	President, Chief Operating Officer and Director	February 23, 2007
/s/ VIKAS SINHA  <b>Vikas Sinha, M.B.A., C.A.</b>	Senior Vice President and Chief Financial Officer (principal financial and accounting officer)	February 23, 2007
/s/ MAX LINK  <b>Max Link, Ph.D.</b>	Chairman of the Board of Directors	February 23, 2007
/s/ LARRY L. MATHIS  <b>Larry L. Mathis</b>	Director	February 23, 2007
/s/ JOSEPH A. MADRI  <b>Joseph A. Madri, Ph.D., M.D.</b>	Director	February 23, 2007
/s/ R. DOUGLAS NORBY  <b>R. Douglas Norby</b>	Director	February 23, 2007
/s/ ALVIN S. PARVEN	Director	February 23, 2007

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

**Alvin S. Parven**

/s/ Ruedi E. Waeger

Director

February 23, 2007

**Ruedi E. Waeger, Ph.D.**

71

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Contents**

**For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,**

**and Years Ended July 31, 2005 and 2004**

	<b>Page(s)</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
Consolidated Financial Statements	
<u>Consolidated Balance Sheets</u>	F-4
<u>Consolidated Statements of Operations</u>	F-5
<u>Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Loss</u>	F-6
<u>Consolidated Statements of Cash Flows</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-8 to F-36

F-1



---

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders

of Alexion Pharmaceuticals, Inc.:

We have completed integrated audits of Alexion Pharmaceuticals, Inc.'s year ended December 31, 2006, five-month period ended December 31, 2005 and year ended July 31, 2005 consolidated financial statements and of its internal control over financial reporting as of December 31, 2006, and an audit of its July 31, 2004 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

*Consolidated financial statements*

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Alexion Pharmaceuticals, Inc. and its subsidiaries (the Company) at December 31, 2006, December 31, 2005 and July 31, 2005, and the results of their operations and their cash flows for the year ended December 31, 2006, the five month period ended December 31, 2005 and each of the two years in the period ended July 31, 2005 in conformity with accounting principles generally accepted in the United States of America. 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 of these statements 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 of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Notes 1 and 11 to the financial statements, effective August 1, 2005, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment.

*Internal control over financial reporting*

Also, in our opinion, management's assessment, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2006 based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control - Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

**Table of Contents**

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

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

/s/ PricewaterhouseCoopers LLP

Hartford, Connecticut

February 23, 2007

F-3

**Table of Contents****Alexion Pharmaceuticals, Inc.****Consolidated Balance Sheets**

(amounts in thousands, except per share amounts)

	December 31, 2006	December 31, 2005	July 31, 2005
<b>ASSETS</b>			
<b>CURRENT ASSETS</b>			
Cash and cash equivalents	\$ 166,826	\$ 43,629	\$ 46,951
Marketable securities	49,728	168,827	148,453
Inventories	2,314		
Prepaid expenses and other current assets	3,973	5,095	5,758
<b>Total current assets</b>	<b>222,841</b>	<b>217,551</b>	<b>201,162</b>
Property, plant and equipment, net	39,135	10,631	11,546
Goodwill, net	19,954	19,954	19,954
Prepaid manufacturing costs	13,935	10,000	10,600
Restricted cash	33,594		
Other assets	4,078	4,575	4,860
<b>Total Assets</b>	<b>\$ 333,537</b>	<b>\$ 262,711</b>	<b>\$ 248,122</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>			
<b>CURRENT LIABILITIES</b>			
Accounts payable	\$ 10,939	\$ 3,865	\$ 7,455
Accrued expenses	16,228	20,629	16,364
Deferred revenue	588	767	820
Current portion of obligations under capital lease	67	129	75
<b>Total current liabilities</b>	<b>27,822</b>	<b>25,390</b>	<b>24,714</b>
Obligations under capital lease	283	88	149
Deferred revenue, less current portion	4,755	5,343	5,588
Mortgage loan	26,000		
Convertible notes	150,000	150,000	150,000
<b>Total Liabilities</b>	<b>208,860</b>	<b>180,821</b>	<b>180,451</b>
<b>COMMITMENTS AND CONTINGENCIES</b>			
<b>STOCKHOLDERS EQUITY</b>			
Preferred stock, \$.0001 par value; 5,000 shares authorized, no shares issued or outstanding			
Common stock, \$.0001 par value; 145,000 shares authorized; 35,568, 30,980 and 28,227 shares issued at December 31, 2006, December 31, 2005 and July 31, 2005, respectively	4	3	3
Additional paid-in capital	763,691	589,250	518,883
Treasury stock, at cost, 57 shares at December 31, 2006, 50 shares at December 31, 2005 and 37 shares at July 31, 2005	(1,260)	(981)	(600)
Accumulated other comprehensive loss	(177)	(315)	(566)
Deferred stock-based compensation expense			(1,938)
Accumulated deficit	(637,581)	(506,067)	(448,111)
<b>Total Stockholders Equity</b>	<b>124,677</b>	<b>81,890</b>	<b>67,671</b>

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

Total Liabilities and Stockholders' Equity	\$ 333,537	\$ 262,711	\$ 248,122
--	------------	------------	------------

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

F-4

**Table of Contents****Alexion Pharmaceuticals, Inc.****Consolidated Statements of Operations**

(amounts in thousands, except per share amounts)

	Year Ended December 31,	Five Month Period Ended December 31,		Year Ended July 31,	
	2006	2005	2004 (unaudited)	2005	2004
CONTRACT RESEARCH REVENUES	\$ 1,558	\$ 664	\$ 245	\$ 1,064	\$ 4,609
OPERATING EXPENSES					
Research and development	83,225	48,238	31,914	91,388	59,840
General and administrative	54,879	12,763	6,160	18,951	14,459
Impairment of fixed assets	539				760
Total operating expenses	138,643	61,001	38,074	110,339	75,059
Operating loss	(137,085)	(60,337)	(37,829)	(109,275)	(70,450)
OTHER INCOME AND EXPENSE					
Investment income	8,076	3,123	1,756	5,266	3,373
Interest expense	(2,837)	(1,192)	(3,153)	(6,125)	(7,709)
Gain from extinguishment of note payable			3,804	3,804	
Loss on early extinguishment of debt				(3,185)	
Other	(41)				
Loss before state tax benefit	(131,887)	(58,406)	(35,422)	(109,515)	(74,786)
STATE TAX BENEFIT	373	450	61	765	691
Net Loss	\$ (131,514)	\$ (57,956)	\$ (35,361)	\$ (108,750)	\$ (74,095)
BASIC AND DILUTED LOSS PER SHARE DATA					
Net loss per common share	\$ (4.15)	\$ (1.90)	\$ (1.28)	\$ (3.90)	\$ (3.43)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS PER COMMON SHARE	31,701	30,523	27,685	27,852	21,622

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

**Table of Contents****Alexion Pharmaceuticals, Inc.****Consolidated Statements of Changes in Stockholders Equity and Comprehensive Loss**

(amounts in thousands)

	Common Stock Shares	Amount	Additional Paid-In Capital	Treasury Stock at Cost Shares	Amount	Other Comprehensive Income (Loss)	Deferred Stock-Based Compensation	Accumulated Deficit	Total Stockholders Equity
Balances, July 31, 2003	18,257	2	385,498	37	(600)	652		(265,266)	120,286
Net loss								(74,095)	(74,095)
Net change in unrealized gains on marketable securities						(999)			(999)
Comprehensive loss									(75,094)
Issuance of common stock from exercise of options	200		2,503						2,503
Noncash compensation expense related to grant of stock options			106						106
Issuance of common stock, net of issuance costs of \$7,301	9,100	1	124,720						124,721
Balances, July 31, 2004	27,557	3	512,827	37	(600)	(347)		(339,361)	172,522
Net loss								(108,750)	(108,750)
Net change in unrealized gains on marketable securities						(219)			(219)
Comprehensive loss									(108,969)
Issuance of common stock from exercise of options	563		3,743						3,743
Issuance of restricted common stock	107		2,150				(2,150)		
Amortization of deferred stock-based compensation							212		212
Noncash compensation expense related to grant of stock options			163						163
Balances, July 31, 2005	28,227	3	518,883	37	(600)	(566)	(1,938)	(448,111)	67,671
Net loss								(57,956)	(57,956)
Foreign currency translation						(8)			(8)
Net change in unrealized gains on marketable securities						259			259
Comprehensive loss									(57,705)
Issuance of common stock, net of issuance costs of \$2,145	2,500		64,517						64,517
Issuance of common stock from exercise of options	233		3,474						3,474
Issuance of restricted common stock	20								
Exchange of common shares for treasury				13	(381)				(381)
Reversal of deferred stock-based compensation			(1,938)				1,938		
Share-based compensation expense			4,314						4,314
Balances, December 31, 2005	30,980	3	589,250	50	(981)	(315)		(506,067)	81,890
Net loss								(131,514)	(131,514)
Foreign currency translation						(120)			(120)
Net change in unrealized gains on marketable securities						258			258

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

Comprehensive loss									(131,376)
Issuance of common stock, net of issuance costs of \$8,121	3,450	1	140,282						140,283
Issuance of common stock from exercise of options	925		13,544						13,544
Issuance of restricted common stock	213								
Exchange of common shares for treasury				7	(279)				(279)
Share-based compensation expense			20,615						20,615
Balances, December 31, 2006	35,568	\$ 4	\$ 763,691	57	\$ (1,260)	\$ (177)	\$	\$ (637,581)	\$ 124,677

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

F-6

**Table of Contents****Alexion Pharmaceuticals, Inc.****Consolidated Statements of Cash Flows**

(amounts in thousands)

	Year Ended December 31,	Five Month Period Ended December 31,		Year Ended July 31,	
	2006	2005	2004 (unaudited)	2005	2004
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>					
Net loss	\$ (131,514)	\$ (57,956)	\$ (35,361)	\$ (108,750)	\$ (74,095)
Adjustments to reconcile net loss to net cash used by operating activities:					
Impairment of fixed assets	539				760
Gain from extinguishment of note payable			(3,804)	(3,804)	
Loss on disposal of property, plant & equipment	141				
Depreciation and amortization	3,706	1,693	1,400	3,808	3,713
Share-based compensation expense	20,615	4,314	7	375	106
Write off of deferred financing costs				1,212	
Changes in operating assets and liabilities:					
Inventories	(2,314)				
Prepaid expenses and other assets	942	663	6,446	4,075	(2,969)
Prepaid manufacturing costs	(3,935)	600	(3,000)	(1,100)	500
Accounts payable	7,074	(3,589)	(3,651)	3,482	(412)
Accrued expenses	(4,401)	4,265	3,476	5,693	(279)
Deferred revenue	(767)	(298)	168	(357)	(588)
Deferred research and development costs			(78)	(1,391)	1,391
Net cash used by operating activities	(109,914)	(50,308)	(34,397)	(96,757)	(71,873)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>					
Purchase of marketable securities	(734,567)	(419,086)	(115,549)	(508,818)	(168,952)
Proceeds from maturity or sale of marketable securities	853,924	398,971	72,023	513,423	205,242
Purchase of property, plant and equipment	(31,856)	(444)	(894)	(2,980)	(3,135)
Increase in restricted cash	(33,594)				
Purchase of patents and license technology					(5)
Net cash (used) provided by investing activities	53,907	(20,559)	(44,420)	1,625	33,150
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>					
Proceeds from convertible debt offering				150,000	
Convertible debt issuance costs				(4,758)	
Redemption of convertible notes				(120,000)	
Payments on capital leases	(224)	(57)	(51)	(126)	(120)
Proceeds from mortgage loan	26,000				
Exchange of treasury shares	(279)	(381)			
Net proceeds from issuance of common stock	153,827	67,991	1,548	3,743	127,223
Net cash provided by financing activities	179,324	67,553	1,497	28,859	127,103
Effect of exchange rate changes	(120)	(8)			



Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

Net change in cash and cash equivalents	123,197	(3,322)	(77,320)	(66,273)	88,380
Cash and cash equivalents at beginning of period	43,629	46,951	113,224	113,224	24,844
Cash and cash equivalents at end of period	\$ 166,826	\$ 43,629	\$ 35,904	\$ 46,951	\$ 113,224

**Supplemental schedule of noncash financing activities:**

A capital lease obligation of \$357 was incurred when the Company entered into new leasing arrangements for office equipment.

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

F-7

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,**

**and Years Ended July 31, 2005 and 2004**

**(amounts in thousands, except share and per share amounts)**

**1. Organization and Summary of Significant Accounting Policies**

**Business**

Alexion Pharmaceuticals, Inc. ( Alexion ) was incorporated in 1992 and is engaged in the development of biologic therapeutic products for the treatment of severe diseases.

In the year ending December 31, 2006, we filed a Biologics License Application, or BLA, with the U.S. Food and Drug Administration, or FDA, and a European Marketing Authorization Application, or MAA, in Europe, for our lead product candidate Soliris (eculizumab) for the treatment of a rare, life-threatening blood disorder known as Paroxysmal Nocturnal Hemoglobinuria, or PNH.

We have incurred operating losses since inception and have had no product sales to date. We will continue to seek financing to establish manufacturing, sales, marketing, and distribution capabilities for our product candidates. We expect to incur substantial expenditures in the foreseeable future for the research, development and commercialization of our product candidates. We may seek to raise necessary funds through public or private equity or debt financings, bank loans, collaborative or other arrangements with corporate sources, or through other sources of financing.

As of December 31, 2005, the consolidated financial statements of Alexion Pharmaceuticals, Inc. included Alexion Pharmaceuticals, Inc., Alexion Antibody Technologies, Inc. Columbus Farming Corporation, and Alexion Europe SAS. During the year ended December 31, 2006, we established several new entities to support our planned growth and preparation for commercialization. Alexion Manufacturing, LLC and Alexion Delaware Holding, LLC are wholly owned by Alexion Pharmaceuticals, Inc. and both are Delaware limited liability companies. The partnership of Alexion Bermuda, LP is ninety percent owned by Alexion Pharmaceuticals, Inc. and ten percent owned by Alexion Delaware Holding, LLC and was formed under the laws of Bermuda as a limited partnership. Alexion International Sarl is ninety-five percent owned by Alexion Bermuda, LP and five percent owned by Alexion Pharmaceuticals, Inc. and was incorporated under the laws of Switzerland. Alexion Holding B.V. is registered as a corporation in the Netherlands and is wholly owned by Alexion Delaware Holding, LLC. Alexion Pharma UK and Alexion Pharma France are wholly owned by Alexion Holding B.V. and incorporated under the laws of the United Kingdom and France, respectively.

**Principles of Consolidation**

The accompanying consolidated financial statements include the accounts of Alexion Pharmaceuticals, Inc. and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

**Use of Estimates in the Preparation of Financial Statements**

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

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,**

**and Years Ended July 31, 2005 and 2004**

**(amounts in thousands, except share and per share amounts)**

amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**Change in Fiscal Year**

On December 9, 2005, our Board of Directors approved a change to our fiscal year from July 31 to December 31 commencing in 2005. Included in the accompanying consolidated financial statements is a five month transitional period from August 1, 2005 to December 31, 2005.

**Foreign Currency Translation**

For foreign subsidiaries with a functional currency different from U.S. dollars, we translate their financial statements into U.S. dollars using the current exchange rate at each balance sheet date for assets and liabilities, the average exchange rate prevailing during each period for revenues and expenses; and the historical exchange rate for investments in our foreign subsidiaries. Adjustments from translating these financial statements into U.S. dollars are included in accumulated other comprehensive loss.

**Cash and Cash Equivalents**

Cash and cash equivalents are stated at fair value, which approximates market, and include short-term highly liquid investments with original maturities of less than 90 days.

**Restricted Cash**

Under the terms of our mortgage loan (see Note 7), we have agreed to maintain a restricted cash balance equal to the amount required under our mortgage loan agreement. At December 31, 2006, \$33,594 of cash is restricted for that purpose.

**Marketable Securities**

We invest in marketable debt securities of highly rated financial institutions and investment-grade debt instruments and limit the amount of credit exposure with any one entity. We have classified our marketable securities as available for sale and, accordingly, carry such securities at aggregate fair value. Unrealized gains or losses are included in accumulated other comprehensive loss as a separate component of stockholders equity.

**Inventories**

Inventories are stated at the lower of cost or estimated realizable value, with cost determined under the first-in, first-out, or FIFO, method.

---

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,**

**and Years Ended July 31, 2005 and 2004**

**(amounts in thousands, except share and per share amounts)**

Our policy is to capitalize inventory costs associated with our products, subsequent to the filing of a Biologics License Application, or BLA, but prior to regulatory approval, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. We assess the regulatory approval process and where the particular product stands in relation to that approval process. Our assessment includes any known constraints and impediments to approval, including safety, efficacy and potential labeling restrictions. We evaluate our anticipated research and development initiatives and constraints relating to the product and the indication for which it will be used. We consider our manufacturing environment including our supply chain in determining logistical constraints that could possibly hamper approval or commercialization. We consider the shelf life of the product in relation to the expected timeline for approval and estimated demand, and we consider patent related or contract issues that may prevent or cause delay in commercialization. We also base our judgment on the viability of commercialization, trends in the marketplace and market acceptance criteria. Finally, we consider the reimbursement strategies that may prevail with respect to the product and assess the economic benefit that we are likely to realize.

There is a risk inherent in these judgments, and we would be required to expense previously capitalized costs related to pre-approval inventory upon a change in such judgment, due to, among other potential factors, a denial or delay of approval by necessary regulatory bodies.

We periodically review our inventories for excess or obsolete inventory and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual realizable value is less than that estimated by us, or if there are any further determinations that inventory will not be marketable based on estimates of demand, additional inventory write-downs may be required. These write-downs are based on management's estimates. Based on this review, there are no write-downs against the value of our inventory, as of December 31, 2006.

At December 31, 2006, our inventory consists entirely of finished goods. We submitted a Marketing Authorization Application in the European Union and a Biologics License Application in the United States in September 2006. We anticipate European Union and United States approvals in 2007 and are preparing for commercial launch thereafter.

**Product Supply**

The Large-Scale Product Supply Agreement dated December 18, 2002, or the Lonza Agreement, between Lonza Biologics PLC, or Lonza, and us, relating to the manufacture of our product candidate Soliris, was amended, or the Lonza Amendment, in April 2004. Under the Lonza Amendment, the facility in which Lonza will manufacture Soliris is changed; the manufacturing capacity we are required to purchase is reduced; and future potential payments of \$10,000 by us to Lonza relating to achievement of Soliris sales milestones and of up to \$15,000 payable by us relating to manufacturing yields achieved by Lonza are eliminated. In August 2004 we paid Lonza an additional \$3,500 advance under the Lonza Amendment. In addition, the amounts we would be required to pay in connection with a voluntary termination of the Lonza Agreement by us have been changed.

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,**

**and Years Ended July 31, 2005 and 2004**

**(amounts in thousands, except share and per share amounts)**

Under the Lonza Agreement if we terminate the Lonza Agreement after September 30, 2006, we may be required to pay for batches of product scheduled for manufacture up to 12 months following termination.

The amounts paid to Lonza in consideration of the Lonza Agreement are reflected as prepaid manufacturing costs within the accompanying balance sheet and are recognized as additional manufacturing costs as the batches are manufactured. On a quarterly basis, we evaluate our plans to proceed with production under the agreement which depends upon our clinical development programs' progress as well as commercialization plans. In addition, we evaluate the prepaid manufacturing costs against estimated net realizable value, or NRV. If estimated NRV is not positive, then all or a portion of the prepaid manufacturing cost may have to be recognized as an expense.

**Prepaid Manufacturing Costs**

Cash advances paid by us to secure future long-term manufacturing production at third-party contract manufacturers are recorded as prepaid manufacturing costs. These costs are recognized over the period of manufacturing production on a unit of production method. The cash advances are subject to refund if the manufacturing facility is unavailable as scheduled or forfeiture if we terminate the scheduled production.

**Property, Plant and Equipment**

Property and equipment are carried at original cost, subject to review of impairment for significant assets whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets. Leasehold improvements are amortized over the lesser of the useful life or the term of the respective lease. Maintenance costs are expensed as incurred. Construction in progress reflects amounts incurred for property, plant, or equipment construction or improvements. For products we expect to commercialize, we capitalize, to construction-in-progress, certain incremental costs associated with the validation effort required for licensing by the FDA of manufacturing equipment for the production of a commercially approved drug. These costs include primarily direct labor and materials and are incurred in preparing the equipment for its intended use. The validation costs are amortized over the life of the related equipment.

**Long-Lived Assets**

We assess the potential impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that we consider important, and which could trigger an impairment review, include, among others, the following:

a significant adverse change in the extent or manner in which a long-lived asset is being used;

a significant adverse change in the business climate that could affect the value of a long-lived asset; and

a significant decrease in market value of assets.



**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,**

**and Years Ended July 31, 2005 and 2004**

**(amounts in thousands, except share and per share amounts)**

In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell.

If we determine that the carrying value of long-lived assets may not be recoverable, based upon the existence of one or more of the above indicators of impairment, we will compare the carrying value of the asset group to the undiscounted cash flows expected to be generated by the group. If the carrying value exceeds the undiscounted cash flows, we will then compare the carrying value of the asset group to its fair value to determine whether an impairment charge is required. If the fair value is less than the carrying value, the asset will be written down to fair value and the difference between the fair value and carrying value will be recognized as an impairment charge.

**Intangible Assets**

Identifiable intangible assets are recorded at original cost. Intangible assets with finite lives are amortized evenly over their estimated useful lives. Intangible assets with indefinite lives are not amortized.

**Goodwill**

Goodwill represents the difference between the purchase price of acquired businesses and the fair value of their net assets, and is not amortized. We test goodwill for impairment at least annually and whenever events or changes in circumstances indicate the carrying amount of goodwill might not be recoverable. No impairment charges have occurred as a result of our annual impairment assessment.

**Revenue Recognition**

We record contract research revenues from research and development support payments, license fees and milestone payments under collaboration with third parties, and amounts received from various government grants. We evaluate all deliverables in our collaborative agreement to determine whether they represent separate units of accounting. Deliverables qualify for separate accounting treatment if they have standalone value to the customer and if there is objective evidence of fair value of the undelivered item.

Up-front, non-refundable license fees received in connection with collaboration are deferred and amortized as revenue over the life of the agreement or period of performance obligations.

Revenues derived from the achievement of milestones are recognized when the milestone is achieved, provided that the milestone is substantive and a culmination of the earnings process has occurred. Revenues derived from the achievement of milestones or recognition of related work when performed under terms of a contract may cause our operating results to vary considerably from period to period. Research and development support revenues are recognized as the related work is performed and expenses are incurred under the terms of the contracts for development activities.

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,**

**and Years Ended July 31, 2005 and 2004**

**(amounts in thousands, except share and per share amounts)**

Deferred revenue results from cash received or amounts receivable in advance of revenue recognition under research and development contracts.

**Research and Development Expenses**

Research and development expenses are comprised of costs incurred in performing research and development activities including salaries and benefits, pre-clinical, clinical trial and related clinical manufacturing costs, manufacturing development and scale-up costs, contract services and other outside contractor costs, research license fees, depreciation and amortization of lab facilities, and lab supplies. These costs are expensed as incurred.

We have entered into a research agreement in which we share costs with our collaborator. We record these costs as research and development expenses as incurred. A portion of these costs are reimbursed by our collaborator and are recorded as a reduction of research and development expense.

**Stock-Based Compensation**

We adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (SFAS 123R), effective August 1, 2005. SFAS 123R requires the recognition of the fair value of stock-based compensation in net earnings. We have one stock-based compensation plan known as the 2004 Incentive Plan. Under this plan, restricted stock, stock options and other stock-related awards may be granted to our directors, officers, employees and consultants or advisors of the Company or any subsidiary. To date, stock-based compensation issued under the plan consists of incentive and non-qualified stock options and restricted stock. Stock options are granted to employees at exercise prices equal to the fair market value of our stock at the dates of grant. Generally, stock options and restricted stock granted to employees fully vest four years from the grant date. Stock options have a term of 10 years. We recognize stock-based compensation expense on a straight-line basis over the requisite service period of the individual grants, generally the service period equals the vesting period.

Prior to August 1, 2005, we accounted for the 2004 Incentive Plan and preceding plans under the intrinsic value method described in Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, (APB No. 25) and related Interpretations as permitted by Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation. (SFAS 123). When applying the intrinsic value method, we generally did not record stock-based compensation cost because the exercise price of our stock options equalled the market price of the underlying stock on the date of grant. We have elected to utilize the modified prospective transition method for adopting SFAS 123R. Under this method, the provisions of SFAS 123R apply to all awards granted or modified after the date of adoption. In addition, the unrecognized expense of awards not yet vested at the date of adoption, determined under the original provisions of SFAS 123, shall be recognized in the periods after the date of adoption.



**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)**

SFAS 123R requires us to present pro forma information for periods prior to the adoption as if we had accounted for all stock-based compensation under the fair value method of SFAS 123. For purposes of pro forma disclosure, the estimated fair value of the options at the date of grant is amortized to expense over the requisite service period, which generally equals the vesting period. The following table illustrates the effect on net loss and loss per share as if we had applied the fair value recognition provisions of SFAS 123 to our stock-based employee compensation.

	<b>Year Ended July 31,</b>	
	<b>2005</b>	<b>2004</b>
Net loss, as reported	\$ (108,750)	\$ (74,095)
Add: Stock-based employee compensation expense included in reported net loss	217	67
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(10,276)	(14,552)
Pro forma net loss	\$ (118,809)	\$ (88,580)
Basic and diluted as reported	\$ (3.90)	\$ (3.43)
Basic and diluted pro forma	\$ (4.27)	\$ (4.10)

The stock-based compensation for grants of stock options as presented above does not include restricted stock expense, which was reported as part of the net loss.

Upon adoption of SFAS 123R, we recognized the compensation expense associated with awards granted after August 1, 2005, and the unvested portion of previously granted awards that remain outstanding as of August 1, 2005. For the year ended December 31, 2006, and the five month period ended December 31, 2005, we recognized total compensation expense of \$17,601 and \$4,054 for stock options and \$3,014 and \$260 for restricted stock, respectively. Due to our net loss position, a windfall tax benefit was not realized during the period. The balance of deferred stock-based compensation at July 31, 2005 related to the restricted stock grants noted above was approximately \$1,938. Upon the adoption of SFAS 123R, we eliminated the deferred stock-based compensation account of \$1,938 through corresponding adjustments to additional paid-in-capital. Compensation expense related to the restricted stock will be recognized in our Statement of Operations over its vesting period.

**Earnings (Loss) per Share (EPS)**

Basic EPS is computed by dividing net loss by the weighted average number of shares of Common Stock outstanding for the period. Diluted EPS reflects the potential dilution that could occur if options or other contracts to issue Common Stock were exercised or converted into Common Stock. Due to our net loss,

---

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,**

**and Years Ended July 31, 2005 and 2004**

**(amounts in thousands, except share and per share amounts)**

convertible debt, unvested restricted stock, and stock options granted under the stock option plan but not yet exercised are antidilutive and therefore not considered for the diluted EPS calculations. The convertible debt, unvested restricted stock, and stock options entitled holders to acquire 10,473,462 shares, 9,994,295 shares, 9,604,003 shares, and 5,669,764 shares of common stock for the year ended December 31, 2006, five month period ended December 31, 2005 and the years ended July 31, 2005 and 2004, respectively. There is no difference between basic and diluted net loss per common share as the effect of other potential common share equivalents is anti-dilutive for all periods presented.

**Income Taxes**

Deferred income taxes are provided for differences between the income tax and the financial reporting bases of assets and liabilities at the statutory tax rates that will be in effect when the differences are expected to reverse. A valuation allowance for deferred tax assets is recorded to the extent we cannot determine that the ultimate realization of net deferred tax assets is more likely than not. In making such determination, we may consider estimated future reversals of existing temporary differences, estimated future earnings and available tax planning strategies. To the extent that the estimates of these items are reduced or not realized, the amount of the deferred tax assets considered realizable could be adversely affected.

**Segment Reporting**

SFAS No. 131, *Disclosure about Segments of an Enterprise and Related Information*, establishes annual and interim reporting standards for an enterprise's operating segments and related disclosures about its products, services, geographic areas and major customers. We have determined that we operate in a single segment. In addition, all revenues are generated from United States entities, and all long-lived assets are maintained in the United States.

**Recently Issued Accounting Standards**

In July 2006, the FASB approved the issuance of FASB Interpretation FIN No. 48, *Accounting for Uncertainty in Income Taxes* (as amended). This Interpretation clarifies the accounting for uncertain income tax positions in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. Additionally, this Interpretation 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. This Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Interpretation is effective for reporting periods beginning after December 15, 2006 with earlier application permitted. For Alexion Pharmaceuticals, Inc., the effective date will be the first quarter of 2007. We are evaluating the impact of adopting this accounting standard on our financial position and results of operations.

---

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,**

**and Years Ended July 31, 2005 and 2004**

**(amounts in thousands, except share and per share amounts)**

**2. Collaboration and License Agreements**

**Procter & Gamble Pharmaceuticals Collaboration**

In January 1999, we and Procter & Gamble Pharmaceuticals, or P&G, entered into an exclusive collaboration to develop and commercialize pexelizumab. We granted P&G an exclusive license to our intellectual property related to pexelizumab, with the right to sublicense.

In December 2001, we and P&G entered into a binding memorandum of understanding, or MOU, pursuant to which the January 1999 collaboration was revised. We and P&G have agreed, as per the MOU, that we will share concurrently 50% of the ongoing U.S. pre-production and development manufacturing costs for pexelizumab as well as any AMI or CABG Phase III clinical trial costs.

P&G has the right to terminate the collaboration or sublicense its rights at any time. If P&G terminates the collaboration, as per the MOU, P&G is required to contribute its share of agreed to obligations and costs incurred prior to the termination, but may not be required to contribute towards obligations incurred after termination. In such circumstance all rights and the exclusive license to our intellectual property related to pexelizumab would revert back to us and we would be entitled to all future pexelizumab revenues, if any, without any sharing of revenues, if any, with P&G. If P&G were to sublicense its rights, the sub-licensee would be required to assume all of P&G's obligations under the collaboration.

We are recognizing a non-refundable up-front license fee of \$10,000 related to the P&G collaboration as revenue over 17 years representing the average of the remaining patent lives of the underlying technologies at the time the payment was received in fiscal 1999. We recorded this payment as deferred revenue. We recorded revenue related to this upfront payment of \$588, \$245, \$588 and \$588 for the year ended December 31, 2006, five month period ended December 31, 2005 and the years ended July 31, 2005 and 2004, respectively. Additionally, we recognized a milestone payment of \$4,000 during the year ended July 31, 2004.

Our net share of total expense related to the collaboration was \$13,816, \$17,805, \$36,358 and \$15,902, for the year ended December 31, 2006, five month period ended December 31, 2005 and the years ended July 31, 2005 and 2004 respectively. The majority of costs incurred under the collaboration were paid by P&G, which in turn obtained reimbursement from us based on the cost sharing arrangement noted above. For the costs we incurred under the collaboration, we received reimbursements from P&G in the amounts of \$24, \$269, \$1,470 and \$1,551 for the year ended December 31, 2006, five month period ended December 31, 2005 and the years ended July 31, 2005 and 2004, respectively.

During 2006, we completed a final Phase III trial of pexelizumab. After reviewing results from that trial, we along with P&G, have determined not to pursue further development of pexelizumab.

Under the terms of our MOU we may be obligated to reimburse P&G for 50% of cancellation costs under P&G's third-party pexelizumab manufacturing contract. Our portion of those cancellation costs amounts to approximately \$2,000.

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)****License and Research and Development Agreements**

We have entered into a number of license and research and development agreements since our inception. These agreements have been made with various research institutions, universities, contractors, collaborators, and government agencies in order to advance and obtain technologies and necessary services management believes important to our overall business strategy.

License agreements generally provide for an initial fee followed by annual minimum royalty payments. Additionally, certain agreements call for future payments upon the attainment of agreed upon milestones, such as, but not limited to, Investigational New Drug, or IND, application or approval of Biologics License Application. These agreements require minimum royalty payments based upon sales developed from the applicable technologies, if any.

Research and development agreements generally provide for us to fund future research projects. Based upon these agreements, we may obtain exclusive and non-exclusive rights and options to the applicable technologies developed as a result of the applicable research.

Clinical and manufacturing development agreements generally provide for us to fund manufacturing development and on-going clinical trials. Clinical trial and development agreements include contract services and outside contractor services including contracted clinical site services related to patient enrolment for our clinical trials. Manufacturing development agreements include clinical manufacturing and manufacturing development and scale-up. We have executed a large-scale product supply agreement with Lonza Biologics PLC for the long-term commercial manufacture of Soliris .

In order to maintain our rights under these agreements, we may be required to provide a minimum level of funding or support. We may elect to terminate these arrangements. Accordingly, we recognize the expense and related obligation related to these arrangements over the period of performance.

The minimum fixed payments (assuming non-termination of the above agreements) as of December 31, 2006, for each of the next five years are as follows:

<b>Years Ending December 31,</b>	<b>License Agreements</b>	<b>Research and Development Agreements</b>	<b>Clinical and Manufacturing Development Agreements</b>
2007	\$ 1,186	\$ 100	\$ 27,805
2008	632		27,300
2009	422		
2010	382		
2011	380		

Should we achieve certain milestones related to product development and product license applications and approvals, additional payments would be required. In addition to the payments above, as of December 31, 2006,



**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)**

these agreements contain milestone payment provisions aggregating approximately \$8,200. The agreements also require us to fund certain future costs associated with the filing of patent applications.

**3. Marketable Securities**

The following table summarizes our marketable securities:

	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
<b>December 31, 2006</b>				
Federal agency obligations	\$ 19,907	\$ 2	\$ (30)	\$ 19,879
Corporate bonds	13,117	4	(17)	13,104
Certificates of deposit	11,820		(5)	11,815
Commercial paper	4,932		(2)	4,930
<b>Total</b>	<b>\$ 49,776</b>	<b>\$ 6</b>	<b>\$ (54)</b>	<b>\$ 49,728</b>
<b>December 31, 2005</b>				
Federal agency obligations	\$ 122,652	\$ 5	\$ (199)	\$ 122,458
Corporate bonds	37,809	4	(84)	37,729
Certificates of deposit	8,669		(29)	8,640
<b>Total</b>	<b>\$ 169,130</b>	<b>\$ 9</b>	<b>\$ (312)</b>	<b>\$ 168,827</b>
<b>July 31, 2005</b>				
Federal agency obligations	\$ 81,171	\$	\$ (336)	\$ 80,835
Corporate bonds	47,506	3	(198)	47,311
Certificates of deposit	10,806		(21)	10,785
Commercial paper	9,533		(11)	9,522
<b>Total</b>	<b>\$ 149,016</b>	<b>\$ 3</b>	<b>\$ (566)</b>	<b>\$ 148,453</b>

Unrealized losses of \$2, \$4 and \$3 related to holdings of cash equivalents are included in Accumulated Other Comprehensive Income for the year ended December 31, 2006, five month period ended December 31, 2005 and year ended July 31, 2005, respectively.

Realized gains of approximately \$101 were recorded during the year ended July 31, 2005. No realized gains were recorded for the year ended December 31, 2006, five month period ended December 31, 2005 and the year ended July 31, 2004. No realized losses were recorded for the year ended December 31, 2006, five month period ended December 31, 2005 and the years ended July 31, 2005 and 2004, respectively. We utilize the specific identification method in computing realized gains and losses. At December 31, 2006, our marketable securities had a

## Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

maximum maturity of approximately 2 years with an average of approximately 1.5 months. The weighted average interest rate associated with marketable debt securities was 5.3 percent, 4.4 percent, 3.7 percent and 1.9 percent at December 31, 2006 and 2005 and July 31, 2005 and 2004, respectively.

F-18

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)**

The following table summarizes the investment maturities at December 31, 2006:

	Amortized Cost	Fair Value
Less than one year	\$ 37,325	\$ 37,279
Matures in one to five years	12,451	12,449
	\$ 49,776	\$ 49,728

We periodically review for impairment those investment securities that have unrealized losses for more than twelve months to determine if such unrealized losses are other than temporary. Gross unrealized losses from all individual investment securities aggregated to \$54, \$312, \$566 and \$411 at December 31, 2006 and 2005 and July 31, 2005 and 2004, respectively. We intend to hold these related investment securities to maturity and have the ability to do so. As a result, we consider these unrealized losses to be temporary and have not recorded a loss in our consolidated statements of operations.

The following tables shows the gross unrealized losses and fair value of our investments with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position at:

**December 31, 2006**

Description of Securities	Less than 12 Months		12 Months or More		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Federal agency obligations	\$ 8,194	\$ (10)	\$ 8,143	\$ (20)	\$ 16,337	\$ (30)
Corporate bonds	7,006	(6)	2,012	(11)	9,018	(17)
Certificates of deposit	9,779	(5)			9,779	(5)
Commercial paper	4,931	(2)			4,931	(2)
	\$ 29,910	\$ (23)	\$ 10,155	\$ (31)	\$ 40,065	\$ (54)

**December 31, 2005**

Description of Securities	Less than 12 Months		12 Months or More		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses



Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

Federal agency obligations	\$ 77,493	\$ (165)	\$ 24,200	\$ (34)	\$ 101,693	\$ (199)
Corporate bonds	11,332	(63)	12,395	(21)	23,727	(84)
Certificates of deposit	8,640	(29)			8,640	(29)
	\$ 97,465	\$ (257)	\$ 36,595	\$ (55)	\$ 134,060	\$ (312)

F-19

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)****July 31, 2005**

Description of Securities	Less than 12 Months		12 Months or More		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Federal agency obligations	\$ 57,406	\$ (257)	\$ 23,178	\$ (79)	\$ 80,584	\$ (336)
Corporate bonds	20,803	(143)	13,544	(55)	34,347	(198)
Certificates of deposit	10,785	(21)			10,785	(21)
Commercial paper	9,521	(11)			9,521	(11)
	\$ 98,515	\$ (432)	\$ 36,722	\$ (134)	\$ 135,237	\$ (566)

For the investments in all categories shown in the above table, the unrealized losses were caused primarily by interest rate increases.

**4. Other Assets**

Prepaid expenses and other current assets consist of the following:

	December 31, 2006	December 31, 2005	July 31, 2005
Prepaid expenses	\$ 2,331	\$ 2,918	\$ 4,303
State tax receivable	1,448	1,766	1,316
Reimbursable contract costs	194	411	139
Milestone receivable			
	\$ 3,973	\$ 5,095	\$ 5,758

Other non-current assets consist of the following:

	December 31, 2006	December 31, 2005	July 31, 2005
Deferred financing costs, net	\$ 3,445	\$ 4,123	\$ 4,404
Deposits and other assets	632	452	456

\$ 4,078	\$ 4,575	\$ 4,860
----------	----------	----------

F-20

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)****5. Property, Plant and Equipment**

A summary of property, plant and equipment is as follows:

Asset	Estimated Useful Lives (years)	December 31, 2006	December 31, 2005	July 31, 2005
Land		\$ 692	\$	\$
Buildings and improvements	5 15	10,163	9,798	9,721
Laboratory equipment	5 7	10,735	10,442	10,454
Furniture and office equipment	3 5	4,453	3,702	3,638
Construction-in-progress		28,827	356	112
		54,870	24,298	23,925
Less: Accumulated depreciation and amortization		(15,735)	(13,667)	(12,379)
		\$ 39,135	\$ 10,631	\$ 11,546

Leasehold improvements are amortized over the term of the lease or the estimated useful life of the asset, whichever is shorter. Depreciation and amortization of fixed assets was approximately \$3,028, \$1,359, \$2,996 and \$2,865 for the year ended December 31, 2006, five month period ended December 31, 2005 and for the years ended July 31, 2005 and 2004, respectively.

In July 2006, we began construction of our manufacturing facility in Smithfield, Rhode Island. We expect the facility to be substantially complete in 2007. During 2006, we capitalized to construction in progress approximately \$28,814 related to the purchase and construction of our Smithfield manufacturing facility. Included in construction in progress in 2006, we capitalized approximately \$928 of interest costs related to the development of our Smithfield manufacturing facility. There was no capitalized interest prior to 2006. See Note 7 for a description of the terms of the related mortgage payable.

During the year ended July 31, 2005, we utilized the services of third party appraisers to perform an inventory of all fixed assets. Performance of the inventory found that assets with a cost of approximately \$4,600 and accumulated depreciation of approximately \$4,500 included in our accounting records at the time were no longer in service and held by us. Consequently, we recorded a loss on disposal of assets of approximately \$100 for the year ended July 31, 2005.

During the year ended July 31, 2003, we concluded that further investment in the UniGraft program did not meet sufficient criteria for continued development. The termination of the UniGraft program resulted in an impairment to Columbus Farming Corporation s, or CFC, UniGraft manufacturing assets, causing a write down of approximately \$760 of those assets for year ended July 31, 2004.

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)**

In February 1999, CFC purchased substantially all of the assets of the UniGraft xenotransplantation program, including principally, land, buildings and laboratory equipment, from its then partner in the program, U.S. Surgical Corporation, now a division of Tyco International, Ltd., or Tyco. The purchase was financed through the issuance by CFC of a \$3,900 note payable to Tyco. Upon CFC's failure to make its quarterly interest payment due Tyco in August 2003, CFC defaulted on the note.

In the quarter ended October 31, 2003, in conjunction with the event of default, we notified Tyco that the UniGraft xenotransplantation program and CFC activities had been terminated. In the quarter ended October 31, 2004 an offer of \$450 from a third-party was accepted by Tyco for CFC's assets. Tyco retained the proceeds from the sale of CFC's assets and extinguished the note and unpaid interest. We transferred the assets to Tyco as of October 31, 2004. Since CFC's assets, consisting of property, plant and equipment, were insufficient to satisfy the \$3,900 note, unpaid interest of \$300, and other obligations of CFC, Tyco formally discharged CFC of any further obligations. As a result, we extinguished the \$3,900 note and unpaid interest of \$300 offset by the transfer of CFC's assets of \$450 to Tyco. Consequently, we recorded the resulting gain of \$3,804 as gain from extinguishment of note payable in August 2004.

**6. Accrued Expenses**

Accrued expenses consist of the following:

	<b>December 31, 2006</b>	<b>December 31, 2005</b>	<b>July 31, 2005</b>
Clinical expense	\$ 4,379	\$ 10,412	\$ 9,459
Pre-commercial expenses	1,136	4,538	585
Deferred rent and other	4,457	2,203	2,079
Payroll and employee benefits	4,465	2,062	3,652
Interest expense	865	865	5
Research and development expenses	926	549	584
	<b>\$ 16,228</b>	<b>\$ 20,629</b>	<b>\$ 16,364</b>

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)****Exit Activities**

In December 2006, we initiated an integration plan with our subsidiary, Alexion Antibody Technologies, Inc., to consolidate certain functions and operations, including the termination of all Alexion Antibody personnel, closure of Alexion Antibody facilities, and impairment of equipment in that facility. These costs have been recognized as liabilities and are included in general and administrative expenses for the year ended December 31, 2006. The following table summarizes the liabilities established for exit activities:

	<b>Employee Related Benefits</b>	<b>Facility Lease Costs</b>	<b>Other Exit Activities</b>	<b>Total Exit Activities</b>
Recorded on exit date	\$ 5,401	\$ 1,147	\$ 539	\$ 7,087
Revision of estimate				
Payments in 2006	(43)			(43)
Balance at December 31, 2006	\$ 5,358	\$ 1,147	\$ 539	\$ 7,044

Employee benefits consist of expenses for severance compensation as well as accelerated vesting of share-based grants. Facility lease costs are associated with the lease on our San Diego, California facility as described in Note 8 and other exit activities consist of impairment charges on equipment. We expect to pay employee related benefits to former employees through the first half of 2007. We are currently exploring options for our facility lease, but as of the year ended December 31, 2006, we are obligated to fulfill the terms of the operating lease agreement which expires in 2012.

**7. Debt**  
**Convertible Notes**

In January 2005 we sold \$150,000 principal amount of 1.375% Convertible Senior Notes due February 1, 2012 (the 1.375% Notes) in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 1.375% per annum on the principal amount from January 25, 2005, payable semi-annually in arrears in cash on February 1 and August 1 of each year, beginning August 1, 2005. The 1.375% Notes is convertible into our common stock at an initial conversion rate of 31.7914 shares of common stock (equivalent to a conversion price of approximately \$31.46 per share) per \$1 principal amount of the 1.375% Notes, subject to adjustment, at any time prior to the close of business on the final maturity date of the notes. We do not have the right to redeem any of the 1.375% Notes prior to maturity.

We incurred deferred financing costs related to this offering of approximately \$4,800 which are recorded in the consolidated balance sheet and are being amortized as a component of interest expense over the seven-year term of the notes.

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,**

**and Years Ended July 31, 2005 and 2004**

**(amounts in thousands, except share and per share amounts)**

A shelf registration statement covering the resale of the notes and the common stock issuable upon conversion of these notes was declared effective by the SEC on May 25, 2005.

The net proceeds of approximately \$145,200 from this offering were used to redeem our entire outstanding \$120,000 principal amount of 5.75% Convertible Subordinated Notes due March 2007 ( 5.75% Notes ) and for general corporate purposes. On March 15, 2005, we redeemed all of the 5.75% Notes outstanding at the redemption price of 101.643% for each \$1 principal amount of 5.75% Notes. We paid a redemption premium related to these notes of approximately \$2,000 during the year ended July 31, 2005. We incurred deferred financing costs related to this offering of approximately \$4,000, which was amortized as a component of interest expense over the term of these notes. The remaining balance of deferred financing costs was approximately \$1,200 at the redemption date. The difference between the amount paid, including the redemption premium, and the carrying value of the notes, including the remaining deferred financing costs, was recognized as a \$3,185 loss from early extinguishment of convertible notes.

Amortization expense associated with deferred financing costs for the year ended December 31, 2006, five month period ended December 31, 2005 and the years ended July 31, 2005 and 2004 was approximately \$0, \$282, \$686 and \$573, respectively.

**Mortgage Loan**

In July 2006, our wholly owned affiliate Alexion Manufacturing, LLC, entered into a mortgage loan agreement to borrow \$26,000 to finance the purchase and construction of our Smithfield, Rhode Island manufacturing facility. The mortgage loan bears interest at a fixed annual rate of 9.17% and all obligations under the loan agreement are guaranteed by Alexion Pharmaceuticals, Inc. The loan principal is required to be repaid in equal monthly instalments of approximately \$289, starting March 2009 and until August 2016, at which time all outstanding balances are due. The loan may not be prepaid in whole or in part prior to July 2009. After that date the loan can be prepaid in whole, but not in part, and must include a prepayment premium as described in the loan agreement. Under the terms of the agreement, among other things, Alexion Manufacturing, LLC is restricted with respect to additional borrowings, leasing arrangements and mergers. In the event that approval to market Soliris (eculizumab) has not been obtained before December 31, 2007, Alexion Manufacturing LLC must deliver an acceptable letter of credit to the lender for the amount of \$13,000. Also, included in the loan agreement are certain provisions which, if satisfied, would allow for additional borrowings of up to \$9,000.

Under the terms of the agreement, among other things, Alexion Manufacturing is restricted with respect to additional borrowings, leasing arrangements and mergers. Alexion Manufacturing also may not modify, amend, or waive material obligations with respect to, or terminate, material agreements or proprietary rights, or engage in any business other than ownership and operation of facility. Alexion Pharmaceuticals, Inc. may not, among other things, liquidate wind-up or dissolve as long as the guarantee remains in effect.

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,**

**and Years Ended July 31, 2005 and 2004**

**(amounts in thousands, except share and per share amounts)**

As a condition of the loan, Alexion Manufacturing, LLC is required to maintain restricted cash accounts. These accounts must be used specifically for the purchase and construction of the manufacturing facility. The lender has a first priority security interest and the right to approve all disbursements from the accounts holding restricted cash. Under the agreement, we are required to maintain a balance in the restricted cash accounts sufficient to complete the project.

**Covenants**

We do not have financial covenants related to debt. However, under the Convertible Senior Notes, there are certain designated events which could occur such as a liquidation, tender offer, consolidation, merger, recapitalization, or otherwise, in connection with which 50% or more of our common stock is exchanged for, converted into, acquired for or constitutes solely the right to receive, consideration which is not at least 90% common stock that is listed on a U.S. national exchange or market. If the holder elects to convert its 1.375% Notes upon the occurrence of a designated event, the holder will be entitled to receive an additional number of shares of common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option, are set according to a table within the offering document, and are capped (in no event will the shares issuable upon conversion of a note exceed 42.9100 per \$1 principal amount).

**Interest Expense**

Cash paid for interest expense for all loan obligations was approximately \$2,081, \$0, \$7,966 and \$6,901, for the year ended December 31, 2006, five month period ended December 31, 2005, and years ended July 31, 2005 and 2004, respectively.

**8. Leases**

**Capital Leases**

We lease office equipment under capital lease agreements expiring in 2010. The assets and liabilities under capital lease are recorded at the lower of the present value of the minimum lease payments or the fair value of the asset. The assets are amortized over the lower of their related lease terms or their estimated useful lives. Amortization of assets under capital lease is included in depreciation expense. As of December 31, 2006, the cost of equipment under capital lease is \$357 and the net book value is \$342.



**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)**

Minimum future lease payments under capital lease as of December 31, 2006 are:

<b>Year</b>	
2007	\$ 155
2008	155
2009	155
2010	130
	595
Less: Amount representing interest	(245)
<b>Present value of minimum lease payments</b>	<b>\$ 350</b>

The interest rate on the above capital leases is approximately 22.1% and is imputed based on our incremental borrowing rate at the inception of each lease.

**Operating Leases**

As of December 31, 2006, we lease our headquarters and primary research and development facilities in Cheshire, Connecticut. The lease commenced in August 2000, it was extended in August 2006 and has a term of seventeen years. We are required to pay a pro rata percentage of real estate taxes and operating expenses. Monthly fixed rent started at approximately \$80, increasing to approximately \$167 over the term of this lease. We have issued a \$200 open letter of credit to secure the lease.

In January 2003, we entered into a lease agreement for our pilot manufacturing plant and associated labs and offices in New Haven, Connecticut. The pilot plant is used for producing compounds for clinical trials. Monthly fixed rent started at approximately \$36, increasing to approximately \$50 over the term of the lease, which expires in 2007. We have the option to extend the lease for an additional three years.

Also, we lease additional research space in San Diego, California, starting at a monthly fixed rent of approximately \$35 increasing to approximately \$55. In connection with the closure of Alexion Antibody Technologies, we accrued the fair value of future payments under the lease. We are currently exploring options for our facility lease, but as of the year ended December 31, 2006, we are obligated to fulfill the terms of the operating lease agreement, which expires in 2012.

Furthermore, we rent office space in Paris, France, at a monthly fixed rent of approximately \$28. The rental agreement expires in December 2008.

Aggregate lease expense for our facilities was \$2,592, \$1,094, \$2,296 and \$2,176 for the year ended December 31, 2006, five month period ended December 31, 2005 and the years ended July 31, 2005 and 2004, respectively. Lease expense is being recorded on a straight-line basis over the applicable lease terms.



**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)**

Aggregate future minimum annual rental payments for the next five years and thereafter under non-cancellable operating leases (including facilities and equipment) as of December 31, 2006 are:

2007	\$ 3,670
2008	3,640
2009	2,380
2010	2,440
2011	2,510
Thereafter	11,140

**9. Commitments and Contingencies****Indemnifications**

We enter into indemnification provisions under our agreements with other companies in our ordinary course of business, typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, we generally indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to our products, or use or testing of our product candidates. The term of these indemnification agreements is generally perpetual. The potential amount of future payments we could be required to make under these indemnification agreements is unlimited. We have not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, we have no liabilities recorded for these agreements as of December 31, 2006.

**10. Income Taxes**

At December 31, 2006, we have available for federal tax reporting purposes, net operating loss carry forwards of approximately \$618,061 which expire from 2007 through 2026. We also have federal and state research and development credit carry forwards of approximately \$21,891 which expire from 2008 through 2026. The exercise of non-qualified stock options gives rise to compensation that is included in the taxable income of the applicable employees and deducted by us for federal and state income tax purposes. As a result of the exercise of non-qualified stock options, we have net operating loss carry forwards of approximately \$46,880 attributable to excess tax benefits from stock compensation deductions which can be used to offset future taxable income, if any. If and when realized, the related tax benefits of these net operating losses carry forwards will be credited directly to paid-in capital.

The Tax Reform Act of 1986 contains certain provisions that can limit a taxpayer's ability to utilize net operating loss and tax credit carry forwards in any given year resulting from cumulative changes in ownership

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)**

interests in excess of 50 percent over a three-year period. We have determined that these limiting provisions were triggered. However, such limitation is not expected to result in the loss of the federal net operating loss and research and development credit.

The State of Connecticut provides companies with the opportunity to exchange certain research and development tax credit carry forwards for cash in exchange for foregoing the carry forward of the research and development credits. The program provides for such exchange of the research and development credits at a rate of 65 percent of the annual incremental and non-incremental research and development credits, as defined. For the year ended December 31, 2006, we plan to file claims to exchange research and tax development credits and, therefore, recognized a state tax benefit of \$372. The state tax benefit excludes our estimated capital-based state taxes of \$139 which was recorded as an operating expense.

The components of deferred income tax assets are as follows:

	<b>Year Ended December 31,</b>	<b>Five Month Period Ended December 31,</b>	<b>Year Ended July 31,</b>
	<b>2006</b>	<b>2005</b>	<b>2005</b>
Deferred income tax assets:			
Operating loss carryforwards, federal & states	\$ 218,169	\$ 176,669	\$ 156,500
Foreign operating loss carryforwards	2,580	178	
Tax credit carryforwards	21,891	17,850	16,127
Deferred revenues	2,096	2,396	2,496
Stock Compensation	4,974	822	
Other	1,743	1,889	781
Total deferred tax assets	251,453	199,804	175,904
Less: valuation allowance	(251,453)	(199,804)	(175,904)
	\$	\$	\$

We have not yet achieved profitable operations. Accordingly, management believes the tax benefits as of December 31, 2006 do not satisfy the realization criteria and have recorded a valuation allowance for the total deferred tax asset.

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)**

The reconciliation of the statutory federal income tax rate to our effective income tax rate is as follows:

	Year Ended December 31,	Five Month Period Ended December 31,	Year Ended July 31,	
	2006	2005	2005	2004
Federal statutory rate	-34%	-34%	-34%	-34%
State tax benefit, net of federal tax effect	-5%	-5%	-5%	-5%
Research & development credits	-5%	-4%	-5%	-3%
Increase in deferred tax valuation allowance	43%	42%	43%	41%
Effective rate	-1%	-1%	-1%	-1%

**11. Stock Options and Restricted Stock  
Stock Options**

At December 31, 2006, we have one stock option plan, the 2004 Incentive Plan ( 2004 Plan ). Both the 2000 Stock Option Plan ( 2000 Plan ) and the 1992 Stock Option Plan for Outside Directors ( 1992 Outside Directors Plan ) was terminated in December 2004 with the adoption of the 2004 Plan. In June 2006, shareholders approved amendments to the 2004 plan, increasing by 775,000 shares the shares available for equity awards. Under the 2004 Plan, Common Stock as well as incentive and non-qualified stock options may be granted for up to a maximum of 3,868,519 shares of Common Stock to our directors, officers, key employees and consultants. The amount of shares authorized for granting includes 2,500,000 initially authorized under then plan, 593,519 shares transferred from the 2000 Plan and an additional 775,000 shares authorized in 2006. Stock options granted under all Plans have a maximum term of ten years from the date of grant, have an exercise price not less than the fair value of the stock on the grant date and generally vest over four years.

The purpose of the 2004 Plan is to aid us in attracting, retaining, motivating and rewarding employees, non-employee directors and consultants of us or our subsidiaries or affiliates, to provide for equitable and competitive compensation opportunities, to recognize individual contributions and reward achievement of our goals, and promote the creation of long-term value for stockholders by closely aligning the interests of Participants with those of stockholders. The Plan authorizes stock-based and cash-based incentives for Participants.

During the year ended July 31, 2001, options to purchase 10,000 shares of common stock were granted to an employee at exercise prices which were less than fair value at the date of the grant. Accordingly, we recorded compensation expense based upon the difference between exercise price and fair value over the vesting period associated with these options. Compensation expense associated with these options is \$5 and \$67 for the years ended July 31, 2005 and 2004, respectively. No compensation expense was recorded for the year ended



**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,**

**and Years Ended July 31, 2005 and 2004**

**(amounts in thousands, except share and per share amounts)**

December 31, 2006 or the five month period ended December 31, 2005 because the options were fully vested. The weighted average exercise price of these options was \$75.51 per share. The weighted average fair value of these options at the date of grant was \$92.27 per option.

We also record compensation expense on certain options to purchase common stock granted prior to July 31, 2001 to employees and consultants. Compensation expense associated with these options was \$17 for the year ended July 31, 2004.

Compensation expense related to options issued to consultants was \$8, \$3, \$132 and \$22 for the years ended December 31, 2006, five month period ended December 31, 2005 and the years ended July 31, 2005 and 2004, respectively.

The weighted average fair value at the date of grant for options granted during the year ended December 31, 2006, five month period ended December 31, 2005 and the years ended July 31, 2005 and 2004 is \$19.87, \$17.21, \$14.27 and 13.25 per option, respectively.

Options exercisable at December 31, 2006 had an aggregate intrinsic value of \$47,130 and a weighted average remaining contractual life of 6.2 years. The intrinsic value of options exercised during the year ended December 31, 2006 was \$20,375. The fair market value of options vested during the year ended December 31, 2006 was \$14,065.

As of December 31, 2006, there was \$30,713 of total unrecognized compensation expense related to non-vested share-based compensation arrangements granted under the Plan. The expense is expected to be recognized over a weighted-average period of 2 years.

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)**

A summary of the status of our stock option plans at December 31, 2006 and 2005, July 31, 2005, 2004 and 2003 and changes during the periods then ended is presented in the table and narrative below:

	Year Ended December 31,	Five Month Period Ended December 31,	Year Ended July 31,	
	2006	2005	2005	2004
Options outstanding, beginning of the period	5,092,085	4,729,793	4,542,210	4,020,810
Options granted	1,462,450	649,300	996,600	972,000
Options cancelled	(256,700)	(61,880)	(245,417)	(251,043)
Options exercised	(925,372)	(225,128)	(563,600)	(199,557)
Options outstanding, end of the period	5,372,463	5,092,085	4,729,793	4,542,210
Options exercisable, end of period	3,371,998	3,293,837	3,196,601	3,100,091
Common stock available for future issuances, end of the period	1,054,177	1,798,967	2,441,828	1,259,129

Weighted average exercise price of options:

granted	\$ 29.72	\$ 26.28	\$ 18.78	\$ 19.88
cancelled	23.37	20.40	24.30	27.94
exercised	14.69	15.44	6.64	12.52
outstanding	26.69	24.16	23.40	22.38
exercisable	26.41	25.81	25.82	23.98

The following table presents weighted average price and life information about significant option groups outstanding at December 31, 2006:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted-Average Remaining Contractual Life (Yrs)	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
\$00.0000 to 10.7875	659,730	3.2	\$ 9.88	644,128	\$ 9.86
\$10.7876 to 21.5750	2,200,171	6.3	19.12	1,466,227	18.96
\$21.5751 to 32.3625	938,905	7.2	25.30	500,833	24.53
\$32.3626 to 43.1500	933,401	8.1	33.46	243,054	34.31
\$43.1501 to 53.9375	145,589	8.6	44.75	23,089	48.20
\$53.9376 to 75.5125	414,167	3.5	64.26	414,167	64.26
\$75.5126 to 107.8750	80,500	2.9	81.47	80,500	81.47



5,372,463	6.2	\$	26.67	3,371,998	\$	26.41
-----------	-----	----	-------	-----------	----	-------

F-31

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)**

The fair value of options at the date of grant was estimated using the Black-Scholes model with the following weighted average assumptions:

	<b>Year Ended December 31,</b>	<b>Five Month Period Ended December 31,</b>	<b>Year Ended July 31,</b>	
	<b>2006</b>	<b>2005</b>	<b>2005</b>	<b>2004</b>
Expected Life in Years	6.25	6.25	7.5	5
Interest Rate	4.70%	4.30%	4.10%	4.30%
Volatility	68%	68%	78%	82%
Dividend Yield				

The expected stock price volatility rates are based on historical volatilities of our common stock. The risk free interest rates are based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. The average expected life represents the weighted average period of time that options granted are expected to be outstanding giving consideration to vesting schedules and our historical exercise patterns. For the year ended December 31, 2006, the average expected life was determined using the simplified approach as permitted by Staff Accounting Bulletin No. 107, or SAB 107. As previously noted, we adopted SFAS 123R on August 1, 2005 and estimated the expected term and the related period over which expected volatility is calculated, in accordance with SAB 107.

**Restricted Stock**

A summary of the status of our non-vested restricted stock and changes during the periods then ended are:

	<b>Year Ended December 31,</b>	<b>Five Month Period Ended December 31,</b>	<b>Year Ended July 31,</b>
	<b>2006</b>	<b>2005</b>	<b>2005</b>
Nonvested restricted stock, beginning of the period	133,500	105,500	
Shares issued	227,559	30,000	109,800
Shares cancelled	(14,770)	(2,000)	(3,000)
Shares exercised	(22,000)		(1,300)
Nonvested restricted stock, end of the period	324,289	133,500	105,500

Weighted average grant date fair value	\$ 32.95	\$ 27.58	\$ 20.38
--	----------	----------	----------

Restricted stock that generally vests over four years from grant date has been issued to certain key employees and consultants. Compensation expense related to restricted stock for the year ended December 31, 2006, five month period ended December 31, 2005 and the year ended July 31, 2005 was approximately \$3,014, \$260 and \$238, respectively. Prior to the year ended July 31, 2005, restricted stock was not issued. Upon the



---

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,**

**and Years Ended July 31, 2005 and 2004**

**(amounts in thousands, except share and per share amounts)**

adoption of SFAS 123R, we had an immaterial cumulative effect on compensation expense for restricted stock grants.

**12. Common and Preferred Stock**  
**Common Stock**

In November 2006, we sold 3,450,000 shares of common stock in a public offering at \$43.00 per share, resulting in gross proceeds from the sale of \$148,350. We incurred underwriting discounts and commissions of \$8,121, or \$2.34 per share as well as other expenses, resulting in net proceeds of \$140,229.

During the year ended December 31, 2006, we increased our holdings of common stock in treasury by 6,919 shares in lieu of withholding taxes on the exercise of restricted stock. The shares were exchanged at fair market value for \$279 in total. During the five month period ended December 31, 2005, we increased our holdings of common stock in treasury by 13,713 through stock-based exercise of employee options. The shares were exchanged at fair market value for \$381 in total.

In August 2005, we sold 2,500,000 shares of common stock in a public offering at \$26.75 per share, resulting in gross proceeds from the sale of \$66,875. We incurred underwriting discounts and commissions of \$2,145, or \$0.86 per share as well as other expenses, resulting in net proceeds of \$64,530.

**Preferred Stock**

In February 1997, our Board of Directors declared a dividend of one preferred stock purchase right for each outstanding share of Common Stock (including all future issuances of Common Stock). Under certain conditions, each right may be exercised to purchase one one-hundredth of a share of a new series of preferred stock at an exercise price of \$75.00 (see below), subject to adjustment. The rights may be exercised only after a public announcement that a party acquired 20 percent or more of our Common Stock or after commencement or public announcement to make a tender offer for 20 percent or more of our Common Stock. The rights, which do not have voting rights, expire on March 6, 2007, and may be redeemed by us at a price of \$0.01 per right at any time prior to their expiration or the acquisition of 20 percent or more of our stock. The preferred stock purchasable upon exercise of the rights will have a minimum preferential dividend of \$10.00 per year, but will be entitled to receive, in the aggregate, a dividend of 100 times the dividend declared on a share of Common Stock. In the event of liquidation, the holders of the shares of preferred stock will be entitled to receive a minimum liquidation payment of \$100 per share, but will be entitled to receive an aggregate liquidation payment equal to 100 times the payment to be made per share of Common Stock.

On September 18, 2000, our Board of Directors amended the purchase price under the preferred stock purchase rights. Such purchase price, for each one one-hundredth of a share of preferred stock to be issued upon

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)**

the exercise of each preferred stock purchase right was increased from \$75.00 to \$725.00. Except for the increase in the purchase price, the terms and conditions of the rights remain unchanged.

In the event that we are acquired in a merger, other business combination transaction, or 50 percent or more of our assets, cash flow, or earning power are sold, proper provision shall be made so that each holder of a right shall have the right to receive, upon exercise thereof at the then current exercise price, that number of shares of Common Stock of the surviving company which at the time of such transaction would have a market value of two times the exercise price of the right.

**13. Accumulated Other Comprehensive Loss**

The components of accumulated other comprehensive losses are:

	<b>Cumulative Translation Adjustment</b>	<b>Unrealized Gains (Losses) on Marketable Securities</b>	<b>Total</b>
Balances, July 31, 2003	\$	\$ 652	\$ 652
Change in Unrealized gains (losses) on marketable securities		(999)	(999)
Translation Adjustment			
Balance at July 31, 2004	\$	\$ (347)	\$ (347)
Change in unrealized gains (losses) on marketable securities		(320)	(320)
Reclassification of realized gains included in net loss		101	101
Translation adjustment			
Balances, July 31, 2005		(566)	(566)
Change in unrealized gains (losses) on marketable securities		259	259
Translation adjustment	(8)		(8)
Balances, December 31, 2005	\$ (8)	\$ (307)	\$ (315)
Change in unrealized gains (losses) on marketable securities		258	258
Translation adjustment	(120)		(120)
Balances, December 31, 2006	\$ (128)	\$ (49)	\$ (177)

**14. 401(k) Plan**

## Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

We have a qualified 401(k) plan covering all eligible employees. Under the plan, employees may contribute up to the statutory allowable amount for any calendar year. We make matching contributions at a rate of \$0.50 for each dollar deferred up to the first 6 percent of compensation. We made matching contributions of approximately \$406, \$202, \$390 and \$330 for the year ended December 31, 2006, five month period ended December 31, 2005 and the years ended July 31, 2005 and 2004, respectively.

F-34

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)****15. Revenues**

We have been awarded various grants by agencies of the U.S. government to fund specific research projects. In July 2004, we received approval for a grant amounting to approximately \$700 from the National Institutes of Health to fund a specific research project. In November 2004, the Department of Defense awarded us a grant for approximately \$700 to fund additional specific research. In August 2005, the Department of Health and Human Services awarded us a grant for approximately \$297 to fund additional specific research. Grant research revenues for the year ended December 31, 2006, five month period ended December 31, 2005 and the years ended July 31, 2005 and 2004, was approximately \$870, \$419, \$476 and \$21, respectively.

**16. Financial Instruments**

The following methods and assumptions were used by us in estimating the fair value disclosures for financial instruments:

Cash, cash equivalents, and marketable securities are carried at approximate fair value.

Reimbursable contract costs, accounts payable, and notes payable are carried at cost which we believe approximate their fair value because of their short term maturity period.

The fair market value of convertible notes is determined based upon trading values reported at December 31, 2006.

	December 31, 2006		December 31, 2005		July 31, 2005	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value	Carrying Amount	Fair Value
Cash and cash equivalents	\$ 200,420	\$ 200,420	\$ 43,629	\$ 43,629	\$ 46,951	\$ 46,951
Marketable securities	49,728	49,728	168,827	168,827	148,453	148,453
Reimbursable contract costs					139	139
Accounts payable	10,939	10,939	3,865	3,865	7,455	7,455
Mortgage loan	26,000	26,000				
Convertible debt	150,000	217,125	150,000	129,750	150,000	153,000

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Year Ended December 31, 2006, Five Month Period Ended December 31, 2005,****and Years Ended July 31, 2005 and 2004****(amounts in thousands, except share and per share amounts)****17. Quarterly Financial Information (unaudited)**

The following is condensed quarterly financial information for the years ended December 31, 2006 and July 31, 2005:

	<b>Mar 31, 2006</b>	<b>Jun 30, 2006</b>	<b>Sep 30, 2006</b>	<b>Dec 31, 2006</b>
Revenue	\$ 768	\$ 340	\$ 262	\$ 188
Operating expenses	29,359	34,884	33,325	41,075
Operating loss	(28,591)	(34,544)	(33,063)	(40,887)
Net loss applicable to common shareholders	(27,226)	(33,166)	(31,872)	(39,250)
Net loss per common share, basic and diluted	(0.88)	(1.06)	(1.02)	(1.19)

	<b>Oct 31, 2004</b>	<b>Jan 31, 2005</b>	<b>Apr 30, 2005</b>	<b>Jul 31, 2005</b>
Revenue	\$ 147	\$ 563	\$ 151	\$ 203
Operating expenses	22,342	24,368	29,798	33,831
Operating loss	(22,195)	(23,805)	(29,647)	(33,628)
Net loss applicable to common shareholders	(19,188)	(24,470)	(32,450)	(32,642)
Net loss per common share, basic and diluted	(0.70)	(0.88)	(1.16)	(1.16)

The following is condensed quarterly financial information for the three month period ended October 31, 2005:

Revenue	\$ 460
Operating expenses	36,758
Operating loss	(36,298)
Net loss applicable to common shareholders	(35,074)
Net loss per common share, basic and diluted	(1.16)

The following table outlines the condensed financial information for the two month period ended December 31, 2005 and 2004:

Revenue	\$ 204	\$ 98
Operating expenses	24,243	15,733
Operating loss	(24,039)	(15,635)
Net loss applicable to common shareholders	(22,882)	(16,173)
Net loss per common share, basic and diluted	(0.75)	(0.58)

Significant increases in operating expenses incurred in the 2 months ending December 31, 2005 compared to the same period in 2004 are primarily caused by clinical development activities, labor expenses and manufacturing development activities. The increased level of activity reflects the progress of our core development programs for Soliris and pexelizumab.



