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

FORM 10-K

Annual report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934

For the fiscal year ended July 31, 2005

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
(State or Other Jurisdiction of
Incorporation or Organization)

13-3648318
(I.R.S. Employer
Identification No.)

352 Knottter Drive, Cheshire Connecticut 06410
(Address of Principal Executive Offices) (Zip Code)

203-272-2596
(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value \$0.0001

Rights to Purchase Junior Participating Cumulative Preferred Stock, par value \$.0001

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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

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

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based upon the last sale price of the Common Stock reported on the National Association of Securities Dealers Automated Quotation (NASDAQ) National Market System on January 31, 2005, was approximately \$691 Million.

The number of shares of Common Stock outstanding as of September 30, 2005 was 30,790,694.

Portions of the registrant's Definitive Proxy Statement to be used in connection with its Annual Meeting of Stockholders to be held on December 9, 2005, are incorporated by reference into Part III of this report.

PART I

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, 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, including SFAS No. 123(R), 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 as a result 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 engaged in the discovery and development of therapeutic products to treat patients with a wide array of severe disease states, including hematologic and cardiovascular disorders, autoimmune diseases, and cancer. Since our incorporation in January 1992, we have devoted substantially all of our resources to drug discovery, research, and product and clinical development. Additionally, through our wholly owned subsidiary, Alexion Antibody Technologies, Inc., or AAT, we are engaged in the discovery and development of a portfolio of additional antibody therapeutics targeting severe unmet medical needs.

We have significant expertise in the discovery and development of antibody therapeutics, as well as in understanding and inhibiting the aberrant manifestation of a component of the human immune system known as complement. Antibodies are proteins that bind specifically to selected targets, or antigens, in the body. After the antibody binds to its target, it may activate the body’s immune system against the target, block activities of the target or stimulate activities of the target. Our two lead product candidates are therapeutic antibodies that address specific diseases that arise when the complement component of the human immune system produces inflammation in the human body.

We are developing eculizumab, an antibody that inhibits complement, for the treatment of a rare blood disorder known as Paroxysmal Nocturnal Hemoglobinuria, or PNH. Eculizumab is in two clinical trials, which we refer to as TRIUMPH and SHEPHERD, that constitute the pivotal Phase III program for eculizumab in PNH. We are developing pexelizumab, a single-chain antibody that also inhibits complement, in collaboration with Procter and Gamble Pharmaceuticals, or P&G, as a therapeutic to reduce the incidence of death, myocardial infarction or heart attack, and other complications associated with coronary artery bypass graft, or CABG, surgery. We are also developing pexelizumab as a therapeutic to reduce the incidence of death and morbidity often experienced by patients suffering acute myocardial infarction, or AMI, who receive angioplasty, a procedure for opening up narrowed or blocked arteries that supply blood to the heart. We designed both of these product candidates with the goal of inhibiting the aberrant manifestation of complement.

[Table of Contents](#)

To date, we have studied our two lead antibody product candidates in a variety of clinical development programs enrolling over 10,000 patients in clinical trials. In addition to our Phase III programs, we are developing a global patient registry for PNH patients, have other product candidates in earlier stages of development, and may also pursue additional potential indications for eculizumab.

To date, we have not received any revenues from the sale of our products. We have incurred operating losses since our inception. As of July 31, 2005, we had an accumulated deficit of approximately \$448.1 million. We expect to incur substantial and increasing 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 will need to obtain additional financing to cover these costs.

We plan to develop and commercialize on our own those product candidates for which the clinical trials and commercialization requirements can be funded and accomplished by our own resources. For those products which require greater resources, our strategy is to form corporate alliances for product development and commercialization.

In January 2005 we sold \$150 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 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. The net proceeds of approximately \$145.2 million from this offering were used to redeem our entire outstanding \$120 million principal amount of 5.75% Convertible Subordinated Notes due March 2007, or the 5.75% Notes, and the balance for general corporate purposes.

In August 2005, we sold 2.5 million 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 \$2.3 million related to the transaction. 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;

[Table of Contents](#)

- 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.

Common heart diseases and procedures in which the complement cascade is activated include:

- cardiopulmonary bypass surgery, or CPB;
- acute myocardial infarction or heart attack;
- unstable angina or painful chest pains associated with an insufficient blood supply to the heart;
- angioplasty; and
- stroke and other peripheral vascular or blood circulatory diseases.

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

- PNH;
- rheumatoid arthritis;
- autoimmune kidney disease;
- lupus;
- inflammatory bowel diseases;
- inflammatory skin and muscle disorders;
- multiple sclerosis;
- asthma; and
- transplantation.

[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 candidates, which are genetically altered antibodies known as C5 complement inhibitors, or C5 Inhibitors, are 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 both of our lead product candidates 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 eculizumab for the treatment of PNH and pexelizumab for use in CABG surgery and following AMI.

Our clinical stage programs are as follows:

| <u>Product Candidate</u> | <u>Indication</u> | <u>Clinical Trial</u> | <u>Status (a)</u> |
|--------------------------|---|---------------------------|--|
| Eculizumab | Paroxysmal Nocturnal Hemoglobinuria (PNH) | TRIUMPH (Phase III) | Enrollment completed |
| | | SHEPHERD (Phase III) | Enrollment completed |
| | | Phase III Extension study | Enrollment ongoing |
| | Membranous Nephritis (MN) | Phase II | Trial completed and program not currently active |
| | Rheumatoid Arthritis (RA) | Phase IIb | Trial completed and program not currently active |
| Pexelizumab | Asthma | | Pre-clinical research |
| | Renal Transplantation | | Pre-clinical research |
| | Coronary Artery Bypass Graft (CABG) surgery with cardiopulmonary bypass (CPB) | PRIMO-CABG (Phase III) | Trial completed |
| | | PRIMO-CABG2 (Phase III) | Enrollment and treatment completed |
| | Acute Myocardial Infarction (AMI) with angioplasty | APEX-AMI (Phase III) | Enrollment on-going |

(a) see discussions of each product candidate below for a description of the results of the trials that have been completed

[Table of Contents](#)

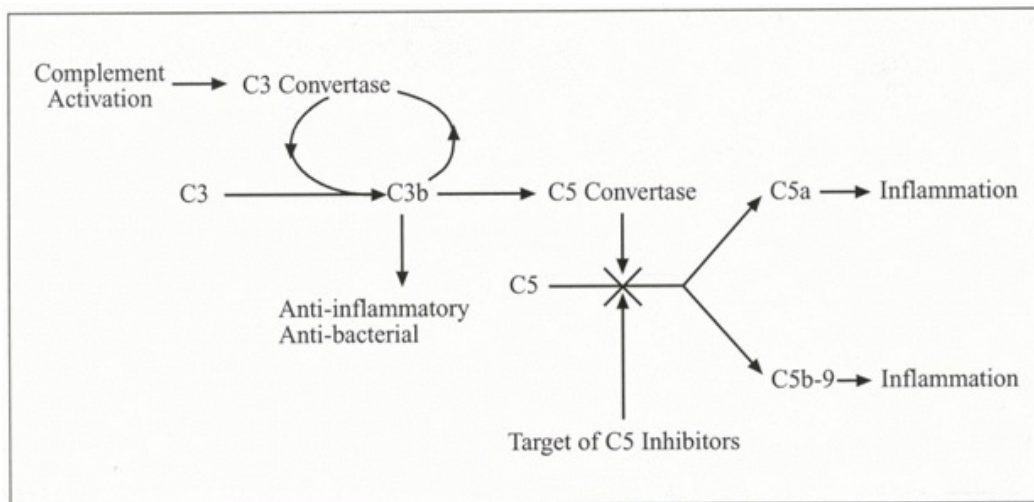
C5 Inhibitors

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:

- 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;
- activation of blood-clotting cells called platelets;
- initiation of cell suicide programs in heart cells; and
- lysis, or destruction, of red blood cells that are deficient in complement inhibitors.

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 disease-promoting effects of the cleavage products of C5, we have identified C5 as a potentially effective anti-inflammatory drug target. Our first two C5 Inhibitors specifically and tightly bind 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 C5 Inhibitor, as compared to placebo, has demonstrated the following:

- 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;

Table of Contents

- prevention and amelioration of asthmatic attacks;
- prevention of lysis of red blood cells and activation of platelets; and
- enhancement of survival in organ transplantation models.

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

- destruction of red blood cells and transfusions in PNH patients;
- inflammation during cardiopulmonary bypass surgery;
- heart tissue damage during cardiopulmonary bypass surgery;
- new cognitive or mental faculty deficits after cardiopulmonary bypass surgery;
- an objective measure of disease activity in rheumatoid arthritis patients; and
- the incidence of proteinuria in lupus patients.

C5 Inhibitor Immunotherapeutic Product Candidates

We are developing one of our two lead C5 Inhibitor product candidates, eculizumab, for the treatment of inflammation related to chronic hematologic disorders and autoimmune disorders. The initial indication for which we are pursuing clinical development activities for eculizumab is PNH. We have also examined eculizumab in clinical trials in membranous nephritis and rheumatoid arthritis patients. We are developing our other C5 Inhibitor product candidate, pexelizumab, for the treatment of inflammation related to acute cardiovascular diseases and procedures. The initial indications for which we are in clinical development of pexelizumab are coronary artery bypass graft surgery with cardiopulmonary bypass and acute myocardial infarction utilizing percutaneous coronary intervention, or PCI, a procedure that includes balloon angioplasty and usually also coronary artery stent insertion to open up and keep open narrowed or blocked arteries that supply the heart muscle. The selection of these indications is based upon our belief that each represents a clinical condition which is:

- closely tied to the production of activated complement byproducts;
- characterized by clear development pathways;
- inadequately treated by current therapies; and
- associated with substantial health care costs.

To date, eculizumab and pexelizumab have been observed to be reasonably well tolerated in completed and ongoing clinical trials in which over 10,000 individuals were treated with either C5 Inhibitor 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. In laboratory studies with eculizumab, administration of eculizumab halted destruction of red blood cells and activation of platelets caused by complement attack. Eculizumab is not included in the collaboration with P&G, and we have retained full rights to eculizumab.

Paroxysmal Nocturnal Hemoglobinuria or PNH

We are conducting clinical trials with eculizumab in patients afflicted with the chronic hematologic disorder, Paroxysmal Nocturnal Hemoglobinuria, or PNH. PNH is a rare autoimmune disorder characterized by severe anemia and risk of blood clotting, or thrombosis. Patients with PNH have a deficiency in certain protective proteins on the surface of their red blood cells and platelets, allowing their own complement system to attack and destroy or activate these blood cells. Patients with PNH 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 frequent bouts of hemoglobinuria or release of blood cell hemoglobin into the urine, abdominal pain, painful swallowing, and disabling fatigue. In patients with particularly severe hemolysis, the red blood cell destruction may be sufficiently large that recurrent blood transfusions are necessary to support normal red blood cell function. Patients with PNH may suffer from severe, life-threatening blood clots that are believed to be caused by the activation and aggregation of platelets, blood cells normally involved in blood clotting. The prevalence, or number of affected patients at any one time, has not been definitively determined but can be estimated at approximately 2,000 –

[Table of Contents](#)

10,000 diagnosed patients in the United States. Approximately one-half of the patients with PNH die from the disease within 10 years of diagnosis. Currently there is no U.S. Food and Drug Administration, or FDA, approved therapy for PNH. In 2003, the FDA and the European Medicines Evaluation Agency, or EMEA, granted Orphan Drug Status for the development of eculizumab in PNH.

In July 2004, we announced that we received written confirmation from the FDA indicating agreement with the protocol designs for two clinical trials that will constitute the pivotal Phase III program of eculizumab in PNH. 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.

Clinical Trials - PNH

In July 2005 we announced that we completed randomization of patients of the pivotal Phase III TRIUMPH efficacy trial of eculizumab in patients with PNH. In accordance with the trial's design, enrolled patients first entered a screening phase of approximately three months to confirm their eligibility to be included in the trial, and then were randomized to receive either eculizumab or placebo in a six month treatment phase. Approximately 85 PNH patients were randomized into the six month treatment phase, which exceeds the patient requirements agreed upon with the FDA as part of the SPA for TRIUMPH. It is anticipated that the final patient will complete the six month treatment phase near the end of calendar year 2005. 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 study has enrolled patients in the U.S., Canada, Europe, and Australia.

The TRIUMPH trial is our second study of eculizumab in PNH patients. Results of the first trial, a three-month, open-label study in 11 patients, reported in the February 5, 2004 issue of the New England Journal of Medicine were that patients treated with 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, a standard questionnaire developed to assess quality of life in cancer patients particularly suffering from severe fatigue and anemia, substantially improved during treatment. In this trial, eculizumab appeared reasonably well tolerated, and in no cases were antibodies against the drug detected. Adverse events reported for eculizumab or placebo were similar in type and frequency to those reported in other controlled trials. 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 eculizumab in a 52-week extension of our pilot open-label PNH trial in 11 patients. In this study, patients who received 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 is similar to that of placebo-treated patients in other patient population trials of eculizumab.

We have also completed enrollment in SHEPHERD, an open-label safety trial which will be primarily aimed at generating additional safety data with eculizumab in approximately 95 PNH patients in the United States, Canada, Europe, and Australia. The SHEPHERD protocol includes twelve months of treatment with a six month interim analysis. It is expected that, if successful, these two studies will complete the filing package that will serve as the primary basis of review for the approval of a Biologics License Application, or BLA, for the PNH indication. We also continue to enroll patients that have completed the TRIUMPH and SHEPHERD trials, as well as patients that have completed the Phase I clinical trial in an open-label extension trial to further evaluate safety data in eculizumab. We retain all rights to eculizumab in all indications worldwide.

[Table of Contents](#)

Lead Pexelizumab Indications

Pexelizumab is a humanized, single chain antibody that has been shown to block complement activity for up to 4-10 hours after a single injection at the doses tested, and for approximately 24 hours with a continuous infusion, and is designed for the treatment of acute inflammatory conditions. The FDA has granted “Fast Track” status for the development of pexelizumab in CPB and in connection with angioplasty following AMI. Fast Track designation provides for potentially expedited product development and eligibility for accelerated FDA review of BLAs. We, along with our collaborator P&G, are working to develop and commercialize pexelizumab. Please also read the section entitled “Strategic Alliance with Procter & Gamble”.

Coronary Artery Bypass Graft Surgery and Cardiopulmonary Bypass

Patients with blockages in their heart blood vessels, or coronary artery disease, frequently suffer from angina, or pain caused by ischemia, which is the reduced delivery of blood, oxygen, and nutrients to, and subsequent starvation of, the heart muscle. If the heart muscle is severely ischemic, the muscle may become starved for blood, oxygen, and nutrients resulting in the death of the starved heart muscle, or myocardial infarction. Many patients with coronary artery disease, particularly those who have already suffered a myocardial infarction, require therapeutic interventions to relieve the blockages in the heart blood vessels. Coronary artery bypass graft, or CABG, surgery involves using a patient’s non-heart blood vessels to surgically detour, or bypass, blood around a blockage in the patient’s heart blood vessels so that the downstream heart muscle is provided with an adequate supply of blood, oxygen, and nutrients. In the overwhelming majority of CABG surgeries, in order to isolate the heart during surgery, cardiopulmonary bypass, or CPB, is employed, in which the patient’s blood is diverted away from the heart and lungs to a cardiopulmonary, or heart-lung bypass machine in the operating room. During the CPB procedure, the bypass machine supports and pumps oxygenated blood to the rest of the body. However since blood flow is stopped to the heart and lungs, these organs may become ischemic as they do not receive blood, oxygen, and nutrients. Although the goal of CABG surgery, and also other similar types of acute cardiac interventions, is to prevent further destruction of heart muscle due to ischemia, the ischemia during the procedure itself, coupled with the successful reperfusion of the heart muscle through the bypass grafts, frequently causes an unintended diffuse inflammatory reaction in the heart, called ischemia-reperfusion, or I-R, injury. In this setting, the heart may become severely injured by the inflammatory reaction resulting in an acute perioperative myocardial infarction, or pMI, of the heart muscle. The effects of pMI may be quite severe as it has been shown that the severity of this acute pMI is positively correlated with the risk of patient death several months later. In other words, the greater the size of the pMI, the more likely a patient is to die within the several months following the surgery. Additionally, I-R injury appears to occur more frequently in patients with multiple risk factors, and patients with previous cardiac damage would be expected to be less tolerant of the subsequent cardiac damage due to pMI.

We believe that I-R injury inappropriately triggers the complement cascade, a powerful series of inflammatory proteins that then cause direct damage to the heart muscle as well as further amplification of the inflammatory reactions. We believe that the dangerous terminal complement products, C5b-9, or the membrane attack complex, as well as C5a, are major factors that cause the unintended inflammation resulting in pMI following CABG-CPB surgery.

Pexelizumab is designed to rapidly penetrate the patient’s tissues and to inhibit complement activation in patients immediately before, during and after CPB in order to reduce potential cardiovascular and brain tissue damage and bleeding complications. We believe inhibition of the inflammatory response during and immediately following CPB may reduce:

- the incidence of death;
- the incidence of perioperative myocardial infarction;
- the incidence of brain tissue damage and learning difficulties;
- post-operative complications;
- the time spent by patients in the hospital after CABG-CPB;

[Table of Contents](#)

- the scope of required treatments associated with CPB; and
- perioperative bleeding resulting in the need for blood transfusions.

Based on data derived from American Heart Association estimates, we believe approximately 400,000 CABG operations were performed in the United States in 2002. Currently, products utilized in patients undergoing CPB are designed to enhance the coagulation of blood to reduce the need for blood transfusions. However, we believe these products have little beneficial effect on the heart and brain inflammatory complications associated with the surgery.

Clinical Trials – Coronary Artery Bypass Graft Surgery

Under the FDA's SPA process, we have reached written agreement with the FDA relating to the protocol design for the pivotal Phase III trial of pexelizumab in patients undergoing CABG with CPB. We, along with P&G, have completed enrollment in this confirmatory, pivotal Phase III trial in multiple risk CABG patients, known as PRIMO-CABG2, which expands upon the objectives of the earlier PRIMO-CABG trial. The primary endpoint of PRIMO-CABG2 is a reduction in death or heart attack at 30 days post-CABG procedure. We announced completion of PRIMO-CABG2 enrollment of approximately 4,250 patients in August 2005. This study is being conducted in six countries in Europe and North America, including the United States. Top line data should be forthcoming by the end of calendar year 2005. It is expected that, if successful, the program will complete the filing package that will serve as the primary basis of review for the approval of a BLA for pexelizumab for the CABG indication.

In February 2003 we completed enrollment in a Phase III clinical trial of pexelizumab, called PRIMO-CABG, in patients undergoing CABG with CPB, and patients undergoing CABG with CPB and concomitant cardiac valve surgery. The multi-center, randomized, double-blind placebo-controlled study was conducted in seven countries in Europe and North America, including the United States. The Phase III trial was designed to assess the safety and efficacy of pexelizumab in reducing the combined incidence of death or myocardial infarction in the CABG-only patient subpopulation. The primary endpoint in this trial was a composite of the reduction in the incidence of death or myocardial infarction, measured at 30 days post-procedure, in the sub-population of 2,746 patients undergoing CABG without concomitant valve surgery. Although there was reduction in the events measured by the primary endpoint, the primary endpoint was not achieved with statistical significance. However, key secondary endpoints were achieved with statistical significance, including the same death or myocardial infarction composite in the overall, or intent-to-treat, study population of 3,099 patients. The pexelizumab regimen appeared to be well-tolerated, with the most common serious adverse events observed being postoperative wound infection, pneumonia, respiratory failure, and pleural effusion. The most common adverse events observed were atrial fibrillation, anemia, nausea, and post-operative pain. Serious and common adverse event rates appeared to be similar between the patients receiving placebo and pexelizumab in the study population. Additionally, a large number of additional key pre-specified measures were reduced with statistical significance. The PRIMO-CABG trial primary analysis was published in the May 19, 2004 issue of the Journal of the American Medical Association and showed that the primary endpoint of the study, Death/MI through Postoperative Day 30 (POD 30) in the CABG-only subpopulation was reduced 18% ($p=0.069$).

In September 2000, we announced completion of enrollment in a Phase IIb clinical trial with pexelizumab in 914 patients undergoing CABG during CPB, with or without accompanying cardiac valve surgery. The objective of this multi-center, double-blind, randomized, placebo-controlled study was to assess the safety and effectiveness of pexelizumab in these patients. Although the primary endpoint, a reduction in the incidence of death, myocardial infarction, heart dysfunction, and mild stroke, did not achieve statistical significance, results of this trial suggested that pexelizumab blocked complement, reduced inflammation and appeared to be well-tolerated. Some patients in the trial experienced serious adverse events which included irregular heartbeat, infection, right heart failure and internal bleeding. The most common adverse events were irregular heartbeat, nausea and anemia. In a post-hoc analysis, in the pre-specified population that included approximately 90% of the patient population, of the approximately 800 patients who had CABG without accompanying cardiac valve surgery, those that received pexelizumab at the highest dose level experienced a statistically significant reduction in the incidence of myocardial infarction or death.

[Table of Contents](#)

Acute Myocardial Infarction

Myocardial infarction is an acute cardiovascular disorder in which the coronary arteries, the blood vessels that supply blood, oxygen, and nutrients to the heart muscle, are blocked to such an extent that the starved heart muscle infarcts, or dies. Upon the reduction in blood flow in the coronary artery, a complex cascade of inflammatory events involving complement proteins, platelets and leukocytes and their secreted factors, and endothelial cells, commences within the blood vessel. In patients suffering a myocardial infarction, activated complement byproducts are significantly elevated. This severe inflammatory response targeting the area of insufficient blood flow to cardiac muscle is believed to be associated with immediate death of heart muscle, delayed death of heart muscle, reduced contractility of heart muscle, and activation of a systemic inflammatory response. Restoration of blood flow in the midst of the acute myocardial infarction, with either angioplasty balloon dilatation, with or without coronary stenting, or with dissolution of clots with thrombolytic drugs, is believed to be also associated with an additional inflammatory reaction and an accompanying production of activated complement byproducts. This combined reaction is sometimes called ischemia-reperfusion, or I-R injury. In addition to the high incidence of sudden cardiac death at the onset, severe complications associated with the initial survival of an acute myocardial infarction include congestive heart failure, cardiogenic shock and death. Based on data derived from the American Heart Association, we estimate that approximately 850,000 people presented to hospitals for treatment of a heart attack in the United States in 2002.

We are also developing pexelizumab to inhibit inflammation associated with complement activation in order to reduce the extent of heart damage and other adverse conditions in patients suffering an acute myocardial infarction. In contrast, most drugs currently being developed or on the market to treat acute myocardial infarction are designed to improve blood flow through the heart, rather than treating the damaging effects of inflammation associated with myocardial infarction. We and our scientific collaborators have performed pre-clinical studies in rodents which have demonstrated that administration of a C5 Inhibitor during periods of insufficient supply of blood to the heart muscle and prior to restoration of normal flow to the heart muscle significantly reduced the extent of subsequent death of heart muscle compared to control animal studies. Additionally, administration of a C5 Inhibitor significantly reduced the extent of cardiac damage associated with reduced heart blood flow without subsequent restoration of blood flow.

Clinical Trials – Acute Myocardial Infarction

Under the FDA's SPA process, written agreement was reached with the FDA relating to the protocol for the pivotal Phase III trial of pexelizumab in AMI patients undergoing angioplasty. In July 2004, we announced that we, along with P&G, commenced enrollment in this pivotal Phase III trial, known as APEX-AMI. The primary endpoint of APEX-AMI is a reduction in death at 90 days. APEX-AMI is a multicenter, randomized, double-blind, placebo-controlled study. This study is being conducted in seventeen countries including the United States and is actively enrolling. It is expected that, if successful, the program will complete the filing package that will serve as the primary basis of review for the approval of a Biologics License Application for the AMI indication

In April 2002, we completed enrollment in a Phase II study with P&G, known as the COMMA trial, in patients receiving angioplasty, a procedure for opening up narrowed or blocked arteries that supply blood to the heart. We also completed enrollment in a second study, called COMPLY, in January 2002 in patients receiving thrombolytic therapy, a procedure for dissolving clots that block heart vessels. Each study enrolled approximately 900 patients. Overall, in the combined COMMA and COMPLY population, pexelizumab appeared to be well-tolerated. The incidence of serious adverse events was similar in placebo and pexelizumab treated patients. Results from these studies were reported at the November 2002 annual meeting of the American Heart Association. In both studies, the primary endpoint of a reduction of myocardial infarction was not reached. However, pexelizumab treatment in the COMMA angioplasty study was associated with a statistically significant, dose-dependent reduction in death.

[Table of Contents](#)

Additional Eculizumab Indications

Membranous Nephritis

Membranous nephritis is characterized by kidney inflammation and dysfunction that may eventually progress to kidney failure. Diagnostic criteria for membranous nephritis include kidney biopsies that may demonstrate the presence of antibodies and activated complement byproducts in the kidneys of affected patients. The subsequent kidney inflammation leads to the abnormal leakage of substantial amounts of proteins into the patient's urine. This condition is known as proteinuria and is recognized as an objective measurement of kidney disease. We estimate, based on an external market study, that there are approximately 150,000 people currently afflicted with membranous nephritis in the United States. Our membranous nephritis program is not currently active.

Clinical Trials - Membranous Nephritis

In February 2002, the Phase II trial patient enrollment for membranous nephritis was completed. In November 2002, preliminary results were reported at the American Society of Nephrology's annual meeting from two clinical trials evaluating eculizumab in patients with membranous nephritis. Results from the first, randomized, placebo controlled double-blind, membranous nephritis study showed that eculizumab was well tolerated, but did not reach its primary clinical efficacy endpoint of reduction in proteinuria after four months of therapy. In this trial, the most common adverse events were upper respiratory tract infection, diarrhea, and headache. In the second membranous nephritis study, both placebo and eculizumab treated patients from the four-month study were treated in an open-label extension trial for an additional twelve months with eculizumab therapy. Although not an efficacy study, in this extension study, eculizumab was well tolerated and associated with an increased remission rate at twelve months and with improvements in proteinuria and other important components of nephrotic syndrome. In this trial, the most common adverse events were upper respiratory infections, nasal congestion/rhinitis, and headache.

The FDA designated Fast Track status for development of eculizumab for the treatment of patients with membranous nephritis. The FDA has also granted Orphan Drug designation for the development of eculizumab in the treatment of membranous nephritis patients. We continue to evaluate our development options for eculizumab in membranous nephritis.

Rheumatoid Arthritis

Rheumatoid arthritis, or RA, is a chronic autoimmune disease directed at various organ and tissue linings, including the lining of the joints, causing inflammation and joint destruction. Clinical signs and symptoms of the disease include weight loss, joint pain, morning stiffness and fatigue. Further, the joint destruction can progress to redness, swelling and pain with frequent and severe joint deformity. Published reports have estimated that more than 2.1 million people are currently affected by rheumatoid arthritis in the United States. Our rheumatoid arthritis program is not currently active.

Clinical Trials - Rheumatoid Arthritis

In January 2004 we announced preliminary results of the 350 patient double-blind, randomized, placebo controlled Phase IIb study of eculizumab in rheumatoid arthritis patients. The primary efficacy endpoint of the trial, improvement in ACR20 score after a six month treatment period, was achieved with statistical significance in the monthly dosing arm but not in the bimonthly dosing arm. In this trial, eculizumab treatment appeared to be safe and well tolerated, with the most common adverse events being upper respiratory tract infection, headache, and nausea. The most common serious adverse events were myocardial infarction, accidental injury, and cerebral infarction. Serious and common adverse event rates appeared to be similar between placebo and eculizumab in the study population. ACR20 is a measure established by the American College of Rheumatology that requires a 20% improvement in tender and swollen joint count plus a 20% improvement in at least 3 of 5 other criteria. We continue to evaluate our development options for eculizumab in rheumatoid arthritis.

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.

[Table of Contents](#)

In collaboration with investigators at the Multi-Organ Transplant Program, London Health Sciences Centre, London, Ontario, Canada, we recently 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.

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, through a merger with our newly organized, wholly owned subsidiary, Alexion Antibody Technologies, Inc., or AAT. AAT possesses extensive research expertise and technologies 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.

Our goal, through utilizing AAT, is to develop new fully human therapeutic antibodies addressing multiple disease areas, including autoimmune and inflammatory disorders, cancer and infectious disease. AAT's 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

[Table of Contents](#)

addition, we believe that these technologies could permit the pre-clinical validation of new gene targets that are coming out of the international effort to sequence 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-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.

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. Our antibody binds to CD200, a molecule that is upregulated on the surface of B-CLL 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 cell surface allows the tumor to inhibit the body's immune response to the tumor. Our antibody targets CLL cells and blocks the interaction of CD200 with the CD200 Receptor with the objective of enhancing the body's immune response to the tumor. Our anti-CD200 antibodies drug candidates may have therapeutic application in patients suffering from B-CLL.

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 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 also in certain inflammatory disorders. This alliance broadens our interest in immune system modulation to now 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.

The CuraGen Corporation Agreement for Target Discovery

We have 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 the other's respective 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, developed by us through AAT, 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.

[Table of Contents](#)

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.

Biodefense Program

We have developed proprietary human antibody libraries that are employed to isolate custom human antibodies. In the area of biodefense, the libraries were generated from blood and bone marrow of donors who had recently been vaccinated against anthrax, botulism toxin, small pox and/or other toxic agents of bioterrorism. The CoALT libraries developed by us through AAT use proprietary methods of construction and proprietary vectors and each has a size of approximately 10 billion antibody members. These antibodies generally display very high binding affinity to these toxic agents. We have exploited this technology to generate high binding affinity human antibodies against anthrax toxins. These antibodies have been shown to be capable of neutralizing anthrax toxin in animal models of anthrax toxin exposure. We have been notified that we have been awarded grants totaling \$1.3 million for our fiscal year 2006 by agencies of the U.S. government in support of this program with additional grants totaling \$1.2 million available for fiscal year 2007 pending annual budget legislation approvals.

Other Pre-Clinical Programs

UniGraft Xenotransplantation Technologies Program

Through our subsidiary, Columbus Farming Corporation, or CFC, we studied and developed a portfolio of UniGraft anti-rejection technologies designed to permit the therapeutic transplantation of cells from other species, known as xenografts, or xenotransplantation, without rejection. We were awarded various grants by agencies of the U.S. government to fund specific research projects related to our UniGraft xenotransplantation technologies program. As of July 31, 2003, we had no additional funding available under these grants. We concluded that further investment in the UniGraft program by us did not meet sufficient criteria for continued development with our own resources, as compared to other internal programs; consequently, we terminated this program.

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 \$3.9 million note payable to Tyco. Upon CFC's failure to make its quarterly interest payment due to 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 January 31, 2004, we and Tyco initiated a plan to sell or liquidate CFC's assets in their present condition. In the quarter ended October 31, 2004 an offer of \$450,000 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 have 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 \$3.9 million note, unpaid interest of \$0.3 million, and other obligations of CFC, Tyco formally discharged CFC of any further obligations. As a result, we extinguished the \$3.9 million note and unpaid interest of \$0.3 million offset by the transfer of CFC's assets of \$450,000 to Tyco. As a result, we recorded the resulting gain of \$3.8 million as other income on a consolidated basis in the first quarter of fiscal year 2005.

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.

[Table of Contents](#)

Strategic Alliance with Procter & Gamble

In January 1999, we entered into collaboration with P&G with respect to the joint development of pexelizumab. 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. Under the revised structure per the MOU, we and P&G will share decision-making and responsibility for all future 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 will 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 will receive royalties on sales in the rest of the world, if any. We are responsible for paying royalties and licensing fees on certain third party intellectual property worldwide, if such intellectual property is necessary in order to commercialize pexelizumab. Additionally, as part of the MOU, we will receive milestone payments for achieving specified development steps, regulatory filings and approvals, but not for previously agreed sales milestones and we will 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 in myocardial infarction patients. 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 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 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 back 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. 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 could amount to as much as \$8.0 million.

Manufacturing

We obtain drug product to meet our requirements for clinical studies using both internal and third-party contract manufacturing capabilities. We have a pilot manufacturing plant suitable for the production and purification of certain of our product candidates for clinical studies. We have also secured the production of clinical supplies of certain other product candidates through third-party manufacturers. In each case, we have contracted product finishing, vial filling, and packaging through third parties.

We do not currently operate our own commercial manufacturing facility. In the longer term, we may contract for the manufacture of our products for commercial sale or may develop large-scale manufacturing capabilities for the commercialization of some of our products.

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 July 31, 2004.

[Table of Contents](#)

Under the Lonza Amendment, if we terminate the Lonza Agreement on or prior to September 30, 2006, we may be required to pay different amounts, depending on when the Lonza Agreement is terminated, which are between zero and approximately \$10 million and, 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 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 fiscal quarterly basis, we evaluate our plans to proceed with production under the Lonza 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 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 will need to continue developing or contract these capabilities to commercialize successfully any of our drug candidates. We may promote our products in collaboration with marketing partners or rely on relationships with one or more companies with established distribution systems and direct sales forces. Under our revised collaboration agreement, P&G is obligated to sell, market, and distribute pexelizumab for all approved indications outside the U.S. We share with P&G co-marketing and co-promotion rights for pexelizumab in the U.S. For other future drug products, as well as for pexelizumab in the U.S., we may elect to establish our own specialized sales force and marketing organization to market our products.

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 licensed several additional U.S. and international patents and patent applications. As of July 31, 2005, approximately 25 of our owned and licensed patents and patent applications relate to technologies or products in the C5 Inhibitor program, approximately 20 relate to recombinant antibodies, and approximately 90 relate to other products and technologies such as cancer, biodefense, dendritic cells and our TPO, MBL, and MP4 programs. 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 pexelizumab and 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.

[Table of Contents](#)

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, and 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 pexelizumab and 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 pexelizumab and eculizumab. We have acquired licenses to certain of these patents which we believe are relevant for the expeditious development and commercialization of certain of our 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 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 could be significantly adversely affected or could be prevented.

It is our policy to require our employees, consultants, members of our scientific advisory board, 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 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 our currently anticipated products will be regulated by the FDA as biologics. 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.

[Table of Contents](#)

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.

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 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 typically are 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 may 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. 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 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. If the FDA refuses to file an application, the FDA will retain 25% percent of the user fee as a penalty. The FDA’s established goals for the review of BLAs is six months for priority applications and 10 months for regular

[Table of Contents](#)

applications. However, the FDA is not legally obligated to complete its review within these periods 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 our 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.

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. 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.

Fast Track Designation

Fast track products are those which are intended for the treatment of a serious or life-threatening condition and which demonstrate the potential to address unmet medical needs for such conditions. Fast track products are eligible for expedited product development, and accelerated review for BLAs. There can be no assurance that any product will receive designation as a fast track product, and even if a product is designated as a fast track product, there can be no assurance that it will be reviewed or approved more expeditiously than would otherwise have been the case.

[Table of Contents](#)

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 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.

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 payors. These health insurance programs may restrict coverage of some products. Many third-party payors use formularies, under which only selected drugs are covered, variable co-payments that make drugs that are not performed 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 particular drug. Payors may especially impose these obstacles to coverage for higher-priced drugs, as our product candidates are 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 our products 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 our product candidates.

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.

[Table of Contents](#)

Many of these companies and organizations have significant experience in pre-clinical testing, human clinical trials, product manufacturing, marketing and distribution and other regulatory approval 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 Abbott Laboratories Inc., Adprotech Ltd., Avant Immunotherapeutics, Inc., Baxter International Inc., Millennium Pharmaceuticals, Inc., Neurogen Corporation, Tanox, Inc., and XOMA Ltd. has publicly announced intentions to develop complement inhibitors to treat diseases related to trauma, inflammation or certain brain or nervous system disorders. Avant is pursuing clinical development for a proposed complement inhibitor to treat acute respiratory distress syndrome, myocardial infarction, and lung transplantation in infants and adults undergoing heart and/or lung bypass procedures. Neurogen has also announced a human study for a proposed complement inhibitor to treat rheumatoid arthritis. We are aware that GlaxoSmithKline plc, Merck & Co., Inc. and Pfizer, Inc. are also attempting 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 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.

We further believe that, under conditions of inflammation, a complement inhibitor compound which only indirectly addresses the harmful activity of complement may be bypassed by pathologic mechanisms present in the inflamed tissue. Each of Amgen Inc. (which acquired Immunex Corp.), Bayer AG, and Pfizer, Inc. sells a product which is used clinically to reduce surgical bleeding during CPB, but has little proven beneficial effect on other significant inflammatory morbidities associated with CPB. Further, Dyax Corporation has conducted clinical trials in patients undergoing CABG-CPB with an enzyme inhibitor and with the objective of reducing blood loss in these patients. We believe that each of these drugs does not significantly prevent complement activation and subsequent inflammation that lead to organ damage and blood loss during CPB, but instead each drug attempts to reduce blood loss by shifting the normal blood thinning/blood clotting balance in the blood towards enhanced blood clotting. Additionally, Aventis has conducted clinical trials aimed at reducing heart damage in patients undergoing CPB with a drug called Cariporide that blocks ion transport but failed to achieve key endpoints. Aventis has publicly announced termination of their program in CABG-CPB.

Each of Cambridge Antibody Technology Group plc, 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 Abgenix, 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 September 1, 2005, we had 222 full-time employees, of which 175 were engaged in research, development, manufacturing, and clinical development, and 47 in administration, commercial and business development and finance. Doctorates are held by 53 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. On our Web site, we make available, free of charge, our annual report 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 2. PROPERTIES.

Facilities

We lease our headquarters and research and development facilities in Cheshire, Connecticut. The lease has an initial term of ten years and six months, expiring in December 2010. At this site, we lease a total of approximately 89,000 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 expected to remain 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. We believe our research and development facilities and our pilot manufacturing facility, together with third party manufacturing facilities, will be adequate for our on-going current clinical activities. Alexion Antibody Technologies, Inc. leases approximately 25,000 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.

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.

None.

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 October 1, 2005 are as follows:

| <u>Name</u> | <u>Age</u> | <u>Position with Alexion</u> |
|--------------------------------------|------------|---|
| * Leonard Bell, M.D. | 47 | Chief Executive Officer, Secretary, Treasurer, Director |
| * David W. Keiser | 54 | President and Chief Operating Officer |
| * Stephen P. Squinto, Ph.D. | 49 | Executive Vice President and Head of Research |
| Katherine S. Bowdish, Ph.D. | 48 | Senior Vice President, Antibody Discovery, and President, Alexion Antibody Technologies |
| * Thomas I.H. Dubin, J.D. | 43 | Senior Vice President and General Counsel |
| * Christopher F. Mojcik, M.D., Ph.D. | 45 | Senior Vice President, Clinical Development |
| Nancy C. Motola, Ph.D. | 53 | Senior Vice President, Regulatory Affairs and Quality |
| Scott A. Rollins, Ph.D. | 42 | Senior Vice President, Drug Development and Project Management |
| Russell P. Rother, Ph. D. | 44 | Senior Vice President, Discovery Research |
| * Vikas Sinha | 42 | Senior Vice President and Chief Financial Officer |
| Paul W. Finnegan M.D, M.B.A | 45 | Vice President, Commercial Operations and Development |
| Barry P. Luke | 47 | Vice President, Finance, Assistant Secretary |
| Daniel N. Caron | 42 | Executive Director, Operations and Engineering |
| M. Stacy Hooks, Ph.D. | 38 | Executive Director, Manufacturing and Technical Services |

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

[Table of Contents](#)

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 three 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 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.

[Table of Contents](#)

Katherine S. Bowdish, Ph.D. has been Senior Vice President, Antibody Discovery since August 2001 and was Vice President of Antibody Discovery from September 2000 upon joining the Company. Dr. Bowdish has also been President of Alexion Antibody Technologies, Inc., a wholly-owned subsidiary of the Company, since September 2000. From May 1997 to January 1999, Dr. Bowdish was a co-founder and Chief Scientific Officer and Executive Vice President of Prolifaron, Inc. and the Chief Executive Officer and Chief Scientific Officer of Prolifaron from January 1999 to September 2000. Prolifaron, a San Diego, California based antibody engineering company was merged into Alexion Antibody Technologies, Inc. in September 2000. Dr. Bowdish previously held positions at The Scripps Research Institute, Monsanto, and Rockefeller University and was a Postdoctoral Research Fellow in the Department of Biological Chemistry at UCLA. Dr. Bowdish is an internationally recognized expert in the field of antibody engineering and has 19 years of experience in biotechnology research. Dr. Bowdish received her B.S. degree in biology from the College of William and Mary, M.A. degree in cell biology from Columbia University, and Ph.D. degree in genetics from Columbia University.

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.

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

[Table of Contents](#)

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 Pharmaceutical Scientists (AAPS). Dr. Motola is Regulatory Affairs (RAC) certified and received her B.A. from Central Connecticut State University and M.S. and Ph.D. degrees in medicinal chemistry from the University of Rhode Island.

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. Since 1992, Dr. Rollins has been responsible for the pre-clinical development of our anti-inflammatory compound pexelizumab. Since 1999, Dr. Rollins has been additionally responsible for the project management functions of pexelizumab, currently under joint development with Procter & Gamble Pharmaceuticals. Prior to 1992, Dr. Rollins was a postdoctoral research fellow in the Department of Immunobiology at Yale University School of Medicine. Dr. Rollins' work has led to over 50 scientific papers and patents in the fields of complement biology. 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, Discovery 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 has 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 targets. Prior 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 30 scientific papers and issued patents in the fields of gene therapy, autoimmunity and complement biology. 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 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, Commercial Operations and Development since February 2002, responsible for marketing, sales, business development, external relations, 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 & Orthopaedic 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 degree of M.D., C.M. from McGill University in Montreal and is a Fellow of the Royal College of Physicians, Canada.

[Table of Contents](#)

Barry P. Luke has been Vice President, Finance and Administration 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 is a director of Gaylord Hospital in Wallingford, CT. 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, validation and operations of all 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 from Adelphi University and M.S. in Biomedical Engineering from Polytechnic University of New York.

M. Stacy Hooks, Ph.D. has been Executive Director, Manufacturing and Technical Services since August 2004 and Senior Director, Manufacturing and Technical Services from January 2004 to August 2004. After joining the Company in 2002, Dr. Hooks was Director of Quality Control from 2002 until 2004. Dr. Hooks has been 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. Dr. Hooks received his B.S. in Chemistry from Murray State University and a Ph.D in Chemistry from Emory University.

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 National Market under the symbol "ALXN." The following table sets forth the range of high and low sales prices for our common stock on The Nasdaq National Market for the periods indicated since August 1, 2003.

| <u>Fiscal 2004</u> | <u>High</u> | <u>Low</u> |
|--|-------------|------------|
| First Quarter (August 1, 2003 to October 31, 2003) | \$21.64 | \$12.03 |
| Second Quarter (November 1, 2003 to January 31, 2004) | \$20.82 | \$16.47 |
| Third Quarter (February 1, 2004 to April 30, 2004) | \$26.14 | \$18.11 |
| Fourth Quarter (May 1, 2004 to July 31, 2004) | \$23.25 | \$14.60 |
| <u>Fiscal 2005</u> | <u>High</u> | <u>Low</u> |
| 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 |

As of September 26, 2005, we had 162 stockholders of record of our common stock and an estimated 5,000 beneficial owners. The closing sale price of our common stock on September 26, 2005 was \$27.64 per share.

In August 2005, we sold 2.5 million 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 intend to use the net proceeds from this offering for general corporate purposes.

In January 2005 we sold \$150 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 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.

[Table of Contents](#)

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 42.91 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 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.

We did not make any repurchases of our common stock during the three month period ended July 31, 2005.

DIVIDEND POLICY

We have never paid cash dividends. We do not expect to declare or pay any dividends on our common stock in the foreseeable 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.

[Table of Contents](#)

Item 6. SELECTED CONSOLIDATED FINANCIAL DATA.

The following selected financial data is qualified by reference to, and should be read in conjunction with, the financial statements, including the notes thereto, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this Report.

| | Fiscal Year Ended July 31, | | | | |
|--|---|-------------|-------------|-------------|-------------|
| | 2005 | 2004 | 2003 | 2002 | 2001 |
| | (amounts in thousands, except per share data) | | | | |
| Consolidated Statements of Operations Data: | | | | | |
| Contract research revenues | \$ 1,064 | \$ 4,609 | \$ 877 | \$ 6,536 | \$ 11,805 |
| Operating expenses: | | | | | |
| Research and development | 91,388 | 59,840 | 71,042 | 60,005 | 38,871 |
| General and administrative | 18,951 | 14,459 | 10,869 | 7,993 | 7,135 |
| Impairment of fixed assets | — | 760 | 2,560 | — | — |
| In-process research and development | — | — | — | — | 21,000 |
| Amortization of goodwill | — | — | — | — | 2,901 |
| Total operating expenses | 110,339 | 75,059 | 84,471 | 67,998 | 69,907 |
| Operating loss | (109,275) | (70,450) | (83,594) | (61,462) | (58,102) |
| Other income (expense), net | (240) | (4,336) | (1,885) | 4,220 | 10,177 |
| State tax benefit, net | 765 | 691 | 1,012 | 700 | — |
| Loss before cumulative effect of adoption of SAB 101 | (108,750) | (74,095) | (84,467) | (56,542) | (47,925) |
| Cumulative effect of adoption of SAB 101 | — | — | — | — | (9,118) |
| Net loss | \$(108,750) | \$ (74,095) | \$ (84,467) | \$ (56,542) | \$ (57,043) |
| Basic and diluted net loss per common share | \$ (3.90) | \$ (3.43) | \$ (4.64) | \$ (3.12) | \$ (3.28) |
| Shares used in computing net loss per common share | 27,852 | 21,622 | 18,209 | 18,146 | 17,371 |
| | Fiscal Year Ended July 31, | | | | |
| | 2005 | 2004 | 2003 | 2002 | 2001 |
| Consolidated Balance Sheet Data: | | | | | |
| Cash, cash equivalents, and marketable securities | \$ 195,404 | \$266,501 | \$215,410 | \$308,584 | \$355,274 |
| Total current assets | 201,162 | 276,333 | 220,910 | 310,784 | 362,747 |
| Total assets | 248,122 | 319,575 | 267,227 | 354,069 | 400,259 |
| Notes payable | — | 3,920 | 3,920 | 3,920 | 3,920 |
| Convertible notes | 150,000 | 120,000 | 120,000 | 120,000 | 120,000 |
| Total stockholders’ equity | 67,671 | 172,522 | 120,286 | 205,478 | 260,408 |

[Table of Contents](#)

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

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 "Risk Factors".

Overview

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 and cardiovascular disorders, autoimmune diseases and cancer. Since our incorporation in January 1992, we have devoted substantially all of our resources to drug discovery, research, and product and clinical development. Additionally, through our wholly owned subsidiary, Alexion Antibody Technologies, Inc., or AAT, we are engaged in the discovery and development of a portfolio of additional antibody therapeutics targeting severe unmet medical needs.

Our two lead product candidates are therapeutic antibodies that address specific diseases that arise when the human immune system produces inflammation in the human body. Antibodies are proteins that bind specifically to selected targets, or antigens, in the body. After the antibody binds to its target, it may activate the body's immune system against the target, block activities of the target or stimulate activities of the target. We are currently examining our two lead antibody product candidates in a variety of clinical development programs. One product candidate, eculizumab, is in Phase III clinical development for treatment of Paroxysmal Nocturnal Hemoglobinuria, or PNH, a chronic hematologic disease; and our second product candidate, pexelizumab, is in clinical development for two distinct acute cardiac indications. We are developing pexelizumab in collaboration with Procter & Gamble Pharmaceuticals, or P&G, and rely on P&G for the timely development and potential commercialization of pexelizumab.

Currently, none of our drug product candidates is available for commercial sale. All of our potential products are in clinical or pre-clinical development and the status of each of our lead product candidates is set forth, by indication, in Item 1 of this Report under the heading "Product Development Programs."

Successful completion of development of a product candidate is contingent on numerous risks, uncertainties and other factors which are described in detail in the section entitled "Risk Factors". These factors include:

- completion of pre-clinical and clinical trials of the product candidate with scientific results that support further development and/or regulatory approval
- receipt of necessary regulatory approvals
- obtaining adequate supplies of product candidates on commercially reasonable terms
- obtaining capital necessary to fund our operations, including our research and development efforts, manufacturing requirements and clinical trials
- performance of third-party collaborators, particularly Procter & Gamble Pharmaceuticals, on whom we rely heavily for the co-development and commercialization of one of our lead product candidates
- performance of third-party manufacturers, particularly Lonza Biologics, on whom we rely heavily for the manufacture of one of our lead product candidates
- obtaining manufacturing, sales and marketing capabilities for which we presently have limited resources

[Table of Contents](#)

As a result of the amount and nature of these factors, many of which are outside of our control, the success, timing of completion, and ultimate cost, of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. The timing and cost to complete drug trials alone may be impacted by, among other things,

- slow patient enrollment;
- 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;
- the failure of patients taking the placebo to continue to participate in our clinical trials;
- lack of effectiveness of the product candidate being tested; and
- lack of sufficient funds.

If we do not successfully complete clinical trials, we will not receive regulatory approval to market our drug products. If we do not obtain and maintain regulatory approval for our products, we will not generate any revenues from the sale of our products and the value of our company and our financial condition and results of operations will be substantially harmed.

To date, we have not received any revenues from the sale of products. We have incurred operating losses since our inception. As of July 31, 2005, we had an accumulated deficit of approximately \$448.1 million. We expect to incur substantial and increasing 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 increasing administrative personnel and professional services to support growth of our operations, and we will need to obtain additional financing to cover these costs.

We plan to develop and commercialize eculizumab on our own and those product candidates for which the clinical trials and commercialization requirements can be funded and accomplished by our own resources. For those products which require greater resources, such as pexelizumab, our plan is to develop and commercialize the drugs through corporate partnerships.

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.

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.

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.

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 the Company's annual impairment assessment.

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, then 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 agreements 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 for the undelivered items.

[Table of Contents](#)

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, 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 certain research agreements 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.

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 account 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.

We believe that it is difficult to accurately measure the value of an employee stock option. 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.

Significantly, we use historical volatility to determine the expected stock price volatility factor. Also, of significance, is our expected term until exercise factor. 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.

[Table of Contents](#)

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

The issuance of SFAS No. 123(R) will significantly change the way we account for grants of stock options. This new pronouncement and its potential impact are discussed in the section titled "Recently Issued Accounting Pronouncements."

Results of Operations

A reclassification has been made to the presentation of operating expenses for the twelve months ended July 31, 2003 in order to conform to current year expense classifications. Our Connecticut capital-based tax in the prior fiscal year was reclassified from state tax benefit to operating expense. In addition, certain reclassifications have been made to prior year balance sheet items to conform to current year classifications.

Fiscal Years Ended July 31, 2005, 2004, and 2003

A summary of revenues generated from contract research collaboration and grant awards is as follows (amounts in thousands):

| | 2005 | 2004 | 2003 |
|------------------------|----------------|----------------|--------------|
| P&G | \$ 588 | \$4,588 | \$673 |
| U.S. government grants | 476 | 21 | 204 |
| Total revenues | \$1,064 | \$4,609 | \$877 |

We earned contract research revenues of \$1.1 million, \$4.6 million, and \$0.9 million for the fiscal years ended July 31, 2005, 2004, and 2003, respectively. In the fourth quarter of 2004, we recognized a \$4 million 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, 2004 and 2003 is a non-cash item representing the amortization of deferred revenue from the \$10 million upfront fee paid to us by P&G in February 1999. Revenue from U.S. government grants totaled \$476,000 in fiscal 2005, \$21,000 in fiscal 2004, and \$204,000 in fiscal 2003. The \$455,000 increase in revenues associated with U.S. government grants obtained in fiscal 2005 resulted from research under the anti-anthrax bio-defense program. The \$183,000 decrease in revenues associated with U.S. government grants from 2003 to 2004 resulted primarily from the reduction in grant reimbursable billings from our various government grants due to the completion of the related research.

During fiscal year 2005, we incurred research and development expenses of \$91.4 million. For fiscal years 2004 and 2003, we incurred research and development expenses of \$59.8 million and \$71.0 million, respectively. We report our 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 following table summarizes the major research and development expense categories for the fiscal years ended July 31, 2005, 2004, and 2003 respectively (amounts in thousands):

| | 2005 | 2004 | 2003 |
|--|-----------------|-----------------|-----------------|
| Research and development expenses: | | | |
| Payroll and benefits | \$17,397 | \$14,749 | \$13,613 |
| Clinical development | 43,314 | 20,398 | 25,122 |
| Manufacturing and manufacturing development | 20,835 | 14,027 | 17,414 |
| Discovery research | 2,431 | 3,592 | 8,241 |
| Operating, occupancy, depreciation, and amortization | 7,411 | 7,074 | 6,652 |
| | \$91,388 | \$59,840 | \$71,042 |

[Table of Contents](#)

The increase in clinical development expenses from 2004 to 2005 is attributable principally to the cost of conducting our two Phase III clinical trials PRIMO-CABG2 and APEX-AMI in 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 increase in manufacturing and manufacturing development expenses from 2004 to 2005 is caused largely by increased production of material used in our clinical trials involving eculizumab and pexelizumab. The decrease in discovery research is due principally to recognition of the \$1.3 million balance of the non-refundable payment received from XOMA. In 2003, XOMA paid an upfront non-refundable fee of \$1.5 million 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 \$1.3 million was recognized as a reduction of research and development expenses.

The \$11.2 million decrease in research and development expenses in fiscal 2004 from fiscal 2003 resulted primarily from i) lower clinical development costs of \$4.7 million due principally to the completion of the pexelizumab Phase III PRIMO-CABG clinical trial; ii) lower costs for discovery research of \$4.6 million due to lower external research and license fees and the suspension of the UniGraft program at CFC; and iii) lower manufacturing development and manufacturing activities of \$3.4 million resulting from the amended manufacturing agreement with Lonza and the timing related to the manufacture of pexelizumab. These lower expenses are partially offset by increased payroll and benefits costs of approximately \$1.1 million and increased occupancy and depreciation costs of \$0.4 million.

We expect research and development expenses will increase in fiscal 2006 due to, among other things, the completion of the PRIMO-CABG2 trial, the continuation of the APEX-AMI trial, the completion of the TRIUMPH and SHEPHERD trials and ongoing enrollment into the extension clinical trial with eculizumab in PNH patients.

Our general and administrative expenses were \$19.0 million, \$14.5 million and \$10.9 million for fiscal years 2005, 2004, and 2003, respectively. The increase in general and administrative expenses of \$4.5 million 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. The increase in general and administrative expenses of \$3.6 million in fiscal year 2004 as compared to 2003 was due principally to increased pre-commercial and business development activities in support of our PNH clinical trials as well as continued growth of our operations. We believe general and administrative costs will increase in fiscal 2006 as we continue to put in place the structure needed to commercialize pexelizumab and eculizumab.

Total operating expenses were \$110.3 million, \$75.1 million, and \$84.5 million for fiscal years 2005, 2004, and 2003, respectively.

[Table of Contents](#)

Investment income was \$5.3 million for fiscal year 2005 compared to \$3.4 million for fiscal year 2004 and \$5.8 million for fiscal 2003. The increase in investment income of \$1.9 million in 2005 resulted primarily from higher interest rates and higher principal amounts. Interest expense was \$6.1 million for fiscal year 2005 compared to \$7.7 million for fiscal year 2004 and \$7.7 million for fiscal 2003. The decrease in interest expense is attributable to the lower interest rate for the 1.375% Notes in fiscal year 2005. We recorded a \$3.2 million 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 \$1.2 million and the redemption premium of approximately \$2.0 million.

During the first fiscal quarter of 2005 we recorded a net gain to other income of \$3.8 million to complete the termination of the Unigraft xenotransplantation program at Columbus Farming Corporation, or CFC. This consisted of the extinguishment of the \$3.9 million note payable used to purchase the xenotransplantation assets and the extinguishment of the accrued interest of \$0.3 million on the note, partially offset by the transfer to Tyco International, Ltd., or Tyco, of the remaining assets of \$450,000 used to secure the note. (See section entitled “Business – Other Preclinical Programs - “Unigraft Xenotransplantation Technologies Program”).

A state tax benefit of \$0.8 million, \$0.7 million and \$1.0 million was recognized in each of fiscal year 2005, 2004 and 2003, respectively, resulting from our estimated exchange of our fiscal 2005 and actual exchange of our fiscal 2004, 2003 and 2002 incremental research and development tax credits.

As a result of the above factors, we incurred net losses of \$108.8 million, \$74.1 million, and \$84.5 million or \$3.90, \$3.43, and \$4.64 basic and diluted net loss per share for fiscal years ended July 31, 2005, 2004, and 2003, respectively.

Liquidity and Capital Resources

Since our inception in January 1992, we have financed our operations and capital expenditures principally through private placements of our common and preferred stock, an initial public offering of our common stock and subsequent follow-on offerings, the sale of convertible notes, other debt financing, payments received under corporate collaborations and grants, and equipment and leasehold improvements financing.

As of July 31, 2005, our cash, cash equivalents, and marketable securities totaled \$195.4 million compared to \$266.5 million as of July 31, 2004. At July 31, 2005, our cash and cash equivalents consisted of \$47.0 million that we hold in short-term highly liquid investments with original maturities of less than three months. The decrease in cash, cash equivalents and marketable securities as compared to July 31, 2004 was due primarily to the redemption of our \$120 million 5.75% Notes and the funding of operating activities, partially offset by the sale of our 1.375% Notes for approximately \$145.2 million net of financing fees. The net proceeds from the sale of the 1.375% Notes, less the redemption of the 5.75% Notes including the redemption premium, were \$23.3 million. During the year ended July 31, 2005, we invested \$3.0 million in property, plant and equipment to support our research and development efforts. We anticipate our research and development expense to increase generally for the foreseeable future to support our clinical and manufacturing development of our product candidates.

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 \$66.9 million. We incurred underwriting discounts and commissions of \$2.1 million or \$0.858 per share as well as other expenses, resulting in estimated net proceeds of \$64.5 million.

[Table of Contents](#)

We anticipate that our existing capital resources as of July 31, 2005, together with the net proceeds from the August 2005 public offering, as well as the addition of our interest and investment income earned on available cash and marketable securities should provide us adequate resources to fund our operating expenses and capital requirements as currently expected for at least the next 24 months. We may pursue additional stock offerings, debt or other sources of funds to finance our operations.

The following table summarizes our contractual obligations at July 31, 2005 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 (amounts in millions):

| | Payments Due by Period | | | | |
|--|------------------------|------------------|-------------|-------------|-------------------|
| | Total | Less than 1 Year | 1 – 3 Years | 3 – 5 Years | More than 5 Years |
| Contractual obligations: | | | | | |
| Convertible senior notes | \$150.0 | \$ — | \$ — | \$ — | \$ 150.0 |
| Interest expense | 14.7 | 2.1 | 4.2 | 6.3 | 2.1 |
| Operating and capital leases | 13.3 | 2.5 | 4.7 | 5.3 | 0.8 |
| Total contractual obligations | \$178.0 | \$ 4.6 | \$ 8.9 | \$11.6 | \$ 152.9 |
| Commercial commitments: | | | | | |
| Clinical and manufacturing development | \$ 99.1 | \$ 39.2 | \$40.5 | \$19.4 | \$ — |
| Licenses | 6.7 | 2.4 | 2.8 | 1.0 | 0.5 |
| Research and development | 0.1 | 0.1 | — | — | — |
| Total commercial commitments | \$105.9 | \$ 41.7 | \$43.3 | \$20.4 | \$ 0.5 |

Contractual Obligations

Our contractual obligations include our \$150 million 1.375% Convertible Senior Notes due February 2012, or 1.375% Notes, our annual payments of approximately \$2.3 million for operating and capital leases, principally for facilities and equipment, and an open letter of credit of \$200,000 which serves as a security deposit on our facility in Cheshire, Connecticut.

Convertible Senior Notes

In January 2005 we sold \$150 million 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 \$1,000 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.

[Table of Contents](#)

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 \$42.91 per \$1,000 principal amount).

We incurred deferred financing costs related to this offering of the 1.375% Notes of approximately \$4.8 million, 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.

Capital Leases

We currently lease office equipment under capital lease agreements expiring in 2008. 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. The interest rate on the above capital lease is 5.625% and is imputed based on the lower of our incremental borrowing rate at the inception of each lease. Amortization and interest expense for the years ended July 31, 2005 and 2004 was \$55,000 and \$0, respectively.

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 has an initial term expiring in December 2010. At this site, we lease a total of 89,000 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 expected to remain 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 25,000 square feet of labs, office space and unimproved storage in San Diego, California. The lease 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 P&G Pharmaceuticals.

[Table of Contents](#)

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 eculizumab, was amended, or the Lonza Amendment, in April 2004. Under the Lonza Amendment, the facility in which Lonza will manufacture eculizumab is changed; the manufacturing capacity we are required to purchase is reduced; and future potential payments of \$10 million by us to Lonza relating to achievement of eculizumab sales milestones and of up to \$15 million payable by us relating to manufacturing yields achieved by Lonza are eliminated. In August 2004 we paid Lonza an additional \$3.5 million 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 Lonza Agreement, as amended by the Lonza Amendment, if we terminate the Lonza Agreement on or prior to September 30, 2006, we may be required to pay different amounts, depending on when the Lonza Agreement is terminated, which are between zero and approximately \$10 million and, 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.

P&G Pharmaceuticals Collaboration

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. Under the revised structure per the MOU, we and P&G share decision-making and responsibility for all future U.S. development and commercialization costs for pexelizumab, including clinical, manufacturing, marketing, and sales efforts. 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 will receive approximately 50% of the gross margin on U.S. sales, if any. P&G agreed to retain responsibility for future development and commercialization costs outside the U.S., with us receiving a royalty on sales outside the U.S., if any. We are responsible for royalties on certain third party intellectual property worldwide, if such intellectual property is necessary. Additionally, as part of the MOU, we will receive milestone payments for achieving specified development steps, regulatory filings and approvals.

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 sublicensee would be required to assume all of P&G's obligations under the collaboration.

We rely on P&G for the development, manufacture and potential commercialization of pexelizumab. Termination of our agreement by P&G or sublicense of its collaboration rights could cause significant delays in the development, manufacture and potential commercialization of pexelizumab and result in significant additional costs to us. 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 could amount to as much as \$8.0 million.

[Table of Contents](#)

Additional Payments

Additional payments, aggregating up to \$20 million, 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 \$3 million of these costs may be incurred in the next three years.

Taxes

For tax reporting purposes, as of July 31, 2005, we have available for federal tax reporting purposes, net operating loss carry forwards of approximately \$439.8 million which expire through 2025 (of which approximately \$27.4 million resulted from the exercise of nonqualified stock options). We also have federal and state research and development credit carry forwards of approximately \$16.1 million which begin to expire commencing in fiscal 2008. The Tax Reform Act of 1986 contains certain provisions that limit our 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 limitation provisions were triggered in 1995. For the years ended July 31 2005 and 2004, the limitation is approximately \$1.4 million annually. There is no future limitation as a result of this change in ownership.

Recently Issued Accounting Standards

In December 2004, the FASB issued SFAS No. 123(R) (revised 2004), "Share-Based Payment", or SFAS 123(R), which replaces SFAS No. 123, "Accounting for Stock-Based Compensation" and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values, beginning with the first annual period after June 15, 2005. Pursuant to revisions to SFAS No. 123(R) in April 2005 by the FASB, we are obligated to start expensing options at the commencement of our fiscal year on August 1, 2005. In addition, in March 2005, the FASB issued Staff Accounting Bulletin No. 107 (SAB 107) which is to provide guidance regarding the interaction between SFAS 123(R) and certain SEC rules and regulations and provide additional guidance regarding the valuation of share-based payment arrangements for public companies. We expect to implement SFAS 123(R) using the modified prospective application method.

In May 2005, the FASB issued SFAS 154, "Accounting Changes and Error Corrections", which replaces APB Opinion 20, "Accounting Changes" and SFAS 3, "Reporting Accounting Changes in Interim Financial Statements" and changes the requirements of the accounting for and reporting of a change in accounting principle. SFAS 154 applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. When a pronouncement includes specific transition provisions, those provisions should be followed. This statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005.

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 risk 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.

[Table of Contents](#)

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 July 31, 2005, we had an accumulated deficit of approximately \$448.1 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. 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.

We are subject to extensive government regulation; if we do not obtain regulatory approval for our drug products, we will not be able to sell our drug products.

We and our partners cannot sell or market our drugs 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. 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, whose approval can also be lengthy, expensive and highly uncertain. 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. Failure to 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; delay in approving or refusal to approve a product candidate; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution.

The FDA has granted “fast track” status for pexelizumab for use during CPB and for treatment of AMI, and for eculizumab in treatment of membranous nephritis. Although fast track status may expedite development and FDA review of an application, there can be no assurance that pexelizumab or eculizumab will be reviewed more expeditiously for their “fast-track” indications than would otherwise have been the case or will be approved promptly, or at all. Further, the FDA could revoke fast track status for pexelizumab or eculizumab.

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.

[Table of Contents](#)

We depend heavily on the success of our lead product candidates, eculizumab and pexelizumab, which are still under development. If we do not obtain FDA approval of our lead product candidates, or if FDA delays approval or narrows the indications for which we may market these product candidates, our business will be materially harmed.

We anticipate that in the near term our ability to generate revenues will depend on the successful development and commercialization of eculizumab and pexelizumab. The commercial success of our lead product candidates will depend on several factors, including the following: successful completion of our ongoing Phase III clinical trials for these product candidates; receipt of marketing approvals from the FDA and similar foreign regulatory authorities; establishing commercial manufacturing capabilities ourselves or through third party manufacturers; successfully launching commercial sales of the products; and acceptance of the products in the medical community and by third party payers.

If the data from our ongoing Phase III pivotal clinical trials for our lead product candidates are not satisfactory, we may not proceed with the filing of a biological license application, or BLA, for one or both of our lead product candidates or we may be forced to delay the filing. Even if the results of the ongoing pivotal trials appear satisfactory and we file a BLA, the FDA and similar foreign regulatory agencies may not accept our filing, may request additional information from us, including data from additional clinical trials, and, ultimately, may not grant marketing approval. Even if the FDA and similar foreign regulatory authorities do grant marketing approval for one or both of our product candidates, they may narrow the indications for which we are permitted to market one or both products, or may pose other restrictions on the use or marketing of the product. A narrowed indication or other restrictions may limit the market potential for the affected product. If we are not successful in commercializing one or both of our lead product candidates, or are significantly delayed or limited in doing so, our business will be materially harmed and we may need to curtail or cease operations.

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 SPA for each of our ongoing Phase III clinical programs for eculizumab and pexelizumab 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 of the product candidate. 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. In addition, the FDA has noted that it may require additional safety information before granting marketing approval. We would need to reevaluate any drug that did not test favorably and either alter the study, the drug or the dose and perform additional or repeat tests, or abandon the drug development project. 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.

[Table of Contents](#)

Clinical trials completed to date have not achieved their primary endpoints.

In September 2000, we announced the completion of enrollment in a Phase IIb trial of pexelizumab for the treatment of complications in patients after CABG with CPB including the reduction of the frequency and severity of myocardial infarctions and frequency of death. The primary therapeutic pre-set goal of the trial, referred to as the primary endpoint, was not achieved. However, in the pre-specified population that included approximately 90% of the patient population, (i.e. the 800 patients who had CABG surgery without valve surgery), those that received pexelizumab at the highest dose level experienced a statistically significant reduction in larger post-surgical heart attacks. Based on these results, in January 2002, we commenced enrollment of a Phase III clinical trial of pexelizumab in patients undergoing CABG with CPB. We completed the target patient enrollment of approximately 3,000 patients in February 2003. In August 2003, we disclosed preliminary results that indicated that the primary endpoint was not achieved with statistical significance. The primary endpoint in this Phase III trial was a composite of the incidence of death or myocardial infarction, measured at 30 days post-procedure, in patients undergoing CABG without simultaneous valve surgery.

We have concluded two Phase II studies with pexelizumab in AMI: one study in patients receiving angioplasty, a procedure for opening up narrowed or blocked arteries that supply blood to the heart, and the other in patients receiving thrombolytic therapy, a procedure for dissolving clots that block heart vessels. The angioplasty study, called COMMA, and the thrombolytic study, called COMPLY, completed patient enrollment in April 2002 and January 2002, respectively. Results from both studies were reported at the November 2002 annual meeting of the American Heart Association. In both studies, the primary endpoint of a reduction of myocardial infarction was not reached; however in the COMMA study, pexelizumab treatment was associated with a statistically significant, dose-dependent reduction in death.

In 2001, we announced the completion of a Phase IIa trial of eculizumab for the treatment of rheumatoid arthritis, or RA. The primary endpoint for this trial was met by the group of patients who received the mid-level, monthly dosing regimen of eculizumab, but patients who received higher or lower doses of eculizumab in the clinical trial did not achieve the primary endpoint. The primary endpoint in this Phase IIa trial was ACR 20 at 3.25 months.

In January 2004, we announced preliminary results of a Phase IIb study of eculizumab in approximately 350 RA patients. Results of the trial indicate that the primary endpoint was achieved with statistical significance in one of the dosing regimens (the monthly dosing arm), but not in the higher, bimonthly dosing arm.

Completion of these and other 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, and reduces the likelihood of timely development of and regulatory approval to market the product candidate.

[Table of Contents](#)

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. Also, 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.

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

- slow patient enrollment;
- 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;
- the failure of patients taking the placebo to continue to participate in our clinical trials;
- lack of effectiveness of the product candidate being tested; and
- lack of sufficient funds.

We may expand our business through new 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

[Table of Contents](#)

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.

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 we have sufficient capital to fund our operations and product development for at least twenty four months. We will need to raise additional capital before or after that time to complete the development and commercialization of our product candidates. We are currently conducting or initiating several clinical trials. Funding needs may shift between programs and potentially accelerate and increase if we initiate new pivotal trials for our product candidates, including any pivotal clinical trial of pexelizumab for AMI patients undergoing angioplasty. We rely heavily on P&G to fund development of pexelizumab. If P&G were to terminate the pexelizumab collaboration, we could have to raise additional capital or find new collaboration partners in order to continue the development of pexelizumab.

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 existence, terms and status of collaborative arrangements and strategic partnerships, such as our collaboration with 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;
- the time and cost necessary to obtain regulatory approvals;
- the time and cost necessary to further develop manufacturing processes, arrange for contract manufacturing or build manufacturing facilities and obtain the necessary regulatory approvals for those facilities;
- 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;
- changes in applicable governmental regulatory policies; and
- any new collaborative, licensing and 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.

[Table of Contents](#)

We are significantly leveraged.

On July 31, 2005, we had outstanding \$150 million principal amount of 1.375% convertible senior notes. These notes 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;
- 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.

If our collaboration with P&G is terminated or P&G reduces its commitment to our collaboration, our ability to develop and commercialize pexelizumab in the time expected, or at all, and our business would be harmed.

We rely heavily on P&G to perform development, obtain commercial manufacturing, and provide sales and marketing for pexelizumab. While we cannot assure you that pexelizumab will ever be successfully developed and commercialized, if P&G does not perform its obligations in a timely manner, or at all, our ability to commercialize pexelizumab will be significantly adversely affected. We rely on P&G to provide funding and additional resources for the development and commercialization of pexelizumab. These include funds and resources for:

- clinical development and clinical and commercial manufacturing;
- obtaining regulatory approvals; and
- sales, marketing and distribution efforts worldwide.

P&G has the right to terminate the collaboration or sublicense its collaboration rights at any time. Termination of our agreement with P&G would cause significant delays in the development of pexelizumab and result in significant additional development costs to us. If we were to continue development of pexelizumab following termination by P&G, we would need to fund the development and commercialization of pexelizumab on our own or identify a new development partner. We would need to develop or acquire replacement expertise in many areas necessary for the development and potential commercialization of pexelizumab, or enter into agreements with other companies with respect to those matters. We do not have the resources to replace some of the functions provided or funded by P&G. Accordingly, we might have to stop the development of pexelizumab or shift resources from other product development programs until alternative resources were obtained. Sublicense by P&G also could cause significant delays in the development of pexelizumab and result in substantial additional development costs to us. We might also have to repeat testing already completed with P&G. In addition, sublicense would introduce a new collaboration partner which could create new and additional risks to the development of pexelizumab that cannot be identified at this time.

[Table of Contents](#)

We cannot guarantee that P&G will devote the resources necessary to successfully develop and commercialize pexelizumab in a timely manner, if at all. Furthermore, P&G may devote the necessary resources, but we may still not successfully develop and commercialize pexelizumab.

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. This would divert funds or other resources from other parts of our business.

We cannot assure you that:

- current collaboration arrangements will be continued 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 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, including, but not limited to P&G, changes in our prospects, 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.

[Table of Contents](#)

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 two leading product candidates, eculizumab and pexelizumab, 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 pexelizumab and 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 pexelizumab and eculizumab. In respect to some of these patents, we have obtained licenses, or expect to obtain licenses. However, with regard to other patents, we have either determined in our judgment that:

- our products do not infringe the patents; or
- 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.

[Table of Contents](#)

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.

If the testing or use of our products harms people, 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 give rise to product liability claims against us. We might have to recall our products, if any, from the marketplace. Some of these risks are unknown at this time.

In addition, we may be sued by people who participate in our trials. A number of patients who participate in such trials are already very ill when they enter the trial. Any informed consents or waivers obtained from people who sign up for our trials may not protect us from liability or litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any covered liabilities. Moreover, we may not be able to maintain our insurance on acceptable terms. In addition, negative publicity relating 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.

Use of C5 Inhibitors, such as pexelizumab and eculizumab, is associated with an increased risk for infection with neisseria bacteria. One patient in our trials of eculizumab for the treatment of membranous nephritis became infected with neisseria bacteria. Serious cases of neisseria infection can result in brain damage, loss of limbs or parts of limbs, kidney failure, or death.

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.

[Table of Contents](#)

If we cannot manufacture our drug candidates in sufficient amounts at acceptable costs and on a timely basis, we may be unable to have the necessary materials for product testing, and later for potential sale in the market. Either event would harm our business.

For our drug trials, we need to produce sufficient amounts of product for testing. Our small manufacturing plant cannot manufacture enough of our product candidates for later stage clinical development or commercial supply. In addition, we do not have the capacity to produce more than one product candidate at a time. We depend on a few outside suppliers for manufacturing. 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. If we are unable to find an acceptable outside manufacturer on reasonable terms, we will have to divert our own resources to manufacturing, which may not be sufficient to produce the necessary quantity or quality of product. 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. We cannot assure you that we or our third-party collaborators will successfully comply with all of those 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 can not 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 can not 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. Inability to contract with third-party manufacturers on commercially reasonable terms, or failure or delay by our third-party manufacturers, if any, 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. If we are unable to establish and maintain commercial scale manufacturing within our planned time and cost parameters, sales of our products and our financial performance would be adversely affected.

Currently, we are relying on P&G to retain appropriate commercial-scale manufacturing for pexelizumab through one or more third-party manufacturers. P&G has contracted with Chiron Corporation for the commercial-scale manufacture of pexelizumab. The failure of P&G to obtain and maintain appropriate commercial-scale manufacturing for pexelizumab in accordance with all regulatory requirements on a timely basis, or at all, may prevent or impede the commercialization of pexelizumab. We have executed a commercial-scale product supply agreement with Lonza Biologics, plc 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 eculizumab. Due to the nature of the current market for third-party commercial manufacturing arrangements, many arrangements require substantial penalty payments by the customer for failure to use the manufacturing capacity contracted for. We could

[Table of Contents](#)

owe substantial penalty payments to Lonza if we were not to use the manufacturing capacity we contracted for, and we could be required to share on an equal basis with P&G substantial penalty payments owed by P&G for its failure to utilize the manufacturing capacity it contracted for with third-party manufacturers for the supply of pexelizumab. 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 sales or distribution personnel or capabilities. We have only recently established core pre-commercial marketing capabilities. If we are unable to continue developing those capabilities, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully sell 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. Currently, we are relying on P&G for sales, marketing and distribution of pexelizumab. P&G, or any future third-party collaborators, may not succeed at selling, marketing or distributing any of our future drug products.

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.

Our products, if commercialized, may be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if we cannot depend on governmental and private third-party payers to defray the cost of our products to the consumer. If these entities refuse to provide reimbursement with respect to our products or determine to provide an insufficient level of reimbursement, our products may be too costly for general use. Our profitability may be adversely impacted if we choose to offer our products at a reduced price. Any limitation on the use of our products or any decrease in the price of our products without a corresponding decrease in expenses will have a material adverse effect on our ability to achieve profitability.

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 the reimbursement for our products in foreign countries is limited.

Since our products will likely be too expensive for most patients to afford without health insurance coverage, adequate coverage and reimbursement by third-party payors is essential to our ability to successfully commercialize our product candidates. In particular, given a number of factors, including the limited PNH population, costs of manufacturing and commercialization, clinical costs and other historic and future costs, it is likely that the price of eculizumab, once established, will be prohibitively expensive without patient access to adequate health insurance coverage and reimbursement by third-party payors. If patients do not have access to adequate coverage or if third party payors do not provide reimbursement at a sufficient level it would likely have a material adverse effect on our business, financial condition or results of operation.

[Table of Contents](#)

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 Abbott Laboratories Inc., Adprotech Ltd., Avant Immunotherapeutics, Inc., Baxter International, Inc., Millennium Pharmaceuticals, Inc., Neurogen Corporation, Tanox, Inc., and XOMA, Ltd. have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. We are also aware that GlaxoSmithKline, plc, Merck & Co., Inc., and Pfizer, Inc. are also attempting to develop complement inhibitor therapies. Each of Cambridge Antibody Technology Group, plc, MorphoSys AG and Dyax Corporation has publicly announced intentions to develop therapeutic human antibodies from libraries of human antibody genes. Additionally, each of Abgenix, 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 before we are able even 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 a key man life insurance policy for Dr. Bell and 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 development objectives.

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 July 31, 2005, we had approximately \$440 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.

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

[Table of Contents](#)

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.

Based upon our review of the aggregate change in percentage ownership during the current testing period, we do not believe that we experienced a change in ownership within the meaning of section 382 as a result of the offering of our common stock in August 2005. However, such a determination is complex and there can be no assurance that the Internal Revenue Service could not successfully challenge our conclusion. Even if the offering of our common stock did not cause an ownership change to occur immediately, the issuance, directly or indirectly, of a relatively large number of shares in that offering may mean that we may not be able to engage in transactions involving the issuance or deemed issuance of stock within the subsequent three-year period without triggering an ownership change within the meaning of section 382. In addition, there are circumstances beyond our control, such as market purchases of our stock by investors who are existing 5% shareholders, or become 5% shareholders as a result of such purchases, which could result in an ownership change with respect to our stock. Thus, there can be no assurance that our future actions, or future actions by our stockholders, will not result in the occurrence of an ownership change, which may limit our use of the NOLs and negatively affect future cash flows.

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

Currently, we maintain approximately 20% of our cash and investments in financial instruments with original maturity dates of three months or less, 15% in financial instruments with original maturity dates of greater than three months and less than one year, and the remaining 65% 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 with a weighted average duration of approximately 4 months at July 31, 2005 would result in a \$600,000 decrease or increase in the fair value of our cash and investments.

Our outstanding long-term liabilities as of July 31, 2005 consisted of \$150.0 million of our 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. Although future borrowings may bear interest at a floating rate, and would therefore be affected by interest rate changes, we cannot reasonably estimate the effect and therefore do not believe that a change of 100 basis points in interest rates would have a material effect on our financial condition.

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.

[Table of Contents](#)

As of July 31, 2005, the market value of our \$150.0 million 1.375% convertible senior notes due February 1, 2012, based on quoted market prices, was estimated at \$153.0 million.

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 July 31, 2005. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of July 31, 2005, 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 Annual 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 July 31, 2005. Based on the assessment, management has concluded that, as of July 31, 2005, our internal control over financial reporting is effective.

[Table of Contents](#)

Management's assessment of the effectiveness of our internal control over financial reporting as of July 31, 2005 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 our fiscal quarter ended July 31, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None

[Table of Contents](#)

PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

Portions of the responses required by this item will be set forth in our definitive Proxy Statement under the caption “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 are incorporated herein by reference to our Proxy Statement.

Set forth below is certain information regarding our executive officers, directors and key employees:

| <u>Name</u> | <u>Age</u> | <u>Position with Alexion</u> |
|---|------------|---|
| Max Link, Ph.D. ^{(1) (4)} | 65 | Chairman of the Board of Directors |
| Leonard Bell, M.D. ⁽⁵⁾ | 47 | Chief Executive Officer, Secretary, Treasurer, Director |
| David W. Keiser ⁽⁵⁾ | 54 | President and Chief Operating Officer, Director |
| Stephen P. Squinto, Ph.D. ⁽⁵⁾ | 49 | Executive Vice President and Head of Research |
| Katherine S. Bowdish, Ph.D. | 48 | Senior Vice President, Antibody Discovery, and President, Alexion Antibody Technologies |
| Thomas I.H. Dubin, J.D. ⁽⁵⁾ | 43 | Senior Vice President and General Counsel |
| Christopher F. Mojcik, M.D., Ph.D. ⁽⁵⁾ | 45 | Senior Vice President, Clinical Development |
| Nancy C. Motola, Ph.D. | 53 | Senior Vice President, Regulatory Affairs and Quality |
| Scott A. Rollins, Ph.D. | 42 | Senior Vice President, Drug Development and Project Management |
| Russell P. Rother, Ph.D. | 44 | Senior Vice President, Discovery Research |
| Vikas Sinha ⁽⁵⁾ | 42 | Senior Vice President and Chief Financial Officer |
| Paul W. Finnegan M.D., M.B.A. | 45 | Vice President, Commercial Operations and Development |
| Barry P. Luke | 47 | Vice President, Finance, Assistant Secretary |
| Daniel N. Caron | 42 | Executive Director, Operations and Engineering |
| M. Stacy Hooks, Ph.D. | 38 | Executive Director, Manufacturing and Technical Services |
| Joseph A. Madri, Ph.D., M.D. ^{(2) (4)} | 59 | Director |
| Larry L. Mathis ^{(1) (3)} | 62 | Director |
| R. Douglas Norby ^{(1) (3)} | 70 | Director |
| Alvin S. Parven ^{(2) (3)} | 65 | Director |
| Ruedi E. Waeger, Ph.D. ^{(2) (4)} | 62 | Director |

(1) Member of our Audit Committee of the Board of Directors.

(2) Member of our Compensation Committee of the Board of Directors.

(3) Member of our Nominating and Corporate Governance Committee of the Board of Directors.

(4) Member of our Compliance and Quality Committee of the Board of Directors

(5) Officer, for purposes of Section 16 of the Securities Exchange Act of 1934.

Each director will hold office until the next annual meeting of stockholders and until his or her successor is elected and qualified or until his or her earlier resignation or removal. Each officer serves at the discretion of the board of directors. Dr. Bell, Mr. Keiser, Dr. Squinto, and Mr. Sinha are each a party to an employment agreement with us.

[Table of Contents](#)

Biographical details of the following persons are incorporated by reference herein to the section of this Report in Part I under the heading “EXECUTIVE OFFICERS AND KEY EMPLOYEES OF THE COMPANY”: *Leonard Bell, M.D., David W. Keiser, Stephen P. Squinto, Ph.D., Katherine S. Bowdish, Ph.D., Thomas I.H. Dubin J.D., Christopher F. Mojcik, M.D., Ph.D., Nancy C. Motola, Ph.D., Scott A. Rollins, Ph.D., Russell P. Rother, Ph.D., Vikas Sinha, Paul W. Finnegan, M.D., M.B.A., Barry P. Luke, Daniel N. Caron and M. Stacy Hooks, Ph.D.*

Max Link, Ph.D. has been the Chairman of our board of directors since December 2002 and a director of Alexion since April 1992. From March 2001 to September 2003, Dr. Link was Chairman of the Board and CEO of Centerpulse AG, a medical implant company. From May 1993 to June 1994, Dr. Link was Chief Executive Officer of Corange (Bermuda), the parent company of Boehringer Mannheim Therapeutics, Boehringer Mannheim Diagnostics and DePuy Orthopedics. From 1992 to 1993, Dr. Link was Chairman of the Board of Sandoz Pharma, Ltd., a manufacturer of pharmaceutical products. From 1987 to 1992, Dr. Link was the Chief Executive Officer of Sandoz Pharma and a member of the Executive Board of Sandoz, Ltd., Basel. Prior to 1987, Dr. Link served in various capacities with the United States operations of Sandoz, including as President and Chief Executive Officer. Dr. Link is the chairman of the board of directors of Protein Design Labs, Inc., CytRx Corporation, and Celsion Corporation, and is also a director of Access Pharmaceuticals, Inc., Discovery Labs, Inc., and Human Genome Sciences, Inc., each a publicly held pharmaceutical and/or life-science company. Dr. Link holds a Ph.D. in economics from University of St. Gallen (Switzerland).

Joseph A. Madri, Ph.D., M.D. is a founder of Alexion and has been a director of Alexion since February 1992. Since 1980, Dr. Madri has been on the faculty of the Yale University School of Medicine and is currently a Professor of Pathology. Dr. Madri serves on the editorial boards of numerous scientific journals and he is the author of over 210 scientific publications. Dr. Madri works in the areas of regulation of angiogenesis, vascular cell-matrix interactions, cell-cell interactions, lymphocyte-endothelial cell interactions and endothelial and smooth muscle cell biology and has been awarded a Merit award from the National Institutes of Health. Dr. Madri received his B.S. and M.S. in Biology from St. John’s University and M.D. and Ph.D. in Biological Chemistry from Indiana University.

Larry L. Mathis has been a director of Alexion since March 2004. Since 1998, Mr. Mathis has served as an executive consultant with D. Petersen & Associates providing counsel to select clients on leadership strategies, integrated systems and governance. For the 27 years prior to joining D. Petersen & Associates, Mr. Mathis served in various capacities within The Methodist Hospital System, in Houston, Texas – an organization comprising 16 corporations and 37 hospital affiliates in the U.S. and abroad. From 1997 to 1998, Mr. Mathis served as a consultant to the Chairman of the Board of The Methodist Hospital System. Prior to that, he was President and Chief Executive Officer, as well as a member of the Board of Directors, from 1983 to 1997. Mr. Mathis received a Master’s degree in Health Administration from Washington University in St. Louis, and a Bachelor of Arts in Social Sciences from Pittsburg State University in Kansas.

R. Douglas Norby has been a director of Alexion since September 1999. Since July 2003, Mr. Norby has been Sr. Vice-President and Chief Financial Officer of Tessera, Inc., a provider of intellectual property for advanced semiconductor packaging. From March 2002 to February 2003, Mr. Norby served as Senior Vice President and Chief Financial Officer of Zambel, Inc., a data storage systems company. From December 2000 to March 2002, Mr. Norby served as Senior Vice President and Chief Financial Officer of Novalux, Inc., a manufacturer of lasers for optical networks. From 1996 until December 2000, Mr. Norby served as Executive Vice President and Chief Financial Officer of LSI Logic Corporation, a

[Table of Contents](#)

semiconductor company, and he has also served as a director of LSI Logic Corporation since 1993. From July 1993 until November 1996, he served as Senior Vice President and Chief Financial Officer of Mentor Graphics Corporation, a software company. Mr. Norby served as President of Phametrix Corporation, a drug delivery company, from July 1992 to September 1993, and from 1985 to 1992, he was President and Chief Operating Officer of Lucasfilm, Ltd., an entertainment company. From 1979 to 1985, Mr. Norby was Senior Vice President and Chief Financial Officer of Syntex Corporation, a pharmaceutical company. Mr. Norby is a director of LSI Corporation, STATS Chip PAC, Ltd, a semi-conductor company, Jazz Semiconductor, Inc., and Engenio Information Systems, Inc., a data storage systems company. Mr. Norby received a B.A. in Economics from Harvard University and an M.B.A. from Harvard Business School.

Alvin S. Parven has been a director of Alexion since May 1999. Since 1997, Mr. Parven has been President of ASP Associates, a management and strategic consulting firm. From 1994 to 1997, Mr. Parven was Vice President at Aetna Business Consulting, reporting to the Office of the Chairman of Aetna. From 1987 to 1994, Mr. Parven was Vice President, Operations at Aetna Health Plans. Prior to 1987, he served in various capacities at Aetna including Vice President, Pension Services from 1983 to 1987. Mr. Parven received his B.A. from Northeastern University.

Ruedi E. Waeger, Ph. D. has been a director of Alexion since March 2005. Dr. Waeger has spent the past 30 years in the pharmaceutical and therapeutic protein industry. Most recently, he was President and Chief Executive Officer of Aventis Behring L.L.C., a global plasma therapeutics product business which was acquired by CSL Ltd last year to form ZLB Behring. While at Aventis Behring, Dr. Waeger played a key role in guiding the company as it refined its product pipeline and extensive manufacturing facilities. Dr. Waeger became the head of Aventis Behring following the merger of the owners of Centeon L.L.C., a leader in plasma proteins, where Dr. Waeger was Chief Executive Officer. Prior thereto, Dr. Waeger was President and Chief Executive Officer of ZLB Central Laboratories, Blood Transfusion Service of Swiss Red Cross and before that spent more than 20 years at Sandoz Ltd., where he had consecutive worldwide responsibilities for Strategic Research and Development Planning, Human Resource Management, and Marketing, including responsibility for three global product launches. Dr. Waeger currently sits on the Boards of Guidant Corporation, Talecris Biotherapeutics, Inc. and Eximas Pharmaceutical Corporation. He earned a Ph.D. in Biochemistry from the Swiss Federal Institute of Technology.

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.

AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has a separate audit committee which was established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934. Currently, the members of the audit committee are Max Link, Larry L. Mathis and R. Douglas Norby. Our board of directors has determined that Mr. Norby is an “audit committee financial expert.” Each of Dr. Link, Mr. Mathis and Mr. Norby is an independent director, as that term is used in Item 7(d)(3)(iv) of Schedule 14A under the Securities Exchange Act of 1934. Mr. Norby is Chairman of the Audit Committee.

[Table of Contents](#)

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 National Market. Our Code of Ethics is located on our website (www.alexionpharm.com). Any amendments or waivers to our Code of Ethics will be promptly disclosed on our website 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 following table sets forth certain information with respect to the beneficial ownership of our common stock as of October 1, 2005, except as otherwise noted in the footnotes: (1) each person known by us to own beneficially more than 5% percent of our outstanding common stock; (2) each director and each named executive officer; and (3) all directors and Section 16 officers of Alexion as a group.

| <u>Name and Address of Beneficial Owner (1)</u> | <u>Number of Shares of Common Stock Beneficially Owned (2)</u> | <u>Percentage of Outstanding Shares of Common Stock</u> |
|--|--|---|
| Fidelity Management & Research Company 82 Devonshire Street Boston, MA 02109 (3) | 2,793,290 | 9.1% |
| Sectoral Asset Management, Inc. 1000 Sherbrooke St Montréal, Canada (3) | 2,210,840 | 7.2% |
| T. Rowe Price Associates, Inc. 100 E. Pratt St. Baltimore, MD 21202 (3) | 2,036,700 | 6.6% |
| Sigma Capital Management LLC 812 Carrington Drive Raleigh, NC 27615 (3) | 1,861,305 | 6.1% |
| Ziff Brothers Investments, LLC 55 Railroad Ave Greenwich, CT (4) | 1,677,773 | 5.4% |
| Leonard Bell, M.D. (5) | 849,654 | 2.7% |

[Table of Contents](#)

| Name and Address of Beneficial Owner (1) | Number of Shares of Common Stock Beneficially Owned (2) | Percentage of Outstanding Shares of Common Stock |
|--|---|--|
| David W. Keiser (6) | 265,930 | * |
| Stephen P. Squinto, Ph.D. (7) | 144,875 | * |
| Thomas I.H. Dubin, J.D. (8) | 114,875 | * |
| Christopher F. Mojcik, M.D., Ph.D. (9) | 107,562 | * |
| Joseph Madri, Ph.D., M.D. (10) | 101,792 | * |
| Max Link, Ph.D. (11) | 71,615 | * |
| R. Douglas Norby (12) | 50,292 | * |
| Alvin S. Parven (13) | 49,192 | * |
| Vikas Sinha (14) | 20,000 | * |
| Larry L. Mathis (15) | 10,625 | * |
| Ruedi E. Waeger, Ph. D. (16) | 0 | * |
| All directors and Section 16 officers as a group (12 persons) (17) | 1,786,412 | 5.6% |

* Less than one percent.

(1) Unless otherwise indicated, the address of all persons is 352 Knotter Drive, Cheshire, Connecticut 06410.

(2) To our knowledge, except as set forth below, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them, subject to community property laws where applicable and the information contained in the footnotes in this table.

(3) These figures are based upon information set forth in Schedule 13F dated June 30, 2005.

(4) This figure is based upon information set forth in Schedule 13G dated January 28, 2005.

(5) Includes 549,093 shares of common stock that may be acquired upon the exercise of options within 60 days of October 1, 2005 and 300 shares, in aggregate, held in the names of Dr. Bell's three children. Excludes 71,669 shares obtainable through the exercise of options, granted to Dr. Bell, which are not exercisable within 60 days of October 1, 2005 and 90,000 shares held in trust for Dr. Bell's children. Dr. Bell disclaims beneficial ownership of the shares held in the names of his children.

(6) Includes 196,130 shares of common stock which may be acquired upon the exercise of options within 60 days of October 1, 2005 and 300 shares, in aggregate, held in the names of Mr. Keiser's three children. Excludes 43,875 shares obtainable through the exercise of options, granted to Mr. Keiser, which are not exercisable within 60 days of October 1, 2005. Mr. Keiser disclaims beneficial ownership of the shares held in the names of his minor children.

(7) Includes 140,875 shares of common stock which may be acquired upon the exercise of options within 60 days of October 1, 2005. Excludes 40,125 shares obtainable through the exercise of options, granted to Dr. Squinto, which are not exercisable within 60 days of October 1, 2005.

(8) Includes 99,875 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of October 1, 2005. Excludes 33,125 shares obtainable through the exercise of options granted to Mr. Dubin, which are not exercisable within 60 days of October 1, 2005.

[Table of Contents](#)

- (9) Includes 104,562 shares of common stock, which may be acquired upon the exercise of options within 60 days of October 1, 2005. Excludes 37,438 shares obtainable through the exercise of options granted to Dr. Mojcik, which are not exercisable within 60 days of October 1, 2005.
- (10) Includes 46,792 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of October 1, 2005. Excludes 10,708 obtainable through the exercise of options granted to Dr. Madri, which are not exercisable within 60 days of October 1, 2005.
- (11) Includes 28,958 shares of common stock which may be acquired upon the exercise of options within 60 days of October 1, 2005. Excludes 10,708 shares obtainable through the exercise of options granted to Dr. Link, which are not exercisable within 60 days of October 1, 2005.
- (12) Includes 50,292 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of October 1, 2005. Excludes 10,708 shares obtainable through the exercise of options granted to Mr. Norby, which are not exercisable within 60 days of October 1, 2005.
- (13) Includes 49,192 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of October 1, 2005. Excludes 10,708 shares obtainable through the exercise of options granted to Mr. Parven, which are not exercisable within 60 days of October 1, 2005.
- (14) Includes 0 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of October 1, 2005. Excludes 85,000 shares obtainable through the exercise of options granted to Mr. Sinha, which are not exercisable within 60 days of October 1, 2005.
- (15) Includes 9,625 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of October 1, 2005. Excludes 9,875 shares obtainable through the exercise of options granted to Mr. Mathis, which are not exercisable within 60 days of October 1, 2005.
- (16) Includes 0 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of October 1, 2005. Excludes 12,000 shares obtainable through the exercise of options granted to Dr. Waeger, which are not exercisable within 60 days of October 1, 2005.
- (17) Consists of shares beneficially owned by Drs. Bell, Link, Madri, Mojcik, Squinto, and Waeger and Messrs. Dubin, Keiser, Mathis, Norby and Sinha. Includes 1,275,394 shares of common stock, which may be acquired upon the exercise of options within 60 days of October 1, 2005.

EQUITY COMPENSATION PLAN INFORMATION

The following table provides information about shares of our common stock that may be issued upon the exercise of options and rights under all of our existing equity compensation plans as of July 31, 2005.

| <u>Plan Category</u> | <u>Number of shares of common stock to be issued upon exercise of outstanding options (2)</u> | <u>Weighted-average exercise price of outstanding options</u> | <u>Number of shares of common stock remaining available for future issuance under equity compensation plans</u> |
|--|---|---|---|
| Equity compensation plans approved by stockholders (1) | 4,694,582 | \$ 23.24 | 2,441,828 |
| Equity compensation plans not approved by stockholders | — | — | — |

(1) Reflects aggregate options outstanding and available for issuance under our 2004 Incentive Plan.

[Table of Contents](#)

- (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.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

In June and October 1992, we entered into patent licensing agreements with Oklahoma Medical Research Foundation, or OMRF, and Yale University, or Yale. The agreements provide that we will pay to these institutions royalties based on sales of products incorporating technology licensed there under and also license initiation fees, including annual minimum royalties that increase in amount based on the status of product development and the passage of time. Under policies of OMRF and Yale, the individual inventors of patents are entitled to receive a percentage of the royalties and other license fees received by the licensing institution. Some of our founders and scientific advisors are inventors under patent and patent applications, including Dr. Bell, one of our directors and our Chief Executive Officer, Dr. Madri, one of our directors, Dr. Squinto, Executive Vice President and Head of Research, and Dr. Rollins, Senior Vice President, Drug Development and Project Management, with respect to patent applications licensed from Yale and therefore, are entitled to receive a portion of royalties and other fees payable by us.

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 fiscal year covered by this Annual Report on Form 10-K, and is incorporated herein by reference to our Proxy Statement.

Item 15(a) 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)

Table of Contents

- 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)
- 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)
- 10.1 Employment Agreement, dated October 20, 2003, between the Company and Dr. Leonard Bell. (10)
- 10.2 Employment Agreement, dated October 20, 2003, between the Company and David W. Keiser. (10)
- 10.3 Employment Agreement, dated October 20, 2003, between the Company and Dr. Stephen P. Squinto. (10)
- 10.4 Administrative, Research and Development Facility Lease, dated May 9, 2000, between the Company and WE Knotter L.L.C.(3)
- 10.5 Company's 1992 Stock Option Plan, as amended. (9)
- 10.6 Company's 2000 Stock Option Plan, as amended. (12)
- 10.7 Company's 1992 Outside Directors Stock Option Plan, as amended. (5)
- 10.8 Company's 2004 Incentive Plan. (14)
- 10.9 Exclusive License Agreement dated as of June 19, 1992 among the Company, Yale University and Oklahoma Medical Research Foundation. (2)
- 10.10 License Agreement dated as of September 30, 1992 between the Company and Yale University, as amended July 2, 1993. (2)+
- 10.11 Exclusive Patent License Agreement dated April 21, 1994 between the Company and the National Institutes of Health. (2)+
- 10.12 License Agreement dated as of January 10, 1995 between the Company and Yale University. (2)+
- 10.13 License Agreement dated as of May 27, 1992 between the Company and Yale University, as amended September 23, 1992. (2)+

Table of Contents

- 10.14 License Agreement dated March 27, 1996 between the Company and Medical Research Council. (5)+
- 10.15 License Agreement dated May 8, 1996 between the Company and Enzon, Inc. (5)+
- 10.16 Asset Purchase Agreement date as of February 9, 1999 between the Company and United States Surgical Corporation. (6)
- 10.17 Collaboration Agreement dated January 25, 1999 between the Company and the Procter & Gamble Company, as amended. (6)+
- 10.18 Binding Memorandum of Understanding dated December 11, 2001 between the Company and the Procter & Gamble Company. (7)+
- 10.19 Research and Development Facility lease, dated February 1, 2002, between the Company and PMSI SRF L.L.C. (8)
- 10.20 Large-Scale Product Supply Agreement, dated December 18, 2002, between the Company and Lonza Biologics plc., as amended. (13)+
- 10.21 Industrial Real Estate lease, dated January 1, 2003, between the Company and SP-K Development, LLC. (9)
- 10.22 Co-Development and Co-Commercialization Agreement between the Company and XOMA (US) LLC, dated December 17, 2003. (11)+
- 10.23 Employment Agreement, dated July 19, 2005, between the Company and Vikas Sinha. (15)
- 10.24 Form of Stock Option Agreement for Directors. (14)
- 10.25 Form of Stock Option Agreement for Executive Officers (Form A). (22)
- 10.26 Form of Stock Option Agreement for Executive Officers (Form B). (22)
- 10.27 Form of Restricted Stock Award Agreement for Executive Officers (Form A). (23)
- 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.
- 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.

Table of Contents

- 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 Annual Report on Form 10-K for the fiscal year ended July 31, 2003.
 - (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.

[Table of Contents](#)

- (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.

+ Confidential treatment was granted for portions of such document.

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: October 11, 2005

By: /s/ DAVID W. KEISER

David W. Keiser
President and Chief Operating Officer
Dated October 11, 2005

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.

| | | |
|--|---|------------------|
| <u>/s/ LEONARD BELL</u> Leonard Bell, M.D. | Chief Executive Officer, Secretary, Treasurer and Director (principal executive officer) | October 11, 2005 |
| <u>/s/ DAVID W. KEISER</u> David W. Keiser | President, Chief Operating Officer and Director | October 11, 2005 |
| <u>/s/ VIKAS SINHA</u> Vikas Sinha | Senior Vice President and Chief Financial Officer (principal financial officer) | October 11, 2005 |
| <u>/s/ BARRY P. LUKE</u> Barry P. Luke | Vice President, Finance (principal accounting officer) | October 11, 2005 |
| <u>/s/ MAX LINK</u> Max Link, Ph.D. | Chairman of the Board of Directors | October 11, 2005 |
| <u>/s/ LARRY L. MATHIS</u> Larry L. Mathis | Director | October 11, 2005 |
| <u>/s/ JOSEPH A. MADRI</u> Joseph A. Madri, Ph.D., M.D. | Director | October 11, 2005 |
| <u>/s/ R. DOUGLAS NORBY</u> R. Douglas Norby | Director | October 11, 2005 |
| <u>/s/ ALVIN S. PARVEN</u> Alvin S. Parven | Director | October 11, 2005 |
| <u>/s/ RUEDI E. WAEGER</u> Ruedi E. Waeger, Ph.D. | Director | October 11, 2005 |

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Consolidated Financial Statements
July 31, 2005 and 2004

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Contents
July 31, 2005 and 2004

| | <u>Page(s)</u> |
|---|----------------|
| Report of Independent Registered Public Accounting Firm | F-2 |
| Consolidated Financial Statements | |
| Consolidated Balance Sheets | F-4 |
| Consolidated Statements of Operations | F-5 |
| Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Loss | F-6 |
| Consolidated Statements of Cash Flows | F-7 |
| Notes to Consolidated Financial Statements | F-9 to F-27 |

[Table of Contents](#)

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
of Alexion Pharmaceuticals, Inc.:

We have completed an integrated audit of Alexion Pharmaceuticals, Inc.'s 2005 consolidated financial statements and of its internal control over financial reporting as of July 31, 2005 and audits of its 2004 and 2003 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 at July 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three 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.

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 July 31, 2005 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 July 31, 2005, 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

[Table of Contents](#)

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.

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.

PricewaterhouseCoopers LLP
Hartford, Connecticut
October 4, 2005

[Table of Contents](#)**Alexion Pharmaceuticals, Inc.**
Consolidated Balance Sheets
July 31, 2005 and 2004
(amounts in thousands)

| | 2005 | 2004 |
|---|-------------------|-------------------|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | \$ 46,951 | \$ 113,224 |
| Marketable securities | 148,453 | 153,277 |
| Prepaid expenses and other current assets | 5,758 | 9,832 |
| Total current assets | 201,162 | 276,333 |
| Property, plant and equipment, net | 11,546 | 11,336 |
| Property, plant and equipment held for sale | — | 450 |
| Goodwill, net | 19,954 | 19,954 |
| Prepaid manufacturing costs | 10,600 | 9,500 |
| Other assets | 4,860 | 2,002 |
| Total Assets | \$ 248,122 | \$ 319,575 |
| LIABILITIES AND STOCKHOLDERS EQUITY | | |
| CURRENT LIABILITIES | | |
| Notes payable | \$ — | \$ 3,920 |
| Accounts payable | 7,455 | 3,973 |
| Accrued expenses | 16,364 | 11,004 |
| Deferred revenue | 820 | 588 |
| Deferred research and development costs | — | 188 |
| Current portion of obligations under capital lease | 75 | — |
| Total current liabilities | 24,714 | 19,673 |
| Obligations under capital lease | 149 | — |
| Deferred revenue, less current portion | 5,588 | 6,177 |
| Deferred research and development costs, less current portion | — | 1,203 |
| Convertible notes | 150,000 | 120,000 |
| Total Liabilities | 180,451 | 147,053 |
| COMMITMENTS AND CONTINGENCIES | | |
| STOCKHOLDERS' EQUITY | | |
| Preferred stock, \$.0001 par value; 5,000 shares authorized, no shares issued or outstanding | — | — |
| Common Stock, \$.0001 par value; 145,000 shares authorized; 28,227 and 27,557 shares issued at July 31, 2005 and 2004, respectively | 3 | 3 |
| Additional paid-in capital | 518,883 | 512,827 |
| Treasury Stock, at cost, 37 shares at July 31, 2005 and 2004, respectively | (600) | (600) |
| Accumulated other comprehensive loss | (566) | (347) |
| Deferred stock-based compensation expense | (1,938) | — |
| Accumulated deficit | (448,111) | (339,361) |
| Total Stockholders' Equity | 67,671 | 172,522 |
| Total Liabilities and Stockholders' Equity | \$ 248,122 | \$ 319,575 |

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

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Consolidated Statements of Operations
For the Years Ended July 31, 2005, 2004 and 2003
(amounts in thousands, except per share amounts)

| | 2005 | 2004 | 2003 |
|--|-------------|------------|------------|
| CONTRACT RESEARCH REVENUES | \$ 1,064 | \$ 4,609 | \$ 877 |
| OPERATING EXPENSES | | | |
| Research and development | 91,388 | 59,840 | 71,042 |
| General and administrative | 18,951 | 14,459 | 10,869 |
| Impairment of fixed assets | — | 760 | 2,560 |
| Total operating expenses | 110,339 | 75,059 | 84,471 |
| Operating loss | (109,275) | (70,450) | (83,594) |
| OTHER INCOME AND EXPENSE | | | |
| Investment income | 5,266 | 3,373 | 5,809 |
| Interest expense | (6,125) | (7,709) | (7,694) |
| Gain from extinguishment of note payable | 3,804 | — | — |
| Loss on early extinguishment of debt | (3,185) | — | — |
| Loss before state tax benefit | (109,515) | (74,786) | (85,479) |
| STATE TAX BENEFIT | 765 | 691 | 1,012 |
| Net Loss | \$(108,750) | \$(74,095) | \$(84,467) |
| BASIC AND DILUTED LOSS PER SHARE DATA | | | |
| Net loss per share | \$ (3.90) | \$ (3.43) | \$ (4.64) |
| SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS PER COMMON SHARE | 27,852 | 21,622 | 18,209 |

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
For the Years Ended July 31, 2005, 2004 and 2003
(amounts in thousands, except per share amounts)

| | Common Stock | | Additional Paid- In Capital | Treasury Stock at Cost | | Other Comprehensive Income (Loss) | Deferred Stock-Based Compensation | Accumulated Deficit | Total Stockholders Equity |
|--|--------------|--------|--------------------------------|------------------------|----------|--------------------------------------|--------------------------------------|------------------------|------------------------------|
| | Shares | Amount | | Shares | Amount | | | | |
| Balances, July 31, 2002 | 18,241 | \$ 2 | \$ 385,197 | 37 | \$ (600) | \$ 1,678 | \$ — | \$ (180,799) | \$ 205,478 |
| Net loss | — | — | — | — | — | — | — | (84,467) | (84,467) |
| Net change in unrealized gains on marketable securities | — | — | — | — | — | (1,026) | — | — | (1,026) |
| Comprehensive loss | — | — | — | — | — | — | — | — | (85,493) |
| Issuance of common stock from exercise of options | 16 | — | 155 | — | — | — | — | — | 155 |
| Noncash compensation expense related to grant of stock options | — | — | 146 | — | — | — | — | — | 146 |
| 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 \$ 7,300 | 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 stocked-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 |

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

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
For the Years Ended July 31, 2005, 2004 and 2003
(amounts in thousands)

| | 2005 | 2004 | 2003 |
|---|------------------|-------------------|------------------|
| CASH FLOWS FROM OPERATING ACTIVITIES: | | | |
| Net loss | \$(108,750) | \$ (74,095) | \$ (84,467) |
| Adjustments to reconcile net loss to net cash used by operating activities: | | | |
| Impairment of fixed assets | — | 760 | 2,560 |
| Gain from extinguishment of note payable | (3,804) | — | — |
| Depreciation and amortization | 3,682 | 3,593 | 3,726 |
| Stock-based compensation expense | 375 | 106 | 146 |
| Write off of deferred financing costs | 1,212 | — | — |
| Changes in operating assets and liabilities | | | |
| Prepaid expenses and other assets | 4,075 | (2,969) | (2,261) |
| Prepaid manufacturing costs | (1,100) | 500 | (7,250) |
| Accounts payable | 3,482 | (412) | (1,133) |
| Accrued expenses | 5,693 | (279) | 28 |
| Deferred revenue | (357) | (588) | (545) |
| Deferred research and development costs | (1,391) | 1,391 | — |
| Net cash used by operating activities | <u>(96,883)</u> | <u>(71,993)</u> | <u>(89,196)</u> |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | | |
| Purchase of marketable securities | (508,818) | (168,952) | (114,116) |
| Proceeds from maturity or sale of marketable securities | 513,423 | 205,242 | 183,534 |
| Purchase of property, plant and equipment | (2,980) | (3,135) | (3,070) |
| Purchase of patents and license technology | — | (5) | (37) |
| Net cash provided by investing activities | <u>1,625</u> | <u>33,150</u> | <u>66,311</u> |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | | |
| Proceeds from convertible debt offering | 150,000 | — | — |
| Convertible debt issuance costs | (4,758) | — | — |
| Redemption of convertible notes | (120,000) | — | — |
| Net proceeds from issuance of common stock | 3,743 | 127,223 | 155 |
| Net cash provided by financing activities | <u>28,985</u> | <u>127,223</u> | <u>155</u> |
| Net change in cash and cash equivalents | (66,273) | 88,380 | (22,730) |
| Cash and cash equivalents at beginning of year | 113,224 | 24,844 | 47,574 |
| Cash and cash equivalents at end of year | <u>\$ 46,951</u> | <u>\$ 113,224</u> | <u>\$ 24,844</u> |

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

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

1. Organization and Summary of Significant Accounting Policies

Business

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

We have incurred consolidated losses since inception and have had no product sales to date. We will continue to seek financing to fund operating losses, and if deemed appropriate, 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 will 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.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Alexion Pharmaceuticals, Inc. and its wholly-owned subsidiaries, Alexion Antibody Technologies (“AAT”) and Columbus Farming Corporation (“CFC”). Intercompany balances and transactions have been eliminated in consolidation.

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.

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.

Property, Plant and Equipment

Property, plant, and equipment are recorded at original cost. Depreciation and amortization on plant and equipment is computed on a straight-line basis over the estimated useful live of the assets.

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.

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. For the year ended July 31, 2005, there were no impairment charges. For the years ended July 31, 2004 and 2003, impairment charges were \$760 and \$2,560, respectively.

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

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 charge resulted upon the adoption of this standard or as a result of the Company's annual impairment assessment.

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. (See Note 10)

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 agreements 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.

Up-front, non-refundable license fees received in connection with collaboration 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, 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 certain research agreements 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.

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

Stock-Based Compensation

We account for stock options and restricted stock utilizing the intrinsic value method in accordance with Accounting Principles Board Opinion (“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. We grant incentive and non-qualified stock options for a fixed number of shares to employees with an exercise price equal to the fair market value of the shares at the date of grant. We have also issued restricted stock to consultants and key employees and record an expense over the vesting periods. We have adopted the disclosure only provisions of SFAS No. 123, “Accounting for Stock-Based Compensation” as amended by SFAS 148, “Accounting for Stock-Based Compensation” – Transition and Disclosure.” The issuance of SFAS No. 123(R) will significantly change the way we account for grants of stock options. This new pronouncement and its potential impact are discussed in the section titled “Recently Issued Accounting Pronouncements.”

We also, on occasion, grant stock options to consultants in accordance with Emerging Issues Task Force (“EITF”) 96-18, “Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring or in Conjunction with Selling, Goods or Services” and accordingly recognize compensation expense equal to the fair value of such awards and amortize such expense over the performance period. The fair value of each award is estimated using the Black-Scholes model at each reporting period until performance is complete with changes in fair value being recorded as compensation expense.

As of July 31, 2005 compensation expense has not been recognized for outstanding stock option grants, except as noted above. Had compensation cost for our outstanding stock option grants been determined based on the fair value at the grant date for awards in 2005, 2004, and 2003 consistent with the fair value provisions of SFAS No. 123, our net loss and loss per share would have been adjusted to the pro forma amounts indicated below:

| | <u>2005</u> | <u>2004</u> | <u>2003</u> |
|---|--------------------|-------------------|-------------------|
| Net loss, as reported | \$(108,750) | \$(74,095) | \$(84,467) |
| Add: Stock-based employee compensation expense included in reported net loss | 217 | 67 | 96 |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards | (10,276) | (14,552) | (15,433) |
| Pro forma net loss | <u>\$(118,809)</u> | <u>\$(88,580)</u> | <u>\$(99,804)</u> |
| Basic and diluted-as reported | \$ (3.90) | \$ (3.43) | \$ (4.64) |
| Basic and diluted-pro forma | \$ (4.27) | \$ (4.10) | \$ (5.48) |

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.

As additional options are expected to be granted in future years and as the options vest over several years, the above pro forma results are not necessarily indicative of future results.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

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, 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 9,604,003, 5,669,764 and 5,148,365 shares of common stock for the years ended July 31, 2005, 2004 and 2003, respectively. There is no difference in basic and diluted net loss per common share as the effect of 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.

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 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.

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 only one segment. In addition, all revenues are generated from United States entities, and all long-lived assets are maintained in the United States.

Reclassifications

Certain reclassifications have been made to the 2004 financial statements in order to conform to the 2005 presentation.

Recently Issued Accounting Standards

In December 2004, the FASB issued SFAS No. 123(R) (revised 2004), "Share-Based Payment" ("SFAS 123(R)"), which replaces SFAS No. 123, "Accounting for Stock-Based Compensation" and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values, beginning with the first annual period after June 15, 2005. Pursuant to revisions to SFAS No. 123(R) in April 2005 by the FASB, we are obligated to start expensing options at the commencement of our fiscal year on August 1, 2005. In addition, in March 2005, SEC issued Staff Accounting Bulletin No. 107 (SAB 107) which provides guidance regarding the interaction between SFAS 123(R) and certain SEC rules and regulations and provides additional guidance regarding the valuation of share-based payment arrangements for public companies. We expect to implement SFAS 123(R) using the modified prospective application method.

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

In May 2005, the FASB issued FASB 154, "Accounting Changes and Error Corrections." The Statement replaces APB Opinion No. 20, Accounting Changes, and FASB Statement No. 3, Reporting Accounting Changes in Interim Financial Statements, and changes the requirements for the accounting for and reporting of a change in accounting principle. The Statement applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. When a pronouncement includes specific transition provisions, those provisions should be followed. This statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005.

2. Collaborations

Procter & Gamble Pharmaceuticals Collaboration

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. Under the revised structure per the MOU, we and P&G share decision-making and responsibility for all future U.S. development and commercialization costs for pexelizumab, including clinical, manufacturing, marketing, and sales efforts. 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 will receive approximately 50% of the gross margin on U.S. sales, if any. P&G agreed to retain responsibility for future development and commercialization costs outside the U.S., with us receiving a royalty on sales outside the U.S., if any. We are responsible for royalties on certain third party intellectual property worldwide, if such intellectual property is necessary. Additionally, as part of the MOU, we will receive milestone payments for achieving specified development steps, regulatory filings and approvals.

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 rely on P&G for the development, manufacture and potential commercialization of pexelizumab. Termination of our agreement by P&G or sublicense of its collaboration rights could cause significant delays in the development, manufacture and potential commercialization of pexelizumab and result in significant additional costs to us. 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 could amount to as much as \$8,000.

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

XOMA Ltd. Collaboration

In December 2003, we and XOMA (U.S.) LLC, or 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 \$1,500 upfront non-refundable payment upon initiation of the collaboration. We originally recorded the payment as a deferred research and development payment. The payment was recognized as a reduction of research and development expenses over 8 years, which represents the estimated length of time to achieve commercial viability. With the termination of the agreement in April 2005, we recognized the remaining balance of approximately \$1,300 of the deferred payment as a reduction of research and development expenses. As of July 31, 2004, the balance was approximately \$1,400.

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 to milestones, such as, but not limited to, Investigational New Drug (IND) application or approval of Biologics License Application (BLA). 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 scale manufacture of eculizumab (see Note 10).

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 July 31, 2005, for each of the next five years are as follows:

| <u>Years Ending July 31</u> | <u>License Agreements</u> | <u>Research and Development Agreements</u> | <u>Clinical and Manufacturing Development Agreements</u> |
|-----------------------------|---------------------------|--|--|
| 2006 | \$ 2,463 | \$ 63 | \$ 39,152 |
| 2007 | 1,613 | — | 22,370 |
| 2008 | 718 | — | 18,130 |
| 2009 | 468 | — | 19,400 |
| 2010 | 493 | — | — |

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

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 July 31, 2005, these agreements contain milestone payment provisions aggregating approximately \$20,300. 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 |
|----------------------------|-------------------------|---|--|-------------------------|
| July 31, 2005 | | | | |
| 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 |
| | <u> </u> | <u> </u> | <u> </u> | <u> </u> |
| Total | \$149,016 | \$ 3 | \$ (566) | \$148,453 |
| | <u> </u> | <u> </u> | <u> </u> | <u> </u> |
| July 31, 2004 | | | | |
| Federal agency obligations | \$ 96,896 | \$ 5 | \$ (303) | \$ 96,598 |
| Corporate bonds | 32,306 | 8 | (74) | 32,240 |
| Certificates of deposit | 24,361 | 1 | (34) | 24,328 |
| Other | 61 | 50 | — | 111 |
| | <u> </u> | <u> </u> | <u> </u> | <u> </u> |
| Total | \$153,624 | \$ 64 | \$ (411) | \$153,277 |
| | <u> </u> | <u> </u> | <u> </u> | <u> </u> |

Unrealized losses of \$3 related to holdings of cash equivalents are included in Accumulated Other Comprehensive Income for the year ended July 31, 2005.

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

Realized gains of approximately \$101 and \$0 were recorded during the year ended July 31, 2005 and 2004, respectively. No realized losses were recorded for the years ended July 31, 2005 and 2004. We utilize the specific identification method in computing realized gains and losses. At July 31, 2005, our marketable securities had a maximum maturity of less than 2 years with an average of approximately 6 months. The weighted average interest rate associated with marketable debt securities was 3.7 percent and 1.9 percent at July 31, 2005 and 2004, respectively.

The following table summarizes the investment maturities at July 31, 2005:

| | <u>Amortized Cost</u> | <u>Fair Value</u> |
|------------------------------|---------------------------|-------------------|
| Less than one year | \$ 27,938 | \$ 27,884 |
| Matures in one to five years | 121,078 | 120,569 |
| | <u>\$149,016</u> | <u>\$148,453</u> |

We periodically review for impairment those investment securities whose unrealized losses have remained unrealized for more than six months to determine if such unrealized losses are other than temporary. Gross unrealized losses from all individual investment securities aggregated \$566 and \$411 at 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 July 31:

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

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 | \$ 13,907 | \$ (16) | \$ 67,013 | \$ (320) | \$ 80,920 | \$ (336) |
| Corporate bonds | 1,255 | (26) | 33,290 | (172) | 34,545 | (198) |
| Certificates of deposit | 3,037 | (1) | 7,770 | (20) | 10,807 | (21) |
| Commercial paper | 9,533 | (11) | — | — | 9,533 | (11) |
| | <u>\$27,732</u> | <u>\$ (54)</u> | <u>\$108,073</u> | <u>\$ (512)</u> | <u>\$135,805</u> | <u>\$ (566)</u> |

2004

| 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 | \$ 15,424 | \$ (30) | \$ 57,005 | \$ (273) | \$ 72,429 | \$ (303) |
| Corporate bonds | 1,613 | (11) | 10,802 | (58) | 12,415 | (69) |
| Certificates of deposit | 17,961 | (30) | 5,102 | (3) | 23,063 | (33) |
| Commercial paper | 11,344 | (6) | — | — | 11,344 | (6) |
| | <u>\$46,342</u> | <u>\$ (77)</u> | <u>\$ 72,909</u> | <u>\$ (334)</u> | <u>\$119,251</u> | <u>\$ (411)</u> |

For the investments in all categories shown in the above table (comprising 43 securities in aggregate), the unrealized losses were caused primarily by interest rate increases.

4. Other Assets

Prepaid expenses and other current assets consist of the following at July 31:

| | 2005 | 2004 |
|-----------------------------|----------------|----------------|
| Prepaid expenses | \$4,303 | \$3,513 |
| State tax receivable | 1,316 | 1,493 |
| Reimbursable contract costs | 139 | 826 |
| Milestone receivable | — | 4,000 |
| | <u>\$5,758</u> | <u>\$9,832</u> |

Other non-current assets consist of the following as of July 31:

| | 2005 | 2004 |
|-------------------------------|----------------|----------------|
| Deferred financing costs, net | \$4,404 | \$1,547 |
| Deposits and other assets | 456 | 455 |
| | <u>\$4,860</u> | <u>\$2,002</u> |

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

5. Property, Plant and Equipment

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

| <u>Asset</u> | <u>Estimated Useful Lives (years)</u> | <u>2005</u> | <u>2004</u> |
|---|---|------------------|------------------|
| Land | — | \$ — | \$ 364 |
| Buildings and improvements | 5 - 15 | 9,721 | 9,897 |
| Laboratory equipment | 5 - 7 | 10,566 | 12,906 |
| Furniture and office equipment | 3 - 5 | 3,638 | 4,177 |
| | | <u>23,925</u> | <u>27,344</u> |
| Less: Accumulated depreciation and amortization | | <u>(12,379)</u> | <u>(15,558)</u> |
| | | <u>\$ 11,546</u> | <u>\$ 11,786</u> |

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 \$2,996, \$2,865 and \$3,108 for the years ended July 31, 2005, 2004 and 2003, respectively.

During the year ended July 31, 2005, we, utilizing the services of third party appraisers, performed 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 currently included in our accounting records 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.

We have classified the property, plant and equipment of CFC as property, plant and equipment held for sale as of July 31, 2004 as per the guidelines set forth in SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" (see Note 6).

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 CFC's UniGraft manufacturing assets, causing a write down of approximately \$760 and \$2,560 of those assets for years ended July 31, 2004 and 2003, respectively.

6. Note Payable

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,

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

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 the first quarter of fiscal 2005.

7. Accrued Expenses

A summary of accrued expenses is as follows as of July 31:

| | <u>2005</u> | <u>2004</u> |
|-----------------------------------|-----------------|-----------------|
| Clinical expense | \$ 9,459 | \$ 3,613 |
| Payroll and employee benefits | 3,652 | 1,689 |
| Deferred rent and other | 2,079 | 1,833 |
| Research and development expenses | 585 | 276 |
| Pre-commercial expenses | 584 | 712 |
| Interest expense | 5 | 2,881 |
| | <u>\$16,364</u> | <u>\$11,004</u> |

8. 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 do not have financial covenants related to debt. 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 42.91 per \$1 principal amount).

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
July 31, 2005 and 2004
(amounts in thousands, except 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 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 each of the years ended July 31, 2005, 2004 and 2003 was approximately \$686, \$573 and \$573, respectively.

Cash paid for interest expense for each of the years ended July 31, 2005, 2004 and 2003 was approximately \$7,966, \$6,901 and \$7,135, respectively.

9. Leases

Capital Leases

We lease office equipment under capital lease agreements expiring in 2008. 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 July 31, 2005, the cost of equipment under capital lease is \$418 and the net book value is \$215.

Minimum future lease payments under capital lease as of July 31, 2005 are:

| Year | |
|---|-------|
| 2006 | \$138 |
| 2007 | 138 |
| 2008 | 11 |
| | <hr/> |
| | 287 |
| Less: Amount representing interest | 63 |
| | <hr/> |
| Present value of minimum lease payments | \$224 |
| | <hr/> |

The interest rate on the above capital lease is 5.625% and is imputed based on the lower of our incremental borrowing rate at the inception of each lease.

Operating Leases

As of July 31, 2005, we lease our headquarters and primary research and development facilities in Cheshire, CT. The lease commenced in August 2000 and has a term of ten years and six months. 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 \$104 over the term of this lease. We have issued a \$200 open letter of credit to secure the lease.

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

In January 2003, we entered into a lease agreement for our pilot manufacturing plant and associated labs and offices in New Haven, CT, which 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.

Furthermore, we lease additional research space in San Diego, CA, starting at a monthly fixed rent of approximately \$35 increasing to approximately \$90 as the facility is expanded. This lease expires in 2012.

Aggregate lease expense for our facilities was \$2,296, \$2,176 and \$1,998 for the years ended July 31, 2005, 2004 and 2003, respectively. Lease expense is being recorded on a straight-line basis over the applicable lease terms.

Aggregate future minimum annual rental payments for the next five years and thereafter under non-cancellable operating leases (including facilities and equipment) as of July 31, 2005 are:

| | |
|------------|---------|
| 2006 | \$2,312 |
| 2007 | 2,454 |
| 2008 | 2,057 |
| 2009 | 1,932 |
| 2010 | 2,026 |
| Thereafter | 2,264 |

10. Commitments and Contingencies

Purchase Commitments

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 eculizumab, was amended, or the Lonza Amendment, in April 2004. Under the Lonza Amendment, the facility in which Lonza will manufacture eculizumab 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 eculizumab 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 Lonza Agreement, as amended by the Lonza Amendment, if we terminate the Lonza Agreement on or prior to September 30, 2006, we may be required to pay different amounts, depending on when the Lonza Agreement is terminated, which are between zero and approximately \$10,000 and, 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

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

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 ("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.

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 July 31, 2005.

11. Income Taxes

At July 31, 2005, we have available for federal tax reporting purposes, net operating loss carry forwards of approximately \$439,800 which expire through 2025 (of which approximately \$27,400 resulted from the exercise of nonqualified stock options as discussed below). We also have federal and state research and development credit carry forwards of approximately \$16,127 which begin to expire commencing in fiscal 2008. The Tax Reform Act of 1986 contains certain provisions that limit our 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 have been triggered, however, the limitation to us is minimal. For the years ended July 31 2005 and 2004, the limitation is approximately \$1,402 annually.

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 tax year ended July 31, 2005, we plan to file claims to exchange our fiscal 2005 research and tax development credits and, therefore, recognized a state tax benefit of approximately \$765. The state tax benefit excludes our estimated capital-based state taxes of approximately \$215 which was recorded as an operating expense.

The components of deferred income tax assets are as follows:

| | 2005 | 2004 |
|------------------------------|------------|------------|
| Deferred income tax assets: | | |
| Operating loss carryforwards | \$ 167,172 | \$ 121,938 |
| Tax credit carryforwards | 16,127 | 12,236 |
| Deferred revenues | 2,496 | 2,635 |
| Other | 781 | 2,096 |
| Total deferred tax assets | 186,576 | 138,905 |
| Less: valuation allowance | (186,576) | (138,905) |
| | \$ — | \$ — |

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

We have not yet achieved profitable operations. Accordingly, management believes the tax benefits as of July 31, 2005 do not satisfy the realization criteria set forth in SFAS No. 109 and have recorded a valuation allowance for the total deferred tax asset.

The exercise of nonqualified stock options gives rise to compensation which 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 nonqualified stock options, we have related net operating loss carry forwards of approximately \$27,400 which can be used to offset future taxable income, if any. If and when realized, the related tax benefits of these net operating loss carry forwards will be credited directly to paid-in capital.

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

| | 2005 | 2004 | 2003 |
|--|------|------|------|
| Federal statutory rate | -34% | -34% | -34% |
| State tax benefit, net of Federal tax effect | -5% | -5% | -5% |
| Research & development credits | -5% | -3% | -2% |
| Increase in deferred tax valuation allowance | 43% | 41% | 40% |
| Effective rate | -1% | -1% | -1% |

12. Stock Options and Restricted Stock

Stock Options

As of the year ended July 31, 2005, 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 at the adoption of the 2004 Plan. Under the 2004 Plan, Common Stock as well as incentive and nonqualified stock options may be granted for up to a maximum of 3,093,519 shares of Common Stock to our directors, officers, key employees and consultants. The amount of shares authorized for granting includes 593,519 shares transferred from the 2000 Plan. 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. As of July 31, 2005, there were 2,441,828 shares available for issuance under the 2004 Plan.

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

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

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, \$67 and \$65 for the years ended July 31, 2005, 2004 and 2003, respectively. 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 \$0, \$17 and \$78 for the years ended July 31, 2005, 2004 and 2003, respectively.

Compensation expense related to options issued to consultants was \$132, \$22 and \$4 for the years ended July 31, 2005, 2004 and 2003, respectively.

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

| | 2005 | 2004 | 2003 |
|--|-----------|-----------|-----------|
| Options outstanding at the beginning of the year | 4,542,210 | 4,020,810 | 3,557,605 |
| Options granted | 996,600 | 972,000 | 662,500 |
| Options cancelled | (245,417) | (251,043) | (182,645) |
| Options exercised | (563,600) | (199,557) | (16,650) |
| Options outstanding at the end of the year | 4,729,793 | 4,542,210 | 4,020,810 |
| Options exercisable at the end of year | 3,196,601 | 3,100,091 | 2,732,900 |
| Common stock available for future issuances at the end of the year | 2,441,828 | 1,259,129 | 671,836 |
| Weighted average exercise price of options: | | | |
| granted | \$ 18.78 | \$ 19.88 | \$ 11.68 |
| cancelled | 24.30 | 27.94 | 31.38 |
| exercised | 6.64 | 12.52 | 9.29 |
| outstanding | 23.40 | 22.38 | 22.84 |
| exercisable | 25.82 | 23.98 | 22.94 |

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

The following table presents weighted average price and life information about significant option groups outstanding at July 31, 2005:

| 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 |
| \$2.37 to 9.00 | 239,825 | 3.1 | \$ 8.86 | 239,825 | \$ 8.86 |
| \$9.01 to 20.99 | 2,477,225 | 6.7 | 14.49 | 1,316,170 | 12.34 |
| \$21.00 to 24.50 | 1,308,365 | 6.8 | 21.88 | 936,228 | 21.48 |
| \$24.51 to 54.00 | 150,211 | 5.3 | 37.74 | 150,211 | 37.74 |
| \$54.01 to 87.00 | 524,167 | 4.8 | 67.06 | 524,167 | 67.06 |
| \$87.01 to 108.00 | 30,000 | 0.2 | 107.88 | 30,000 | 107.88 |
| | 4,729,793 | 6.3 | \$ 23.40 | 3,196,601 | \$ 25.82 |

The weighted average fair value at the date of grant for options granted during 2005, 2004, and 2003 is \$14.27, \$13.25, and \$8.58 per option, respectively.

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

| | 2005 | 2004 | 2003 |
|------------------------|-------|-------|-------|
| Expected Life in Years | 7.5 | 5 | 5 |
| Interest Rate | 4.10% | 4.30% | 3.70% |
| Volatility | 78% | 82% | 92% |
| Dividend Yield | — | — | — |

Restricted Stock

During the year ended July 31, 2005, 109,800 shares of restricted stock, which generally vest over four years from grant date, were issued to certain key employees and consultants. Compensation expense of approximately \$238 related to restricted stock was recorded during the year then ended. There were 3,000 shares of restricted stock cancelled during the year ended 2005. Prior to 2005, restricted stock was not issued. The balance of deferred compensation related to the restricted stock grants noted above was approximately \$1,938.

13. Common and Preferred Stock

Common

In September 2003, we sold 3,600,000 shares of our Common Stock at a price of \$13.00 per share resulting in net proceeds of approximately \$43,900, net of underwriting discounts, fees and other expenses of approximately \$2,900 related to the transaction.

In July 2004, we sold 5,500,000 shares of our Common Stock at a price of \$15.50 per share resulting in net proceeds of approximately \$80,900, net of underwriting discounts, fees and other expenses of approximately \$4,400 related to the transaction.

During the year ended July 31, 2005, the only sales of Common Stock occurred with the exercise of stock options.

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

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 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.

14. Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive losses as of July 31 are:

| | <u>2005</u> | <u>2004</u> | <u>2003</u> |
|---|----------------|----------------|---------------|
| Other comprehensive (loss) income | \$(347) | \$ 652 | \$ 1,678 |
| Reclassification of realized gains included in net loss | 101 | — | — |
| Unrealized losses on marketable securities | (320) | (999) | (1,026) |
| | <u>\$(566)</u> | <u>\$(347)</u> | <u>\$ 652</u> |

15. 401(k) Plan

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 \$390, \$330 and \$291 for the years ended July 31, 2005, 2004 and 2003, respectively.

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

16. Contract Research Revenues

We have been awarded various grants by agencies of the U.S. government to fund specific research projects. In July of 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.

For the years ended July 31, 2005, 2004, and 2003, we recorded approximately \$588 of revenue previously deferred related to an upfront payment received from P&G. Our fiscal year 2004 P&G revenue primarily included a milestone receivable of \$4,000 concurrent with the dosing of our first patient in the APEX-AMI clinical trial. (see Note 2)

A summary of revenues generated from contract research collaboration and grant awards as of July 31 is as follows:

| | <u>2005</u> | <u>2004</u> | <u>2003</u> |
|------------------------|----------------|----------------|--------------|
| P&G | \$ 588 | \$4,588 | \$673 |
| U.S. government grants | 476 | 21 | 204 |
| Total revenues | \$1,064 | \$4,609 | \$877 |

17. 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.
- Milestone receivable, 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 July 31, 2005.

[Table of Contents](#)

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2005 and 2004
(amounts in thousands, except per share amounts)

| | 2005 | | 2004 | |
|-----------------------------|-----------------|------------|-----------------|------------|
| | Carrying Amount | Fair Value | Carrying Amount | Fair Value |
| Cash and cash equivalents | \$ 46,951 | \$ 46,951 | \$113,224 | \$113,224 |
| Marketable securities | 148,453 | 148,453 | 153,277 | 153,277 |
| Milestone receivable | — | — | 4,000 | 4,000 |
| Reimbursable contract costs | 139 | 139 | 826 | 826 |
| Notes payable | — | — | 3,920 | 3,920 |
| Accounts payable | 7,455 | 7,455 | 3,973 | 3,973 |
| Convertible debt | 150,000 | 153,000 | 120,000 | 120,000 |

18. Subsequent Event

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.

19. Quarterly Financial Information (unaudited)

The following is condensed quarterly financial information:

| | Fiscal 2005 | | | |
|--|-------------|----------|----------|----------|
| | First | Second | Third | Fourth |
| Contract research revenues | \$ 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) |

| | Fiscal 2004 | | | |
|--|-------------|----------|----------|----------|
| | First | Second | Third | Fourth |
| Contract research revenues | \$ 147 | \$ 147 | \$ 168 | \$ 4,147 |
| Operating expenses | 19,502 | 17,824 | 14,361 | 23,372 |
| Operating loss | (19,355) | (17,677) | (14,193) | (19,225) |
| Net loss applicable to common shareholders | (20,212) | (18,547) | (15,213) | (20,123) |
| Net loss per common share, basic and diluted | (1.01) | (0.85) | (0.69) | (0.88) |

SUBSIDIARIES OF ALEXION PHARMACEUTICALS, INC.

Alexion Antibody Technologies, Inc. (California)
100% owned by Registrant

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-128085, 333-127471, 333-123828, 333-47594, 333-91265, 333-29617, 333-41397, 333-47645, 333-89343, 333-36738, 333-52886, 333-59702, 333-110828 and 333-114449) and Form S-8 (No. 333-123212, 333-119749, 333-24863, 333-52856, 333-69478, 333-71879, 333-71985 and 333-106854) of Alexion Pharmaceuticals, Inc. of our report dated October 4, 2005 relating to the financial statements, management's assessment of the effectiveness of internal control over financial reporting and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

PricewaterhouseCoopers LLP
Hartford, Connecticut
October 6, 2005

I, Leonard Bell, M.D., certify that:

1. I have reviewed this annual report on Form 10-K of Alexion Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: October 11, 2005

/s/ Leonard Bell, M.D.

Leonard Bell, M.D.
Chief Executive Officer

I, Vikas Sinha, certify that:

1. I have reviewed this annual report on Form 10-K of Alexion Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: October 11, 2005

/s/ Vikas Sinha

Vikas Sinha
Senior Vice President and Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of Alexion Pharmaceuticals, Inc. (the "Company") for the year ended July 31, 2005 as filed with the Securities and Exchange Commission (the "Report"), I, Leonard Bell M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: October 11, 2005

/s/ Leonard Bell, M.D.

Leonard Bell, M.D.
Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of Alexion Pharmaceuticals, Inc. (the "Company") for the year ended July 31, 2005 as filed with the Securities and Exchange Commission (the "Report"), I, Vikas Sinha, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: October 11, 2005

/s/ Vikas Sinha

Vikas Sinha
Senior Vice President and Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.