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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, 2004

or

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

For the transition period from _____ to _____

Commission file number: 0-27756

ALEXION PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**13-3648318**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

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

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

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 ☐

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 30, 2004, was approximately $398,107,000.

The number of shares of Common Stock outstanding as of September 22, 2004 was 27,610,750.

Portions of the registrant's definitive Proxy Statement to be used in connection with its Annual Meeting of Stockholders to be held on December 10, 2004, are incorporated by reference into Part III of this report.

PART I

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. 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. 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 set forth herein under "important factors regarding forward-looking statements," in 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, cardiovascular, and autoimmune disorders. Since our incorporation in January 1992, we have devoted substantially all of our resources to drug discovery, research, and product and clinical development. During the fiscal years ended July 31, 2004, 2003, and 2002, we recorded net losses of $74.1 million, $84.5 million, and $56.5 million, respectively. We spent $59.8 million, $71.0 million, and $60.0 million on research development activities during the fiscal years ended July 31, 2004, 2003, and 2002, respectively.

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 human immune system produces inflammation in the human body. One of our product candidates, eculizumab, is in Phase III clinical development for treatment of a chronic hematologic disease and our second product candidate, pexelizumab, is in Phase III clinical development for two distinct acute cardiac indications. We designed both of these product candidates with the goal of eliciting the intended clinically therapeutic effect by inhibiting the aberrant manifestation of complement.

We are developing eculizumab, an antibody that inhibits complement, for the treatment of a rare blood disorder known as Paroxysmal Nocturnal Hemoglobinuria, or PNH. We are developing pexelizumab in collaboration with Procter and Gamble Pharmaceuticals, or P&G, a single-chain antibody that also inhibits complement, 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.

To date, we have studied our two lead antibody product candidates in a variety of clinical development programs enrolling over 6,600 patients in clinical trials. In addition to our Phase III programs, we have other product candidates in earlier stages of development, and we may also pursue additional indications for eculizumab.

Phase III Product Candidates

Eculizumab for PNH. PNH is a rare chronic disease in which a patient's complement system attacks the individual's own blood cells. As a result, PNH patients suffer from chronic hemolysis, or destruction of red blood cells, which leads to severe anemia and risk of blood clotting, or thrombosis. This hemolysis is also believed to lead to frequent bouts of hemoglobinuria, or the release of proteins from blood cells into the urine, abdominal pain, painful swallowing, disabling fatigue, and life-threatening blood clots. According to published studies, about 2 to 6 new patients per million individuals in the population are identified with PNH each year. The prevalence, or number of affected patients at any one time, has not been definitively determined but can be estimated at approximately 2,000 – 10,000 patients in the United States. Approximately one-half of the patients with PNH die from the disease within 10 years of diagnosis. Recurrent blood transfusions are often necessary to support normal red blood function and currently there is no U.S. Food and Drug Administration, or FDA, approved therapy for PNH.

We completed an 11 patient, open-label three month Phase I trial in PNH patients in 2002, and an open-label extension trial is ongoing to help us evaluate long-term safety and drug activity. In the Phase I trial, eculizumab was well-tolerated and associated with a statistically significant 71% reduction in the need for blood transfusions, up to an 81% reduction in biochemical parameters of hemolysis, or destruction of red blood cells, and a 96% reduction in clinical paroxysms.

In July 2004, we announced that we received written confirmation from the FDA indicating agreement with the protocols 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. 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 have commenced site initiation for one of these Phase III trials, which we refer to as TRIUMPH. This placebo-controlled pivotal efficacy trial will examine the efficacy of eculizumab in approximately 75 PNH patients who require blood transfusions. There will be two primary endpoints in TRIUMPH in hemolytic transfusion-dependent PNH patients during six months of therapy: i) hemoglobin stabilization, and ii) reduction in blood transfusions. An endpoint is the primary therapeutic, pre-set goal of a trial. We are also preparing to commence SHEPHERD, an open-label trial which will be primarily aimed at generating additional safety data with eculizumab in approximately 75 PNH patients. We retain all rights to eculizumab in all indications worldwide. In 2003, the FDA and the European Medicines Evaluation Agency, or EMEA, granted Orphan Drug designation for the development of eculizumab in PNH.

Pexelizumab for CABG. 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. Severe inflammation caused by the CABG procedure with cardiopulmonary bypass, or CPB, can often result in a perioperative myocardial infarction, other morbidity, or death. According to data derived from the American Heart Association, it is estimated that approximately 400,000 CABG operations were performed in the United States in 2002.

In 2003, we completed a Phase III clinical trial of pexelizumab, known as the PRIMO-CABG trial, in approximately 3,000 patients undergoing CABG with CPB. 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 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. Additionally, a large number of additional key pre-specified measures were reduced with statistical significance.

In June 2004, we announced that, under the FDA's SPA process, we reached written agreement with the FDA relating to the protocol for the pivotal Phase III trial of pexelizumab in patients undergoing CABG with CPB. We, along with P&G, have commenced enrollment in this confirmatory, pivotal Phase III trial in CABG patients, known as PRIMO-CABG2, to expand upon and confirm observations from the earlier PRIMO-CABG trial. The primary endpoint of PRIMO-CABG2 will be a reduction of death or heart attack at 30 days. PRIMO-CABG2 is expected to enroll approximately 4,000 patients. 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 the CABG indication. By September 2000, the FDA granted "Fast Track" status for the development of pexelizumab in CPB and in connection with angioplasty following AMI. Fast Track designation provides for potentially expediting product development and FDA review of BLAs .

Pexelizumab for AMI. 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. According to data derived from the American Heart Association, it is estimated that approximately 850,000 people were presented to hospitals for treatment of a heart attack in the United States in 2002.

In 2002, we completed a Phase II study, known as the COMMA trial, with pexelizumab in patients suffering AMI who received angioplasty, a procedure for opening up narrowed or blocked arteries that supply blood to the heart. The trial's primary endpoint of a reduction of myocardial infarction, or death of heart muscle, was not reached; however, pexelizumab treatment in this trial was associated with a statistically significant, dose-dependent reduction in death.

In June 2004, we announced that, 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. We, along with P&G, have commenced enrollment in this pivotal Phase III trial, known as APEX-AMI. The primary endpoint of APEX-AMI will be a reduction of death at 90 days. APEX-AMI is expected to enroll approximately 8,500 patients. 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 the AMI indication.

Other Development Programs

Eculizumab for Membranous Nephritis. In addition to PNH, eculizumab is in development for the treatment of a variety of chronic inflammatory diseases, including membranous nephritis. Membranous nephritis is a chronic inflammatory kidney disease in which patients suffer loss of protein into the urine, or proteinuria, which may progress to kidney failure. In a four-month, placebo-controlled Phase II trial, eculizumab treatment was not associated with a significant change in proteinuria. However, in a twelve-month open-label extension trial, eculizumab treatment was associated with a significant reduction in proteinuria and an increased rate of remission. We continue to evaluate our development options for eculizumab in membranous nephritis.

Eculizumab for Rheumatoid Arthritis. Eculizumab is also in development for the treatment of rheumatoid arthritis. We announced in January 2004 preliminary results of our approximately 350 patient 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. 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.

Thrombocytopenia Antibody. We have developed a rationally designed human antibody that stimulates platelet production in order to treat a variety of thrombocytopenia conditions including chemotherapy-induced thrombocytopenia. Thrombocytopenia is an abnormal blood condition in which the number of platelets is reduced, potentially leading to bleeding complications. We are developing this product candidate in collaboration with

XOMA, Ltd. We will share preferentially in the potential revenues from this product candidate and bear a corresponding share of development and commercialization expenses, including clinical development, manufacturing and marketing costs world-wide.

Through Alexion Antibody Technologies, Inc., or AAT, our wholly owned subsidiary with extensive combinatorial human antibody library technologies and expertise, we have developed important additional capabilities to discover and develop additional antibody product candidates for the treatment of inflammatory diseases and cancer.

We have executed a large-scale product supply agreement with Lonza Biologics, plc, or Lonza, for the long-term commercial manufacture of 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, 2004, we had an accumulated deficit of approximately $339.4 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 manufacturing, pre-commercialization activities and developing a sales and marketing force. 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 partnerships for product development and commercialization, where we will still play a major role.

In September 2003, we sold 3.6 million shares of our common stock at a price of $13.00 per share resulting in net proceeds of approximately $43.9 million, net of underwriting discounts, fees and other expenses of approximately $2.9 million related to the transaction. In July 2004, we sold 5.5 million shares of our common stock at a price of $15.50 per share resulting in net proceeds of approximately $80.9 million, net of underwriting discounts, fees and other expenses of approximately $4.4 million related to the transaction. We expect to use the net proceeds of these sales of common stock to fund working capital and other general corporate purposes, including additional clinical trials of pexelizumab and eculizumab, as well as other research and product development activities.

The Immune System

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

- harmful micro-organisms;
- cells containing foreign proteins known as antigens; and
- disease-causing combinations of antigens and antibodies known as immune complexes.

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

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.

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.

Our product candidates are as follows:

Product candidate	Technology	Indication	Status(a)
Lead Indications			
Eculizumab	C5 Inhibitor (whole antibody)	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Phase I trial completed; extension study on-going; Protocols for two Phase III clinical trials agreed with FDA. One is for efficacy and safety (TRIUMPH); and one is for safety (SHEPHERD). TRIUMPH site initiation commenced.
Pexelizumab	C5 Inhibitor (single chain antibody)	Coronary Artery Bypass Graft (CABG) surgery with cardiopulmonary bypass (CPB)	Phase III trial completed (PRIMO-CABG); Protocol for second Phase III clinical trial agreed with FDA; Commenced enrollment in second Phase III trial (PRIMO-CABG2).

		Acute Myocardial Infarction (AMI) with angioplasty	Phase II COMMA trial completed; Protocol for Phase III clinical trial agreed with FDA; Commenced enrollment in Phase III trial (APEX-AMI).
Additional Indications			
Eculizumab	C5 Inhibitor (whole antibody)	Membranous Nephritis	Phase II trial completed; extension trial completed.
		Rheumatoid Arthritis	Phase IIb trial completed; extension study on-going.

(a) see discussions of each product candidate below for a description of the results of these trials

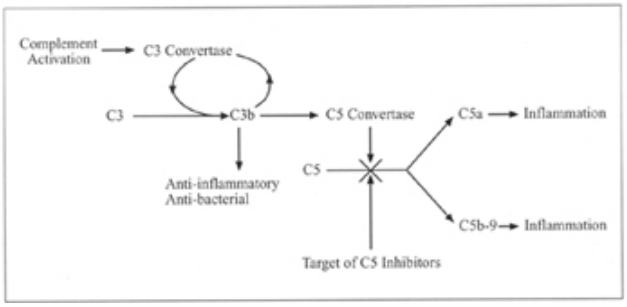
C5 Inhibitors

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 blood-clotting cells called platelets;
- initiation of all 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 and are designed to 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, is effective in:

- preventing inflammation during cardiopulmonary bypass;
- reducing heart tissue damage during myocardial infarction;
- reducing brain damage in cerebral ischemia, or reduced blood flow to brain tissue;
- enhancing survival in a model of lupus;
- preserving kidney function in nephritis, or inflammation of kidney tissue;
- preventing and ameliorating asthmatic attacks;
- preventing lysis of red blood cells and activation of platelets: and
- enhancing survival in organ transplantation models.

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

- 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;
- the incidence of proteinuria in lupus patients; and
- destruction of red blood cells in PNH 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 indications for which we are pursuing clinical development activities for eculizumab are PNH, membranous nephritis, and rheumatoid arthritis. We are developing our other C5 Inhibitor product candidate, pexelizumab, for the treatment of inflammation related to acute cardiovascular diseases and procedures. Our initial indications for pexelizumab are coronary artery bypass graft surgery with cardiopulmonary bypass surgery and acute myocardial infarction utilizing

percutaneous coronary intervention or PCI, a procedure that includes balloon angioplasty and 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 safe and well tolerated in completed and ongoing clinical trials in which over 6,600 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 at the doses tested and is designed for the chronic treatment of hematologic disorders such as PNH and autoimmune diseases such as rheumatoid arthritis and membranous nephritis. 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 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 – 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 FDA approved therapy for PNH.

In laboratory studies with eculizumab, administration of eculizumab halts destruction of red blood cells and activation of platelets caused by complement attack.

Clinical Trials - PNH

We completed an 11 patient, open-label three month Phase I trial in PNH patients in 2002, and an open-label extension trial is ongoing to help us evaluate long-term safety and drug activity. In the Phase I trial, eculizumab was well-tolerated and associated with a statistically significant 71% reduction in the need for blood transfusions, up to an 81% reduction in biochemical parameters of hemolysis, or destruction of red blood cells, and a 96% reduction in clinical paroxysms.

We received written confirmation from the FDA indicating agreement with the protocols 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 SPA process. 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 for the PNH indication. We have commenced site initiation for one of these Phase III trials, which we refer to as TRIUMPH. This placebo-controlled pivotal efficacy trial will examine the efficacy of eculizumab in approximately 75 PNH patients who require blood transfusions. There will be two primary endpoints in

TRIUMPH in hemolytic transfusion-dependent PNH patients during six months of therapy: i) hemoglobin stabilization and ii) a reduction in blood transfusions. We are also preparing to commence SHEPHERD, an open-label trial which will be primarily aimed at generating additional safety data with eculizumab in approximately 75 PNH patients. The SHEPHERD protocol includes a six month interim analysis and a further six months of safety observations. We will determine whether the interim six months of SHEPHERD data is sufficient for filing the PNH biologics license application after review of TRIUMPH results. We retain all rights to eculizumab in all indications worldwide. In 2003, the FDA and the European Medicines Evaluation Agency, or EMEA, granted Orphan Drug Status for the development of eculizumab in PNH.

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 is designed for the treatment of acute inflammatory conditions. In January 1999, we entered into a collaboration arrangement with Procter & Gamble Pharmaceuticals, or P&G, to develop and commercialize pexelizumab. Under this collaboration, we are pursuing the development of pexelizumab for the treatment of inflammation caused by various acute cardiovascular indications and procedures such as coronary artery bypass graft surgery with cardiopulmonary bypass surgery, and myocardial infarction utilizing angioplasty. 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, we and P&G share decision-making and responsibility for all future United States development and commercialization costs for pexelizumab, including clinical, manufacturing, marketing, and sales efforts. P&G has contracted with a third party manufacturer for the large scale commercial manufacture of pexelizumab over 5 years. 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 inflammatory heart attack resulting in PMI during 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 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;
- the scope of required treatments associated with CPB; and
- perioperative bleeding resulting in the need for blood transfusions.

According to data derived from American Heart Association estimates,, 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

In January 1999, we commenced dosing in a Phase IIb clinical trial with pexelizumab in 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. 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. The primary endpoint, a reduction in the incidence of death, myocardial infarction, heart dysfunction, and mild stroke, was not achieved. However, in a post-hoc analysis, in the pre-specified population that included approximately 90% of the patient population, 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.

In January 2002, we commenced a Phase III clinical trial of pexelizumab, called PRIMO-CABG, in patients undergoing CABG-only with CPB, and patients undergoing CABG with CPB and concomitant cardiac valve surgery. This study completed the target patient enrollment of approximately 3,000 patients in February 2003. 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 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. Additionally, a large number of additional key pre-specified measures were reduced with statistical significance.

Under the FDA's SPA process, we have reached written agreement with the FDA relating to the protocol for the pivotal Phase III trial of pexelizumab in patients undergoing CABG with CPB. We, along with P&G, have commenced enrollment in this confirmatory, pivotal Phase III trial in CABG patients, known as PRIMO-CABG2, to expand upon and confirm observations from the earlier PRIMO-CABG trial. The primary endpoint of PRIMO-CABG2 will be a reduction in death or heart attack at 30 days. PRIMO-CABG2 is expected to enroll

approximately 4,000 patients. 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 CABG indication. By September 2000, the FDA granted "Fast Track" status for the development of pexelizumab in CPB and in connection with angioplasty following AMI. Fast Track designation provides for potentially expediting product development and FDA review of BLAs.

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. According to data derived from the American Heart Association, it is estimated that approximately 850,000 people presented to hospitals for treatment of a heart attack in the United States in 2002.

We are 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 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

We have completed patient enrollment in two Phase II clinical trials, each enrolling approximately 900 patients, with our collaborator P&G, which tested the safety and effectiveness of pexelizumab for the treatment of acute inflammation in patients suffering an acute myocardial infarction. One study, called COMPLY was in patients receiving thrombolytic therapy, a procedure for dissolving clots that block heart vessels, and the other called COMMA was in patients receiving angioplasty, a procedure for opening up narrowed or blocked arteries that supply blood to the heart. The COMPLY study completed patient enrollment in January 2002 and the COMMA study completed patient enrollment in April 2002. 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 angioplasty study, pexelizumab treatment was associated with a statistically significant, dose-dependent reduction in death.

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. We, along with P&G, have

commenced enrollment in this pivotal Phase III trial, known as APEX-AMI. The primary endpoint of APEX-AMI will be a reduction in death at 90 days. APEX-AMI is expected to enroll approximately 8,500 patients. 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.

Additional Eculizumab Indications

Membranous Nephritis

The kidneys are responsible for filtering blood to remove toxic metabolites, or breakdown by-products, and maintaining the minerals and proteins in the blood that are required for normal metabolism. Each kidney consists of millions of individual filtering units, or glomeruli. When glomeruli are damaged, the kidney can no longer adequately maintain its normal filtering function. This may result in the build-up of toxins in the blood and the loss of valuable minerals and proteins in the urine. Clinically severe nephritis, or kidney inflammation, is found in many patients suffering from lupus and other autoimmune diseases.

Many forms of damage to the glomeruli are mediated by the immune system, particularly by antibodies and activated complement proteins. Membranous nephritis is a form of kidney inflammation that is believed to be caused by a chronic autoimmune disorder that targets the kidney. We estimate, based on an external market study, that there are approximately 150,000 people currently afflicted with membranous nephritis in the United States.

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 blood proteins into the patient's urine. This condition is known as proteinuria and is recognized as an objective measurement of kidney disease. Additional clinical signs associated with proteinuria may include:

- abnormally low levels of protein in the blood;
- abnormal lipid or fat elevations;
- a propensity for abnormal blood clotting; and
- substantial swelling in the abdomen, under the skin and in the legs.

Current therapies for membranous nephritis include potentially toxic drugs more frequently used to treat other diseases such as cancer. These drugs generally act to broadly suppress the proliferation of many types of cells, including white blood cells. We believe that the usefulness of such therapies is generally limited due to their unfavorable side effects. Even with current therapies, in such a severe disease population more than 30% of the patients are expected to progress to renal, or kidney, failure, which may require dialysis or transplantation. In contrast to current therapies, eculizumab directly targets the inhibition of deleterious complement activation. We believe eculizumab may exert more selective and effective anti-inflammatory activity without the adverse effects associated with current therapies.

Clinical Trials - Membranous Nephritis

We have studied eculizumab for kidney and kidney-related chronic autoimmune disorders, with a focus on membranous nephritis. In August 1999, we commenced a Phase II multi-center, double-blind, randomized, placebo-controlled clinical safety and efficacy trial with multiple doses of eculizumab at two to four week dosing intervals that enrolled approximately 120 membranous nephritis patients. This trial was followed by an open-label extension trial.

The Phase II trial patient enrollment for membranous nephritis was completed in February 2002. In November 2002, preliminary results were reported at the American Society of Nephrology 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 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 12 months with eculizumab therapy. In this second study, eculizumab was well tolerated and associated with an increased remission rate at 12 months and with significant improvements in proteinuria and other important components of nephrotic syndrome.

In February 2000, we announced that the FDA designated Fast Track status for development of eculizumab for the treatment of patients with membranous nephritis. This designation provides for expedited development and application review for approval of a drug through the FDA. The FDA has also granted Orphan Drug designation for the development of eculizumab in the treatment of membranous nephritis patients. Depending on the circumstances at the time of approval, the Orphan Drug designation may lead to market exclusivity for eculizumab for this indication for seven years from the drug's approval date. 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.

Clinical Trials – Rheumatoid Arthritis

In November 2001, we presented the results of our Phase IIa clinical trial testing the safety and effectiveness of repetitive dosing of eculizumab in approximately 200 patients with RA at the American College of Rheumatology meetings. Results showed that eculizumab appeared to be safe and well tolerated in patients in this trial. The most commonly observed adverse events were nausea and diarrhea. The results of this study showed a statistically significant three-month efficacy as measured by ACR 20 criteria for the active arm with a dosage regimen starting with five weekly loading doses followed by monthly intravenous, or IV administration, compared to placebo. The primary endpoint for this trial was met by the group of patients who received this mid-level dosing regimen of eculizumab. Patients who received higher or lower doses of eculizumab in the clinical trial, did not achieve the primary endpoint. Our six-month safety data from this clinical trial showed that eculizumab appeared to be safe and well tolerated in this study population. We also completed a 12 month open-label extension study in RA to help us assess long-term safety.

In January 2004 we announced preliminary results of the 350 patient 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. 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 are conducting a 12 month open-label extension study of this Phase IIb study to help us assess long-term safety. We continue to evaluate our development options for eculizumab in rheumatoid arthritis.

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 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-TPO Receptor Antibody

We are developing a rationally designed antibody-based therapeutic for the treatment of chemotherapy-induced thrombocytopenia, an abnormal decrease in the number of blood platelets. Our compound employs an antibody structure that incorporates an active peptide genetically inserted into the antibody. The active peptide replaces a region of the antibody that is important for the binding properties of the antibody. These changes modify the binding characteristics such that the new antibody will act to bind to and stimulate the receptor on megakaryocytes, called c-mpl, the natural receptor for the hormone thrombopoietin, or TPO. Once stimulated to grow, the megakaryocytes will generate more platelets to replace those lost during treatment with the chemotherapeutic agent. As a result, it is possible that treatment with the TPO receptor agonist antibody could lead to the regeneration of platelets reducing the need for platelet transfusions. This new class of agonist antibody takes advantage of a rational design and selection process proprietary to us through AAT.

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.

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 entered a drug target discovery and validation agreement with CuraGen Corporation, or CuraGen, focused on oncology, the study of tumors and/or cancers. This agreement will enable 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 will apply 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 will use our CoALT antibody discovery platform, developed by us through AAT, to determine the therapeutic utility of the targets. We will own rights to develop and commercialize all antibody and small molecule therapeutics against drug targets across all disease areas. CuraGen is eligible to receive licensing fees, development milestone payments and sales royalties from pharmaceutical products stemming from this alliance.

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 a grant totaling $700,000 for fiscal 2005 by agencies of the U.S. government in support of this program with additional grants totaling $3.2 million available for the next three years pending annual budget legislation approvals.

UniGraft Xenotransplantation Technologies Program

Through our subsidiary, Columbus Farming Corporation, or CFC, we have 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. Interest on the $3.9 million note payable, at 6% per annum, is payable quarterly by CFC. The xenotransplantation manufacturing assets of CFC that were purchased from Tyco, including the real estate, are pledged as security for this note. The principal balance under the note is due in May 2005. Upon CFC's failure to make its quarterly interest payment due to Tyco in August 2003, CFC defaulted on the note. We continue to recognize CFC's interest expense on the note payable as such obligations have not been discharged.

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. CFC is seeking to liquidate itself to fulfill its debt obligation in whole or in part. CFC further notified Tyco that it does not have the funds or assets to satisfy the $3.9 million note and unpaid interest. During the quarter ended January 31, 2004, we and Tyco initiated a plan to sell or liquidate CFC's assets in their present condition. We anticipate that Tyco will retain the proceeds from the sale of CFC's assets and discharge the note and unpaid interest. In August 2004, a written offer of $450,000 was accepted by Tyco for CFC's assets. We used the accepted offer as the basis for determining the fair-market value of CFC's assets and accordingly, we have written down the fair-market value of these assets from $1.2 million to $450,000 as of July 31, 2004. Since CFC's assets, consisting of property, plant and equipment, are insufficient to satisfy the $3.9 million note and unpaid interest, and other obligations of CFC, we expect the unpaid amount of the note and interest will be discharged debt, recognized as other income in fiscal 2005 to CFC. As of July 31, 2004 we have classified the property, plant and equipment of CFC as property, plant and equipment held for sale as per the guidelines set forth in SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets".

Strategic Alliance with Procter & Gamble

In January 1999, we entered into a 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 to 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. 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. In the fourth quarter of 2004, we recognized a $4 million milestone receivable from P&G for the dosing of our first patient in the APEX-AMI clinical trial.

Per the MOU we agreed to bear the first 50% of projected costs associated with the Phase III clinical trial of pexelizumab called PRIMO-CABG in coronary artery bypass graft surgery, or CABG, and P&G agreed to bear the second 50%. During the first quarter ended October 31, 2003, we and P&G both completed each of our obligations with respect to the originally projected costs. Additional costs incurred over the original projected costs are shared equally by us and P&G. Reimbursements received by us from P&G in connection with P&G's 50% 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 $9.8 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.

To date, we have not invested in the development of our own commercial manufacturing capabilities. Although we have established a pilot manufacturing facility for the production of material for clinical trials for some of our potential products, we do not have sufficient capacity to manufacture more than one drug candidate at a time or to manufacture our drug candidates for later stage clinical development or commercialization. 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. The key factors when making the determination of which products will be manufactured internally and which will be manufactured through contractual arrangements will include the availability and expense of contracting this activity, control issues and the expertise and level of resources required for us to manufacture products. In addition, as our product development efforts progress, we expect that we will need to hire additional personnel skilled in product testing and regulatory compliance.

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. Per the Lonza Agreement, we remitted cash advances aggregating $10 million through July 31, 2004 for the long-term commercial manufacture of our C5 inhibitor antibody, eculizumab. The Lonza Agreement was amended, or the Lonza Amendment, on April 9, 2004.

Under the Lonza Amendment, the facility in which Lonza will manufacture eculizumab was changed, the manufacturing capacity we were required to purchase was 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 were 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 were changed. Under the Lonza Agreement, prior to the Lonza Amendment, if we were to terminate the Lonza Agreement, we could have been required to complete the purchase of product scheduled for manufacture up to 18 months following termination, or at our election make a termination payment of up to $25 million, less partial return of the unused portion of prepaid manufacturing costs. 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 reflected as prepaid manufacturing costs within the accompanying balance sheet and are recognized as additional manufacturing costs as the batches are manufactured. On a quarterly basis, we evaluate our plans to proceed with production under the 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 were not to be positive, then all or a portion of the prepaid manufacturing cost may have to be recognized as an expense.

Sales and Marketing

We currently have established core marketing capabilities and have plans to establish sales and distribution capabilities at an appropriate time triggered by milestone events. 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, 2004, 25 of our owned and licensed patents and patent applications relate to technologies or products in the C5 Inhibitor program, 11 relate to other technologies, 29 relate to the UniGraft program, 49 relate to the recombinant human antibody program and 1 relates to our high throughput compound screening program. 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.

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 relevant to 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) the 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) the submission to the FDA of a BLA; and

(5) FDA review and approval of such application.

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. 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.

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 within the same phase of development in similar or differing patient populations. In Phase I, the initial introduction of the drug into human subjects, the drug is usually tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmaco-dynamics and pharmaco-kinetics.

Phase II usually involves studies in a limited patient population to:

- evaluate preliminarily the efficacy of the drug for specific, targeted indications;
- determine dosage tolerance and optimal dosage; and
- identify possible 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. 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. 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 certain FDA expedited review programs for BLAs. One of these review programs is the Continuous Marketing Application, or CMA, which allows for review of portions of a BLA before the sponsor submits the complete BLA, thereby expediting the date on which review of a portion of the BLA can begin. 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. If a product is approved, the approval will impose limitations on the indicated uses for which the product may be marketed. 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.

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.

For clinical investigation and marketing outside the U.S., we are also subject to 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.

Competition

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

- substantially greater financial and other resources;
- larger research and development staffs;
- lower labor costs; and/or
- more extensive marketing and manufacturing organizations.

Many of these companies and organizations have significant experience in pre-clinical testing, human clinical trials, product manufacturing, marketing 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, 2004, we had 204 full-time employees, of which 164 were engaged in research, development, manufacturing, and clinical development, and 40 in administration, commercial and business development and finance. Doctorates are held by 48 of our employees. Each of our employees is required to sign a confidentiality agreement. 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.

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, which includes approximately 69,000 square feet related to research and laboratories. We have made initial leasehold improvements aggregating approximately $8.3 million. In addition, we are paying 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 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.

In addition, our subsidiary, Columbus Farming Corporation or CFC, retains real estate consisting of farmland and buildings used in the development and manufacture of xenotransplantation or UniGraft cells and tissues. We have terminated the UniGraft program in order to focus our resources on our other discovery targets and development programs. CFC’s real estate secures a $3.9 million note payable by CFC to Tyco International, Ltd., or Tyco. The CFC real estate will be sold, with proceeds paid to Tyco. See “UniGraft Xenotransplantation Technologies Program.”

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 September 1, 2004 are as follows:

Name	Age	Position with Alexion
*Leonard Bell, M.D.	46	Chief Executive Officer, Secretary, Treasurer, Director
*David W. Keiser	53	President and Chief Operating Officer, Director
*Stephen P. Squinto, Ph.D.	48	Executive Vice President and Head of Research
*Katherine S. Bowdish, Ph.D.	47	Senior Vice President, Antibody Discovery, and President, Alexion Antibody Technologies
*Christopher F. Mojcik, M.D., Ph.D.	44	Senior Vice President, Clinical Development
*Nancy C. Motola, Ph.D.	52	Senior Vice President, Regulatory and Quality
*Scott A. Rollins, Ph.D.	41	Senior Vice President, Drug Development and Project Management
*Carsten Boess	38	Vice President and Chief Financial Officer
*Thomas I.H. Dubin, J.D.	42	Vice President and General Counsel
Paul W. Finnegan, M.D., M.B.A.	44	Vice President, Commercial Operations and Development
*Barry P. Luke	46	Vice President, Finance and Administration, Assistant Secretary
Russell P. Rother, Ph.D.	43	Vice President, Discovery Research
Daniel N. Caron	41	Executive Director, Operations and Engineering
M. Stacy Hooks, Ph.D.	37	Executive Director, Manufacturing and Technical Services

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

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

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. 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.

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. 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, Dr. Motola served as Assistant, Associate and then Deputy Director, Regulatory Affairs for the Bayer Corporation Pharmaceuticals Division where she was responsible for regulatory aspects of product development programs for cardiovascular, neuroscience, metabolic and oncology drugs. These programs included drugs targeting arthritis, cardiac disorders, stroke and cognitive dysfunction. Dr. Motola has been responsible for the filing of numerous INDs, other regulatory submissions and has filed New Drug Applications for marketing approval resulting in three currently marketed drugs. 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 1983 to 1989. She also served as past Chairperson of the Regulatory Affairs Section of the American Association of Pharmaceuticals Scientists. Dr. Motola received her B.A. from Central Connecticut State University and M.S. and Ph.D. degrees in medical 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 1994, 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.

Carsten Boess has been Vice President and Chief Financial Officer since January 2004. From 1991 until January 2004, Mr. Boess was employed by Novo Nordisk, a large multi-national Danish pharmaceutical company. He started as Corporate Controller and subsequently took on various assignments including Manager Investor Relations and Finance for Novo Nordisk North America, based in New York, as well as Senior Director Finance and Information Technology of Novozymes' North American operations. Besides these U.S. positions, Mr. Boess has held Finance Director/Vice President positions in China, Denmark, Switzerland & France. Mr. Boess holds Bachelor's and Master's degrees in economics and finance from the University of Odense, Denmark.

Thomas I.H. Dubin, J.D. has been Vice President and General Counsel since January 2001. 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.

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.

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.

Russell P. Rother, Ph.D. has been Vice President, Discovery Research since August 2001, 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.

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, 2002.

Fiscal 2003	High	Low
First Quarter (August 1, 2002 to October 31, 2002)	$15.64	$ 9.05
Second Quarter (November 1, 2002 to January 31, 2003)	$17.98	$ 9.50
Third Quarter (February 1, 2003 to April 30, 2003)	$15.06	$10.00
Fourth Quarter (May 1, 2003 to July 31, 2003)	$20.15	$12.80

Fiscal 2004	High	Low
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

As of September 24, 2004, we had 119 stockholders of record of our common stock and an estimated 4,000 beneficial owners. The closing sale price of our common stock on September 24, 2004 was $17.93 per share.

In March 2000, we completed a $120 million private placement of our 5.75% Convertible Subordinated Notes due March 15, 2007. The notes bear interest semi-annually on September 15 and March 15 of each year, beginning September 15, 2000. The holders of the notes may convert all or a portion of the notes into common stock at any time on or before March 15, 2007 at a conversion price of $106.425 per share. The notes were offered to qualified institutional buyers under the exemption from registration provided by Rule 144A under the Securities Act of 1933, as amended, and to persons outside the United States under Regulation S under the Securities Act. 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 are being amortized into interest expense over the seven-year term of the notes.

In September 2003, we sold 3.6 million shares of our common stock at a price of $13.00 per share resulting in net proceeds of approximately $43.9 million, net of underwriting discounts, fees and other expenses of approximately $2.9 million related to the transaction. In July 2004, we sold 5.5 million shares of our common stock at a price of $15.50 per share resulting in net proceeds of approximately $80.9 million, net of underwriting discounts, fees and other expenses of approximately $4.4 million related to the transaction. We expect to use the net proceeds of these sales of common stock to fund working capital and other general corporate purposes, including additional clinical trials of pexelizumab and eculizumab, as well as other research and product development activities.

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.

Item 6. SELECTED CONSOLIDATED FINANCIAL DATA.

(in thousands, except per share data)

	Fiscal Year Ended July 31,				
Consolidated Statements of Operations Data:	**2004**	**2003**	**2002**	**2001**	**2000**
Contract research revenues	$ 4,609	$ 877	$ 6,536	$ 11,805	$ 21,441
Operating expenses:					
Research and development	59,840	71,042	60,005	38,871	40,187
General and administrative	14,459	10,869	7,993	7,135	4,175
Impairment of fixed assets	760	2,560	—	—	—
In-process research and development (IPRD)	—	—	—	21,000	—
Amortization of goodwill (GW)	—	—	—	2,901	—
Total operating expenses	75,059	84,471	67,998	69,907	44,362
Operating loss	(70,450)	(83,594)	(61,462)	(58,102)	(22,921)
Other income (expense), net	(4,336)	(1,885)	4,220	10,177	2,694
State tax benefit, net	691	1,012	700	—	—
Loss before cumulative effect of SAB 101	(74,095)	(84,467)	(56,542)	(47,925)	(20,227)
Cumulative effect of adoption of SAB 101	—	—	—	(9,118)	—
Net loss	$ (74,095)	$ (84,467)	$ (56,542)	$ (57,043)	$ (20,227)
Basic and diluted net loss per common share	$ (3.43)	$ (4.64)	$ (3.12)	$ (3.28)	$ (1.45)
Shares used in computing net loss per common share	21,622	18,209	18,146	17,371	13,914

	As of July 31,				
Consolidated Balance Sheet Data:	**2004**	**2003**	**2002**	**2001**	**2000**
Cash, cash equivalents, and marketable securities	$ 266,501	$ 215,410	$ 308,584	$ 355,274	$ 174,529
Total current assets	276,333	220,910	310,784	362,747	180,080
Total assets	319,575	267,227	354,069	400,259	192,702
Notes payable, less current portion	—	3,920	3,920	3,920	3,920
Convertible subordinated notes	120,000	120,000	120,000	120,000	120,000
Total stockholders' equity	172,522	120,286	205,478	260,408	61,604

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 "Important Factors Regarding Forward-Looking Statements" 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, cardiovascular, and autoimmune disorders. Since our incorporation in January 1992, we have devoted substantially all of our resources to drug discovery, research, and product and clinical development. 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 "Phase III Product Candidates."

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

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;
- adverse medical events or side effects in treated patients;
- 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, 2004, we had an accumulated deficit of approximately $339.4 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 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 may 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 partnerships for product development and commercialization, where we will stay play a major role.

Critical Accounting Policies and the Use of Estimates

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

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

Research and development expenses - We record research and development expenses when they are incurred unless recoverable under contract. Research and development expenses include the following major types of costs: salaries and benefit costs, research license fees and various contractor costs, costs of products developed for clinical trials, depreciation and amortization of lab facilities and leasehold

improvements, building and utilities costs related to research space, and lab supplies. Research and development expenses can fluctuate significantly from milestone payments due to third parties upon the attainment or triggering of contractual milestones such as the grant of a patent, FDA filing, FDA approval, or achieving a manufacturing or sales objective. Accrued research and development expenses are comprised of amounts owed to suppliers for research and development work performed on behalf of us. At each period end 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.

Long-lived assets - We assess the 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, 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-market value to determine whether an impairment charge is required. If the fair-market value is less than the carrying value, such amount is recognized as an impairment charge. (See section entitled “Liquidity and Capital Resources”).

Goodwill, net – At July 31, 2004, we carry $20.0 million of goodwill, net, acquired in connection with our fiscal 2001 acquisition of Prolifaron, representing the excess cost over fair value of the net assets acquired. On a prospective basis, this goodwill or any long-lived investment asset is subject to annual impairment reviews. Impairment charges, if any, will be recorded as a component of operating expenses in the period in which the impairment is determined, if any.

Prepaid manufacturing costs – At July 31, 2004, we carry $9.5 million of prepaid manufacturing costs for cash remitted to Lonza pursuant to a large-scale product supply agreement for the long-term commercial manufacture of our C5 inhibitor antibody, eculizumab. We are recognizing this advance over the large-scale manufacture of eculizumab. Per the Lonza Amendment, as defined in section entitled “Liquidity and Capital Resources”, the amounts advanced are not refundable and are subject to forfeiture pursuant to contractual terms related to cancellation, termination, or failure to purchase a minimum manufacturing capacity. We evaluate the prepaid manufacturing costs against estimated net realizable value, or NRV. If estimated NRV were not to be positive, then all or a portion of the prepaid manufacturing cost may have to be recognized as an expense.

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. Reimbursable contract costs that had previously been netted in accounts payable for 2003 has been disclosed as a separate item in the balance sheet.

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

	Year Ended July 31,		
	2004	2003	2002
Collaboration/Grant Awards			
P&G	$4,588	$673	$4,591
U.S. government grants	21	204	1,745
Other	—	—	200
Total revenues	$4,609	$877	$6,536

Fiscal Years Ended July 31, 2004, 2003, and 2002

We earned contract research revenues of $4.6 million, $0.9 million, and $6.5 million for the fiscal years ended July 31, 2004, 2003, and 2002, 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. All other revenue in fiscal year 2004 and 2003 is primarily a non-cash item representing the amortization of the $10 million upfront fee paid to us by P&G in February 1999. U.S. government grants totaled $21,000 in fiscal 2004 and $204,000 in fiscal 2003. The $183,000 decrease in revenues associated with U.S. government grants resulted primarily from the reduction in grant reimbursable billings from our various government grants as a result of our completion of the related research. The decrease in revenues in fiscal year 2003 as compared to fiscal year 2002 was principally due to decreased research payments from P&G resulting from our December 2001 agreement per a binding memorandum of understanding, or MOU, to revise our 1999 collaboration agreement with P&G.

During fiscal year 2004, we incurred research and development expenses of $59.8 million. For fiscal years 2003 and 2002, we incurred research and development expenses of $71.0 million and $60.0 million, respectively. We track our research and development costs by category incurred rather than by project. Our research and development costs consist primarily of payroll and benefits costs, clinical trial costs and other clinical-related development costs, manufacturing development and manufacturing costs, discovery research costs, depreciation and amortization expense, and occupancy related facility operating costs. The following table summarizes the major research and development expense categories for the fiscal years ended July 31, 2004, 2003, and 2002 respectively ($ in thousands):

	Fiscal year ended July 31,		
($ in thousands)	2004	2003	2002
Research and development expenses:			
Payroll and benefits	$ 14,749	$ 13,613	$ 11,044
Clinical development	20,398	25,122	19,778
Manufacturing development and manufacturing	14,027	17,414	13,017
Discovery research	3,592	8,241	10,339
Operating, occupancy, depreciation, and amortization	7,074	6,652	5,827
Total research and development	$ 59,840	$ 71,042	$ 60,005

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 of costs 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 believe research and development expenses will increase in fiscal 2005 due to, among other things, the confirmatory pivotal Phase III clinical trial with pexelizumab in CABG patients, a pivotal Phase III clinical trial with pexelizumab in AMI patients receiving angioplasty, and the preparation and initiation of the pivotal Phase III program with eculizumab in PNH patients. The increase in research and development expenses for fiscal year 2003 as compared to 2002 was due to greater clinical trial costs while sustaining greater manufacturing costs for our two lead product candidates – pexelizumab and eculizumab. Our agreement with P&G to bear the first 50% of the Phase III pexelizumab PRIMO-CABG trial costs, along with our concurrent clinical trials with eculizumab in PNH, rheumatoid arthritis, and membranous nephritis patients, resulted in higher clinical trial costs in fiscal 2003 as compared to 2002.

Our general and administrative expenses were $14.5 million, $10.9 million and $8.0 million for fiscal years 2004, 2003, and 2002, respectively. The increase in general and administrative expenses of $3.6 million in fiscal year 2004 as compared to 2003 was due principally from increased pre-marketing and business development activities of approximately $1.8 million in support of our PNH clinical trials as well as continued growth of our operations. This growth resulted in increased payroll and benefits cost of approximately $438,000, increased occupancy costs of $584,000, increased professional and legal fees of approximately $520,000, an increase in personal and franchise taxes of approximately $118,000, as well as an increase in directors and officers liability insurance and general liability insurance of approximately $252,000, partially offset by a decrease in capital-based state taxes of approximately $135,000. The increase in general and administrative expenses in fiscal year 2003 as compared to 2002 was principally due to increased costs associated with our pre-marketing and business development activities and increased personnel and professional services to support growth of our operations.

The termination of our UniGraft program resulted in an impairment to our UniGraft manufacturing assets, principally the real estate, building, building improvements and capital lab and farm equipment at our subsidiary, Columbus Farming Corporation, or CFC. These assets were purchased from U.S. Surgical Corporation, now a division of Tyco through the issuance of a $3.9 million note by CFC to Tyco. The purchased assets are pledged as security for the note. CFC will liquidate the assets to satisfy its debt obligation in whole or in part. We anticipate that Tyco will retain the proceeds from the sale of CFC's assets and discharge the note and unpaid interest. In August 2004, a written offer of $450,000 was accepted by Tyco for CFC's assets. We used the accepted offer as the basis for determining the fair-market value of CFC's assets and accordingly, we have written down the fair- market value of these assets by $760,000 from $1.2 million to $450,000 as of July 31, 2004. (See section entitled "Unigraft Xenotransplantation Technologies Program")

Total operating expenses were $75.1 million, $84.5 million, and $68.0 million for fiscal years 2004, 2003, and 2002, respectively.

Other income (expense), net, was an expense of $4.3 million and $1.9 million in fiscal years 2004 and 2003, respectively, and income of $4.2 million for fiscal year 2002, and represents interest expense offset by investment income. The increase in other expense, net, in fiscal year 2004 and 2003 as compared to 2002 was due to approximately the same amount of interest expense partially offset by lower investment income from lower market interest rates and lower cash balances. A state tax benefit of $691,000, $1,012,000 and $700,000 was recognized in each of fiscal year 2004, 2003 and 2002, respectively, resulting from our estimated exchange of our fiscal 2004 and actual exchange of our fiscal 2003, 2002 and 2001 incremental research and development tax credits.

As a result of the above factors, we incurred net losses of $74.1 million, $84.5 million, and $56.5 million or $3.43, $4.64, and $3.12 basic and diluted net loss per share for fiscal years ended July 31, 2004, 2003, and 2002, 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 subordinated notes, other debt financing, payments received under corporate collaborations and grants, and equipment and leasehold improvements financing.

As of July 31, 2004, our cash, cash equivalents, and marketable securities totaled $266.5 million compared to $215.4 million as of July 31, 2003. At July 31, 2004, our cash and cash equivalents consisted of $113.2 million that we hold in short-term highly liquid investments with original maturities of less than three months. The increase in cash, cash equivalents and marketable securities as compared to July 31, 2003 was due principally to the sale of 5.5 million shares of common stock in July 2004 at a price of $15.50 per share resulting in net proceeds of approximately $80.9 million, net of underwriting discounts, fees and other expenses of approximately $4.4 million related to the transaction, and the sale of 3.6 million shares of common stock in September 2003 at a price of $13.00 per share resulting in net proceeds of approximately $43.9 million, net of underwriting discounts, fees and other expenses of approximately $2.9 million related to the transaction. This increase in cash, cash equivalents, and marketable securities is partially offset by the use of funds to fund our operations, including prepaid manufacturing costs to reserve commercial manufacturing capacity, and capital equipment investments. During the year ended July 31, 2004, we invested $3.1 million in property, plant and equipment to support our research and development efforts. We anticipate our research and development expense will increase generally for the foreseeable future to support our clinical and manufacturing development of our product candidates. We anticipate that our existing capital resources together with the anticipated funding from our revised collaboration with P&G, 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 planned for at least the next twenty-four months.

The following table summarizes our contractual obligations at July 31, 2004 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):

	2005	2006	2007	2008	2009	2010 and thereafter
Contractual obligations:						
Note payable	$ 3.9	$ —	$ —	$ —	$ —	$ —
Subordinated convertible notes	—	—	120.0	—	—	—
Interest expense	6.9	6.9	6.9	—	—	—
Operating leases	2.3	2.4	2.5	2.0	1.9	4.1
Total contractual obligations	$13.1	$ 9.3	$129.4	$ 2.0	$ 1.9	$ 4.1
Commercial commitments:						
Clinical and manufacturing development	$70.0	$32.4	$ 23.9	$23.4	$20.8	$ —
Licenses	0.4	0.3	0.4	0.3	0.3	—
Research and development	0.3	0.1	—	—	—	—
Total commercial commitments	$70.7	$32.8	$ 24.3	$23.7	$21.1	$ —

Contractual Obligations

Our contractual obligations include our $120 million of convertible subordinated notes due March 2007, our annual payments of approximately $2.3 million for operating 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. In addition, CFC is the payor under a $3.9 million note.

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 $3.9 million note payable to Tyco. Interest on the $3.9 million note payable, at 6% per annum, is payable quarterly by CFC. The xenotransplantation manufacturing assets of CFC that were purchased from Tyco, including the real estate, are pledged as security for this note. Upon CFC's failure to make its quarterly interest payment due to Tyco in August 2003, CFC defaulted on the note. We continue to recognize CFC's interest expense on the note payable as such obligations have not been discharged.

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. CFC is seeking to liquidate itself to fulfill its debt obligation in whole or in part. CFC further notified Tyco that it does not have the funds or assets to satisfy the $3.9 million note and unpaid interest. During the quarter ended January 31, 2004, we and Tyco initiated a plan to sell or liquidate CFC's assets in their present condition. We anticipate that Tyco will retain the proceeds from the sale of CFC's assets and will discharge the note and unpaid interest. In August 2004, a written offer of $450,000 was accepted by Tyco for CFC's assets. We used the accepted offer as the basis for determining the fair-market value of CFC's assets and accordingly, we have written down the fair-market value of these assets from $1.2 million to $450,000 as of July 31, 2004. Since CFC's assets, consisting of property, plant and equipment, are insufficient to satisfy the $3.9 million note and unpaid interest, and other obligations of CFC, we expect the unpaid amount of the note and interest will be discharged debt, recognized as other income in fiscal 2005 to CFC.

Subordinated Convertible Notes

Interest on our $120 million 5.75% convertible subordinated notes due March 15, 2007 is payable semi-annually in September and March of each year. The holders may convert all or a portion of the notes into common stock any time on or before March 15, 2007 at a conversion price of $106.425 per common share. Beginning March 20, 2003, we may redeem some or all of the notes per the declining redemption prices listed for the notes. We may also elect to pay the repurchase price for some or all the notes in cash or common stock. We may, from time to time, depending on market conditions, repurchase some of our outstanding convertible debt for cash, exchange debt for shares of our common stock, preferred stock, debt or other consideration, or a combination of any of the foregoing. If we exchange shares of our capital stock, or securities convertible into or exercisable for our capital stock, for outstanding convertible debt, the number of shares that we might issue as a result of such exchanges would significantly exceed that number of shares originally issuable upon conversion of such debt and, accordingly, such exchanges could result in material dilution to holders of our common stock. There can be no assurance that we will repurchase or exchange any outstanding convertible debt.

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, which includes approximately 69,000 square feet related to research and laboratories. We have incurred costs relating to initial leasehold improvements aggregating approximately $8.3 million. In addition, we are paying 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 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 current ongoing activities. 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.

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.

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 $9.8 million.

Additional Payments

Additional payments, aggregating up to $24 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, 2004, we had approximately $319.9 million of federal net operating loss carryforwards, which expire through 2024 (of which approximately $19.6 million resulted from the exercise of nonqualified stock options) and $14.6 million of tax credit carryforwards, which expire commencing in fiscal 2008. Provisions of the Tax Reform Act of 1986 may limit our ability to utilize net operating loss and tax credit carryforwards in any given year if certain events occur, including a provision relating to cumulative changes in ownership interests in excess of 50% over a three-year period. We believe that we have triggered these limitation provisions.

Recently issued accounting standards

In November 2003, the Emerging Issues Task Force ("EITF") reached a consensus on EITF Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," regarding the issue of disclosures for marketable securities and debt securities accounted for under SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." The EITF requires additional quantitative disclosure related to unrealized losses, specifically presentation of the aging of such losses. It also requires additional qualitative disclosures to help users understand why the quantitative disclosures are not other-than-temporarily impaired. The adoption of these disclosure requirements are effective for companies with fiscal years ending after December 15, 2003. The adoption of this standard did not have a material impact on either our operating results or financial position.

In December 2003, the SEC issued Staff Accounting Bulletin No. 104 ("SAB 104"), "Revenue Recognition", which supercedes SAB 101, "Revenue Recognition in Financial Statements." SAB 104's primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements, superceded as a result of the issuance of EITF 00-21, "Accounting for Revenue Arrangements with Multiple

Deliverables." The issuance of SAB 104 reflects the concepts contained in EITF 00-21; the other revenue recognition concepts contained in SAB 101 remain unchanged. The issuance of SAB 104 did not have a material impact on our operating results or financial position.

In April 2004, the EITF reached consensus on EITF Issue No. 03-6, "Participating Securities and the Two Class Method under FASB Statement No. 128" ("EITF 03-6"). EITF 03-6 addresses a number of questions regarding the computation of earnings per share by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the company when, and if, it declares dividends on its common stock. EITF 03-6 also provides further guidance in applying the two-class method of calculating earnings per share, clarifying what constitutes a participating security and how to apply the two-class method of computing earnings per share once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. EITF 03-6 is effective for fiscal periods beginning after March 31, 2004 and requires retroactive restatement of prior earnings per share amounts. The adoption of this standard did not have a material impact on either our operating results or financial position.

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.

*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, 2004, we had an accumulated deficit of approximately $339 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 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 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.

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. 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.

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

In December 1999, we completed 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 the 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, 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.

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 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;
- 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 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 stock, which could dilute current stockholders' ownership interest in our company, or securities convertible into our 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 may 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 f 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.

We are significantly leveraged.

We currently have outstanding $120 million principal amount of 5 3/4% convertible subordinated notes. 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.

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 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 subordinated 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 stock may result in considerable uncertainty for an investor.

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 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 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, including our in-licensed, technology, techniques and proprietary compounds and potential drug candidates may conflict with 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 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 claiming that their patents may be relevant to the development, manufacture or sale of some of our drug candidates, including pexelizumab and eculizumab. In response to some of these notices, 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;
- 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 patent holders 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.

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 the 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.

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 manufacturing for pexelizumab through one or more third-party manufacturers. P&G has contracted with one third-party manufacturer for the large-scale commercial manufacture of pexelizumab. The failure of P&G to obtain appropriate commercial manufacturing for pexelizumab on a timely basis, or at all, may prevent or impede the commercialization of pexelizumab. We have executed a large-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 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 payors 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.

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 carryforwards to reduce future tax payments may be limited if there is a change in ownership of Alexion.

As of July 31, 2004, we had approximately $320 million of net operating loss carryforwards, 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 thereunder, increase their aggregate percentage ownership of our stock by more than 50 percentage points over the lowest percentage of our stock owned by these stockholders at any time during the testing period, which is generally the three-year period preceding the potential ownership change. In the event of an ownership change, section 382 imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change NOLs. The limitation imposed by section 382 for any post-change year would be determined by multiplying the value of our stock immediately before the ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Any unused limitation may be carried over to later years, and the limitation may under certain circumstances be increased by built-in gains which may be present with respect to assets held by us at the time of the ownership change that are recognized in the five-year period after the ownership change. Our use of NOLs arising after the date of an ownership change would not be affected.

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 on July 30, 2004. However, 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.

As part of our investment portfolio we own financial instruments that are sensitive to market risks. The investment portfolio is used to preserve our capital until it is required to fund operations, including our research and development activities. Our short-term investments and investments consist of U.S. Government obligations, high-grade corporate notes and commercial paper. All of our investments in debt securities are classified as “available-for-sale” and are recorded at fair value. Our investments are subject to interest rate risk, and could decline in value if interest rates increase. Due to the conservative nature of our short-term investments and investments policy we do not believe that we have a material exposure to interest rate risk. Although our investments are subject to credit risk, our investment policies specify credit quality standards for our investments and limit the amount of credit exposure from any single issue, issuer or type of investment.

Our “available-for-sale” marketable securities are sensitive to changes in interest rates. Interest rate changes would result in a change in the fair value of these financial instruments due to the difference between the market interest rate and the rate at the date of purchase of the financial instrument. A 10% decrease in year-end market interest rates would result in no material impact on the net fair value of such interest-sensitive financial instruments.

A 10% increase or decrease in market interest rates would result in no material impact on our 5.75% Subordinated Convertible Notes.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The consolidated financial statements and supplementary data of the Company required in this item are set forth at the pages indicated in Item 15(a)(1).

Item 9A. CONTROLS AND PROCEDURES.

We have carried out an evaluation, as of the end of the period covered by this report, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level in ensuring that material information relating to us and required to be included in the reports we file under the Securities and Exchange Act of 1934, as amended, is accumulated and communicated to the Chief Executive Officer and Chief Financial Officer or other persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

There have been no changes in our internal controls over financial reporting in connection with the evaluation required under paragraph (d) of Rule 13a-15 under the Exchange Act that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

PART III

Item 10. DIRECTORS and EXECUTIVE OFFICERS of the REGISTRANT.

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

Name	Age	Position with Alexion
Max Link, Ph.D.(1)	64	Chairman of the Board of Directors
Leonard Bell, M.D.(4)	46	Chief Executive Officer, Secretary, Treasurer, Director
David W. Keiser (4)	53	President and Chief Operating Officer, Director
Stephen P. Squinto, Ph.D.(4)	48	Executive Vice President and Head of Research
Katherine S. Bowdish, Ph.D. (4)	47	Senior Vice President, Antibody Discovery, and President, Alexion Antibody Technologies
Christopher F. Mojcik, M.D., Ph.D. (4)	44	Senior Vice President, Clinical Development
Nancy Motola, Ph.D. (4)	52	Senior Vice President, Regulatory and Quality
Scott A. Rollins, Ph.D. (4)	41	Senior Vice President, Drug Development and Project Management
Carsten Boess (4)	38	Vice-President and Chief Financial Officer
Thomas I.H. Dubin, J.D. (4)	42	Vice President and General Counsel
Paul W. Finnegan M.D., M.B.A.	44	Vice President, Commercial Operations and Development
Barry P. Luke (4)	46	Vice President, Finance and Administration, Assistant Secretary
Russell P. Rother, Ph.D.	43	Vice President, Discovery Research
Daniel N. Caron	41	Executive Director, Operations and Engineering
M. Stacy Hooks, Ph.D.	37	Executive Director, Manufacturing and Technical Services
Jerry T. Jackson (2)(3)	63	Director
Joseph A. Madri, Ph.D., M.D. (3)	58	Director
Larry L. Mathis (1)(2)	61	Director
R. Douglas Norby (1)	69	Director
Alvin S. Parven (2)(3)	64	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 Governance Committee of the Board of Directors.
(4) 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, and Dr. Squinto are each a party to an employment agreement with us.

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., Christopher F. Mojcik, M.D., Ph.D., Nancy Motola, Ph.D., Scott A. Rollins, Ph.D., Carsten Boess, Thomas I.H. Dubin, J.D., Paul W. Finnegan, M.D., M.B.A., Barry P. Luke, Russell P. Rother, Ph.D., 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., Cell Therapeutics, Inc., CytRx Corporation, as well as Celsion Corporation, and is also a director of Access Pharmaceuticals, Inc., Columbia Laboratories, 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).

Jerry T. Jackson has been a director of Alexion since September 1999. He was employed by Merck & Co. Inc., a major pharmaceutical company, from 1965 until his retirement in 1995. During this time, he had extensive experience in sales, marketing and corporate management, including joint ventures. From 1993 until 1995, Mr. Jackson served as Executive Vice President of Merck with broad responsibilities for numerous operating groups including Merck's International Human Health, Worldwide Human Vaccines, the AgVet Division, Astra/Merck U.S. Operations, as well as worldwide marketing. During 1993, he was also President of the Worldwide Human Health Division. He served as Senior Vice President of Merck from 1991 to 1992 responsible for Merck's Specialty Chemicals and previously, he was President of Merck's Sharp & Dohme International. Mr. Jackson serves as a director of Langford I.C. Systems, Inc., IntraBiotics Pharmaceuticals, Inc., and Myogen, Inc., each a small pharmaceutical company. He received his B.A. from University of New Mexico.

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 175 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 Care 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 Care 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 Zambeel, 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 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 Pharmetrix 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, Chip PAC, Inc., a semiconductor company, and Verisity Design, Inc., an electronic design automation software 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.

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, 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.

CODE OF ETHICS

We have adopted a Code of Ethics (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.

PROCEDURE TO NOMINATE DIRECTORS

The information required by Item 401(j) of Regulation S-K 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 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 BENEFICAL 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 September 1, 2004, 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 executive officers of us as a group.

Name and Address of Beneficial Owner (1)	Number of Shares of Common Stock Beneficially Owned (2)	Percentage of Outstanding Shares of Common Stock
OppenheimerFunds, Inc. 498 Seventh Avenue New York, NY 10018 (3)	2,838,700	10.3%
Fidelity Management & Research Company 82 Devonshire Street Boston, MA 02109 (3)	2,189,290	7.9%
Sectoral Asset Management, Inc. 1000 Sherbrooke St Montréal, Canada (3)	1,957,753	7.1%
RS Investment Management LP 388 Market Street San Francisco, CA 94111 (3)	1,343,040	5.0%
Leonard Bell, M.D. (4)	903,489	3.2%
David W. Keiser (5)	292,326	1.1%
Stephen P. Squinto, Ph.D. (6)	263,027	1.0%
Joseph Madri, Ph.D., M.D. (7)	89,134	*
Christopher F. Mojcik, M.D., Ph.D. (8)	88,889	*
Max Link, Ph.D. (9)	57,157	*
Thomas I.H. Dubin, J.D. (10)	64,875	*
Jerry T. Jackson (11)	35,834	*
R. Douglas Norby (12)	35,834	*
Alvin S. Parven (13)	34,734	*
Larry L. Mathis (14)	1,000	*
All directors and executive officers as a group (16 persons)(15)	2,295,643	7.8%

* 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, 2004.

(4) Includes 686,044 shares of common stock that may be acquired upon the exercise of options within 60 days of September 1, 2004 and 300 shares, in aggregate, held in the names of Dr. Bell's three children. Excludes 41,644 shares obtainable through the exercise of options, granted to Dr. Bell, which are not exercisable within 60 days of September 1, 2004 and 90,000 shares held in trust for Dr. Bell's children of which Dr. Bell disclaims beneficial ownership. Dr. Bell disclaims beneficial ownership of the shares held in the names of his children.

(5) Includes 260,526 shares of common stock which may be acquired upon the exercise of options within 60 days of September 1, 2004 and 300 shares, in aggregate, held in the names of Mr. Keiser's three children. Excludes 35,974 shares obtainable through the exercise of options, granted to Mr. Keiser, which are not exercisable within 60 days of September 1, 2004. Mr. Keiser disclaims beneficial ownership of the shares held in the names of his minor children.

(6) Includes 224,202 shares of common stock which may be acquired upon the exercise of options within 60 days of September 1, 2004; 7,106 shares held in trust for the benefit of Dr. Squinto's three minor children of which Dr. Squinto's spouse is the trustee; and 8,118 shares held in a charitable remainder trust of which Dr. Squinto and his spouse are the trustees and income beneficiaries. Excludes 28,173 shares obtainable through the exercise of options, granted to Dr. Squinto, which are not exercisable within 60 days of September 1, 2004. Dr. Squinto disclaims beneficial ownership of the shares held in the names of his minor children and the foregoing trusts.

(7) Includes 39,134 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of September 1, 2004. Excludes 17,666 obtainable through the exercise of options granted to Dr. Madri, which are not exercisable within 60 days of September 1, 2004.

(8) Includes 88,889 shares of common stock, which may be acquired upon the exercise of options within 60 days of September 1, 2004. Excludes 29,111 shares obtainable through the exercise of options granted to Dr. Mojcik, which are not exercisable within 60 days of September 1, 2004.

(9) Includes 19,500 shares of common stock which may be acquired upon the exercise of options within 60 days of September 1, 2004. Excludes 17,666 shares obtainable through the exercise of options granted to Dr. Link, which are not exercisable within 60 days of September 1, 2004.

(10) Includes 64,875 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of September 1, 2004. Excludes 36,125 shares obtainable through the exercise of options granted to Mr. Dubin, which are not exercisable within 60 days of September 1, 2004.

(11) Includes 35,834 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of September 1, 2004. Excludes 17,666 shares obtainable through the exercise of options granted to Mr. Jackson, which are not exercisable within 60 days of September 1, 2004.

(12) Includes 35,834 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of September 1, 2004. Excludes 17,666 shares obtainable through the exercise of options granted to Mr. Norby, which are not exercisable within 60 days of September 1, 2004.

(13) Includes 34,734 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of September 1, 2004. Excludes 17,666 shares obtainable through the exercise of options granted to Mr. Parven, which are not exercisable within 60 days of September 1, 2004.

(14) Includes 0 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of September 1, 2004. Excludes 12,000 shares obtainable through the exercise of options granted to Mr. Mathis, which are not exercisable within 60 days of September 1, 2004.

(15) Consists of shares beneficially owned by Drs. Bell, Link, Madri, Mojcik, and Squinto and Messrs. Dubin, Jackson, Keiser, Mathis, Norby and Parven, and certain other officers. Includes 1,868,420 shares of common stock, which may be acquired upon the exercise of options within 60 days of September 1, 2004.

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, 2004.

Plan Category	Number of shares of common stock to be issued upon exercise of outstanding options (2)	Weighted-average exercise price of outstanding options	Number of shares of common stock remaining available for future issuance under equity compensation plans
Equity compensation plans approved by stockholders (1)	4,506,999	$ 22.20	1,259,129
Equity compensation plans not approved by stockholders	—	—	—

(1) Reflects aggregate options outstanding and available for issuance under our 1992 Stock Option Plan, 1992 Stock Option Plan for Outside Directors, and 2000 Stock Option Plan.

(2) Does not include 35,211 shares of common stock to be issued upon exercise of options granted under Prolifaron Inc. 1999 Long Term Incentive and Stock Option Plan with a vested weighted 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 thereunder 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. PRINCIPLE ACCOUNTANT FEES AND SERVICES.

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 15. EXHIBITS and FINANCIAL STATEMENT SCHEDULES.

(a) (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.

(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)
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. (4)
10.8	Exclusive License Agreement dated as of June 19, 1992 among the Company, Yale University and Oklahoma Medical Research Foundation. (2)

10.9	License Agreement dated as of September 30, 1992 between the Company and Yale University, as amended July 2, 1993.(2)+
10.10	Exclusive Patent License Agreement dated April 21, 1994 between the Company and the National Institutes of Health.(2)+
10.11	License Agreement dated as of January 10, 1995 between the Company and Yale University.(2)+
10.12	License Agreement dated as of May 27, 1992 between the Company and Yale University, as amended September 23, 1992.(2)+
10.19	License Agreement dated March 27, 1996 between the Company and Medical Research Council.(5)+
10.20	License Agreement dated May 8, 1996 between the Company and Enzon, Inc.(5)+
10.21	Asset Purchase Agreement date as of February 9, 1999 between the Company and United States Surgical Corporation.(6)
10.22	Collaboration Agreement dated January 25, 1999 between the Company and the Procter & Gamble Company, as amended.(6)+
10.24	Binding Memorandum of Understanding dated December 11, 2001 between the Company and the Procter & Gamble Company.(7)+
10.25	Research and Development Facility lease, dated February 1, 2002, between the Company and PMSI SRF L.L.C.(8)
10.26	Large-Scale Product Supply Agreement, dated December 18, 2002, between the Company and Lonza Biologics plc., as amended. (13)+
10.27	Industrial Real Estate lease, dated January 1, 2003, between the Company and SP-K Development, LLC. (9)
10.28	Co-Development and Co-Commercialization Agreement between the Company and XOMA (US) LLC, dated December 17, 2003 (11)+
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.
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 Quarterly Report on Form 10-Q for the quarter ended April 30, 2004.
+ Confidential treatment was granted for portions of such document.

(b) Exhibits

See (a) (3) above.

(c) Financial Statement Schedules

See (a) (2) above.

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: September 23, 2004

By: /s/ DAVID W. KEISER

David W. Keiser
President and Chief Operating Officer
Dated September 23, 2004

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ LEONARD BELL Leonard Bell, M.D.	Chief Executive Officer, Secretary, Treasurer and Director (principal executive officer)	September 23, 2004
/s/ DAVID W. KEISER David W. Keiser	President, Chief Operating Officer and Director	September 23, 2004
/s/ CARSTEN BOESS Carsten Boess	Vice-President and Chief Financial Officer (principal financial officer)	September 23, 2004
/s/ BARRY P. LUKE Barry P. Luke	Vice President, Finance and Administration (principal accounting officer)	September 23, 2004
/s/ MAX LINK Max Link, Ph.D.	Chairman of the Board of Directors	September 23, 2004
/s/ LARRY L. MATHIS Larry L. Mathis	Director	September 23, 2004
/s/ JERRY T. JACKSON Jerry T. Jackson	Director	September 23, 2004
/s/ JOSEPH A. MADRI Joseph A. Madri, Ph.D., M.D.	Director	September 23, 2004
/s/ R. DOUGLAS NORBY R. Douglas Norby	Director	September 23, 2004
/s/ ALVIN S. PARVEN Alvin S. Parven	Director	September 23, 2004

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Consolidated Financial Statements
July 31, 2004 and 2003

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of stockholders' equity and of cash flows present fairly, in all material respects, the financial position of Alexion Pharmaceuticals, Inc. and its subsidiaries at July 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended July 31, 2004 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 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.

/s/ PriceWaterhouseCoopers LLP

PriceWaterhouseCoopers
Hartford, CT
September 15, 2004

Alexion Pharmaceuticals, Inc.
Consolidated Balance Sheets
July 31, 2004 and 2003
(in thousands)

	July 31, 2004	July 31, 2003
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 113,224	$ 24,844
Marketable securities	153,277	190,566
Milestone receivable	4,000	—
Reimbursable contract costs	826	1,540
State tax receivable	1,493	1,012
Prepaid expenses and other current assets	3,513	2,948
Total current assets	276,333	220,910
Property, plant and equipment, net	11,336	12,276
Property, plant and equipment held for sale	450	—
Goodwill	19,954	19,954
Prepaid manufacturing costs	9,500	10,000
Deferred financing costs, net	1,547	2,119
Other assets	455	1,968
Total assets	$ 319,575	$ 267,227
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Note payable	$ 3,920	$ —
Accounts payable	8,298	8,710
Accrued expenses	3,798	4,312
Accrued interest	2,881	2,646
Deferred revenue	588	589
Deferred research and development payments	188	—
Total current liabilities	19,673	16,257
Deferred revenue, less current portion included above	6,177	6,764
Deferred research and development payments, less current portion included above	1,203	—
Note payable	—	3,920
Convertible subordinated notes	120,000	120,000
Total liabilities	147,053	146,941
COMMITMENTS AND CONTINGENCIES (see Note 9)		
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; 27,557 and 18,257 shares issued at July 31, 2004 and 2003, respectively	3	2
Additional paid-in capital	512,827	385,498
Accumulated deficit	(339,361)	(265,266)
Accumulated other comprehensive income (loss)	(347)	652
Treasury stock, at cost, 37 shares at July 31, 2004 and 2003	(600)	(600)
Total stockholders' equity	172,522	120,286
Total liabilities and stockholders' equity	$ 319,575	$ 267,227

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

Alexion Pharmaceuticals, Inc.
Consolidated Statements of Operations
For the Years Ended July 31, 2004, 2003 and 2002
(in thousands, except per share amounts)

	For the Years Ended July 31,		
	2004	2003	2002
CONTRACT RESEARCH REVENUES	$ 4,609	$ 877	$ 6,536
OPERATING EXPENSES			
Research and development	59,840	71,042	60,005
General and administrative	14,459	10,869	7,993
Impairment of fixed assets (Note 4)	760	2,560	—
Total operating expenses	75,059	84,471	67,998
Operating loss	(70,450)	(83,594)	(61,462)
OTHER INCOME AND EXPENSE			
Investment income	3,373	5,809	11,920
Interest expense	(7,709)	(7,694)	(7,700)
Loss before state tax benefit	(74,786)	(85,479)	(57,242)
STATE TAX BENEFIT	691	1,012	700
Net loss	$ (74,095)	$ (84,467)	$ (56,542)
BASIC AND DILUTED PER SHARE DATA			
Net loss per share	$ (3.43)	$ (4.64)	$ (3.12)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS PER COMMON SHARE	21,622	18,209	18,146

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

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Alexion Pharmaceuticals, Inc.
Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Loss
For the Years Ended July 31, 2004, 2003 and 2002
(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Other Comprehensive Income (Loss)	Treasury Stock at Cost		Total Stockholders' Equity	Total Comprehensive Loss
	Shares	Amount				Shares	Amount		
Balance, July 31, 2001	18,119	$ 2	$ 384,091	$ (124,257)	$ 572	12	$ —	$ 260,408	
Issuance of common stock from exercise of options	122	—	926	—	—	25	(600)	326	
Noncash compensation expense related to grant of stock options	—	—	180	—	—	—	—	180	
Net change in unrealized gains (losses) on marketable securities	—	—	—	—	1,106	—	—	1,106	$ 1,106
Net loss	—	—	—	(56,542)	—	—	—	(56,542)	(56,542)
Comprehensive loss	—	—	—	—	—	—	—	—	$ (55,436)
Balance, July 31, 2002	18,241	$ 2	$ 385,197	$ (180,799)	$ 1,678	37	$ (600)	$ 205,478	
Issuance of common stock from exercise of options	16	—	155	—	—	—	—	155	
Noncash compensation expense related to grant of stock options	—	—	146	—	—	—	—	146	
Net change in unrealized gains on marketable securities	—	—	—	—	(1,026)	—	—	(1,026)	$ (1,026)
Net loss	—	—	—	(84,467)	—	—	—	(84,467)	(84,467)
Comprehensive loss	—	—	—	—	—	—	—	—	$ (85,493)
Balance, July 31, 2003	18,257	$ 2	$ 385,498	$ (265,266)	$ 652	37	$ (600)	$ 120,286	
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 $7.3 million	9,100	1	124,720	—	—	—	—	124,721	
Net change in unrealized gains on marketable securities	—	—	—	—	(999)	—	—	(999)	$ (999)
Net loss	—	—	—	(74,095)	—	—	—	(74,095)	(74,095)
Comprehensive loss	—	—	—	—	—	—	—	—	$ (75,094)
Balance, July 31, 2004	27,557	$ 3	$ 512,827	$ (339,361)	$ (347)	37	$ (600)	$ 172,522	

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

Alexion Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
For the Years Ended July 31, 2004, 2003 and 2002
(in thousands)

	For the Years Ended July 31,		
	2004	2003	2002
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (74,095)	$ (84,467)	$ (56,542)
Adjustments to reconcile net loss to net cash used in operating activities			
Impairment of fixed assets	760	2,560	—
Depreciation and amortization	3,593	3,726	3,562
Gain on sale of marketable securities	—	—	(1,891)
Compensation expense related to grant of stock options	106	146	180
Changes in assets and liabilities			
Milestone receivable and reimbursable contract costs	(3,286)	(677)	6,117
State tax receivable	(481)	(1,012)	—
Prepaid expenses	(565)	(1,611)	(844)
Other assets	1,363	1,039	(2,769)
Prepaid manufacturing costs	500	(7,250)	(2,750)
Accounts payable	(412)	(1,133)	8,121
Accrued expenses	(514)	9	2,008
Accrued interest	235	19	(19)
Deferred revenue	(588)	(545)	(1,394)
Deferred research and development payments	1,391	—	—
Net cash used in operating activities	(71,993)	(89,196)	(46,221)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of marketable securities	(168,952)	(114,116)	(533,117)
Proceeds from maturity or sale of marketable securities	205,242	183,534	495,190
Purchases of property, plant and equipment	(3,135)	(3,070)	(4,096)
Investments in patents and licensed technology	(5)	(37)	(36)
Net cash received in acquisition of Prolifaron	—	—	340
Net cash provided by (used in) investing activities	33,150	66,311	(41,719)
CASH FLOWS FROM FINANCING ACTIVITIES			
Net proceeds from issuance of common stock	127,223	155	326
Net cash provided by financing activities	127,223	155	326
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	88,380	(22,730)	(87,614)
CASH AND CASH EQUIVALENTS, beginning of year	24,844	47,574	135,188
CASH AND CASH EQUIVALENTS, end of year	$ 113,224	$ 24,844	$ 47,574
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid for interest expense	$ 6,901	$ 7,135	$ 7,077
SUPPLEMENTAL DISCLOSURE OF NONCASH FINANCING ACTIVITIES			
Exercise of stock options through tendering of mature common stock	$ —	$ —	$ 600

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

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2004 and 2003

1. Organization and Operations

Alexion Pharmaceuticals, Inc. (“Alexion”) was organized in 1992 and is engaged in the development of therapeutic products for the treatment of a wide array of severe diseases, including hematologic, cardiovascular, and autoimmune disorders. 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.

We have incurred consolidated losses since inception and have made no product sales to date. We will continue to seek financing to obtain regulatory approvals for our product candidates, fund operations losses, and if deemed appropriate, establish manufacturing, sales, marketing and distribution capabilities. We expect to incur substantial expenditures in the foreseeable future for the research and 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.

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. Reimbursable contract costs that had previously been netted in accounts payable for 2003 has been disclosed as a separate item in the balance sheet.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include Alexion Pharmaceuticals, Inc. and its wholly-owned subsidiaries, Alexion Antibody Technologies (“AAT”) and Columbus Farming Corporation (“CFC”). Results of operations of AAT are included in our consolidated statements of operations since September 23, 2000, the effective date of the Prolifaron acquisition (see Note 5). CFC was formed on February 9, 1999 to acquire certain research and development assets from U.S. Surgical Corporation, a subsidiary of Tyco International, Ltd. (“Tyco”). All significant inter-company balances and transactions have been eliminated in consolidation. With the abandonment of our UniGraft xenotransplantation research and development program in fiscal 2003, CFC activities were terminated (see Notes 4 and 6).

Cash and Cash Equivalents

Cash and cash equivalents are stated at cost, which approximates market, and includes 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 component of stockholders’ equity. No realized gains or losses were recorded during the years ended July 31, 2004 and 2003. During the year ended July 31, 2002, we realized a gain on sales of marketable securities of approximately $1.9 million. We utilize the

specific identification method in computing realized gains and losses. At July 31, 2004, our marketable securities had a maximum maturity of less than 2 years with an average of approximately 8 months. The weighted average interest rate associated with marketable debt securities was 1.9 percent and 1.4 percent as of July 31, 2004 and 2003, respectively.

The following is a summary of marketable securities at July 31, 2004 and 2003 (amounts in thousands):

	Amortized Cost	Net Unrealized Gains (Losses)	Fair Value
Federal agency obligations	$ 96,896	$ (298)	$ 96,598
Corporate bonds	32,306	(66)	32,240
Certificates of deposit	24,361	(33)	24,328
Other	61	50	111
Total marketable securities at July 31, 2004	$ 153,624	$ (347)	$ 153,277
Federal agency obligations	$ 116,301	$ 466	$ 116,767
Corporate bonds	54,383	138	54,521
Certificates of deposit	19,171	5	19,176
Other	59	43	102
Total marketable securities at July 31, 2003	$ 189,914	$ 652	$ 190,566

Per EITF 03-1, we review periodically those investment securities whose unrealized losses have remained unrealized for more than six months to determine if such unrealized losses are not temporary. Gross unrealized losses from all individual investment securities aggregated $411,000 and $269,000 at July 31, 2004 and 2003, respectively. We intend to hold these related investment securities to maturity and have the ability to do so. As a result, we consider these losses to be temporary and have not recorded a loss on our consolidated statements of operations.

Goodwill

We adopted SFAS No. 142 (“Goodwill and Other Intangible Assets,”) effective August 1, 2001. The adoption of SFAS No. 142 caused the amortization related to the $22.9 million of goodwill acquired in connection with the acquisition of Prolifaron (see Note 5) to cease effective August 1, 2001. This goodwill will be reviewed for impairment at least annually and whenever events or changes in circumstances indicate the carrying amount of goodwill might not be recoverable. We conduct our annual impairment review during March each year. The first step of the annual review is to compare the fair market capitalization of Alexion on that date to our net stockholders’ equity. If fair market capitalization is greater than net stockholders’ equity, then no impairment charges are necessary. The analysis is impacted by the price of the stock on the date of the test. Impairment charges, if any, will be recorded as a component of operating expenses in the period in which the impairment is determined. No impairment charge resulted upon the adoption of this standard and as a result of the Company’s annual impairment assessment.

Long-Lived Assets

We account for our long-lived assets, including property, plant, and equipment, pursuant to SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets”. Accordingly, we assess the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable (see Note 4). Factors that we consider important, 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.

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 units 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 3).

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. EITF-00-21 requires evaluation of 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 a 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 (see Note 3).

Research and Development Expenses

Research and development expenses are comprised of costs incurred in performing research and development activities including salaries and benefits, 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 leasehold improvements, building, facilities and utilities related costs related to research space, and lab supplies. We have entered into certain research agreements in which we share costs with our collaborator. We record these costs as research and development expenses. Certain of these costs are reimbursed by our collaborator and are recorded as a reduction of research and development expense.

Accrued research and development expenses include amounts owed to suppliers for research and development work performed on behalf of us. At each period end 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. During fiscal year 2004, we incurred research and development expenses of $59.8 million. For fiscal years 2003 and 2002, we incurred research and development expenses of $71.0 million and $60.0 million, respectively.

Comprehensive Loss

We report and present comprehensive loss in accordance with SFAS No. 130 “Reporting Comprehensive Income,” which establishes standards for reporting and display of comprehensive income or loss and its components in a full set of general purpose financial statements. The objective of the statement is to report a measure of all changes in equity of an enterprise that result from transactions and other economic events of the period other than transactions with owners (comprehensive income or loss). Our other comprehensive loss arises from net unrealized gains (losses) on marketable securities. We have elected to display comprehensive loss as a component of the statements of changes in stockholders’ equity and comprehensive loss.

Stock Options

At July 31, 2004, we have two stock-based compensation plans for our employees, directors, and consultants. We account for stock options granted to employees in accordance with Accounting Principles Board Opinion (“APB”) No. 25. We account for stock options granted 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”. We may incur charges to operations in connection with awards from these stock option plans. In accordance with APB No. 25 and related interpretations, we record compensation expense from employee stock-based awards under certain conditions. Generally, when the terms of the award and the amount the employee must pay to acquire the stock are fixed, compensation expense for options will total the grant date intrinsic value, if any, amortized over the vesting period.

Additionally, as required by SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure - an amendment of SFAS 123," we provide the following table which illustrates the effect on net income and earnings per share if we had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation for the years ended July 31, 2004, 2003 and 2002 (dollars in thousands, except per share amounts):

	Years Ended July 31,		
	2004	2003	2002
Net loss, as reported	$(74,095)	$(84,467)	$(56,542)
Add: Stock-based employee compensation expense included in reported net loss	67	96	168
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(14,552)	(15,433)	(16,080)
Pro forma net loss	$(88,580)	$(99,804)	$(72,454)
Net loss per share:			
Basic and diluted-as reported	$ (3.43)	$ (4.64)	$ (3.12)
Basic and diluted-pro forma	$ (4.10)	$ (5.48)	$ (3.99)

For the purposes of this pro forma disclosure, the estimated value of each employee and non-employee option grant was calculated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option-pricing models require the use of subjective assumptions, including the expected stock price volatility. The effects of applying the fair value recognition provisions of SFAS No. 123 in this pro forma disclosure are not indicative of future amounts. The additional disclosures required by SFAS No. 123 are included in Note 11.

Net Loss Per Common Share

We compute and present net loss per common share in accordance with SFAS No. 128, "Earnings Per Share". Basic net loss per common share is based on the weighted average shares of common stock outstanding during the period. Diluted net loss per common share assumes in addition to the above, the dilutive effect of common share equivalents outstanding during the period. Common share equivalents represent dilutive stock options and convertible subordinated debt. These outstanding stock options and convertible subordinated debt entitled holders to acquire 5,669,764, 5,148,365 and 4,685,160 shares (prior to the application of the treasury stock method) of common stock at July 31, 2004, 2003 and 2002, 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.

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.

Fair Value of Financial Instruments

Financial instruments include cash and cash equivalents, marketable securities, milestone receivable, reimbursable contract costs, accounts payable, notes payable and convertible subordinated notes. Cash and cash equivalents and marketable securities are carried at fair value. Milestone receivable, reimbursable contract costs,

accounts payable, notes payable and convertible subordinated notes are carried at cost. We believe milestone receivable, reimbursable contract costs and accounts payable approximate fair value. The carrying value of convertible subordinated notes approximated fair value based upon trading values reported at July 31, 2004 (see Note 8). We believe the fair value of the CFC note payable approximates the estimated fair value of the underlying collateral of approximately $450,000 at July 31, 2004 (see Note 6).

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.

Recently Issued Accounting Standards

In November 2003, the Emerging Issues Task Force (“EITF”) reached a consensus on EITF Issue No. 03-1, “The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments,” regarding the issue of disclosures for marketable securities and debt securities accounted for under SFAS No. 115, “Accounting for Certain Investments in Debt and Equity Securities.” The EITF requires additional quantitative disclosure related to unrealized losses, specifically presentation of the aging of such losses. It also requires additional qualitative disclosures to help users understand why the quantitative disclosures are not other-than-temporarily impaired. The adoption of these disclosure requirements are effective for companies with years ending after December 15, 2003. The adoption of this standard did not have a material impact on either our operating results or financial position

In December 2003, the SEC issued Staff Accounting Bulletin No. 104 (“SAB 104”), “Revenue Recognition”, which supersedes SAB 101, “Revenue Recognition in Financial Statements.” SAB 104’s primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements, superseded as a result of the issuance of EITF 00-21, “Accounting for Revenue Arrangements with Multiple Deliverables.” EITF-00-21 requires evaluation of 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. The issuance of SAB 104 reflects the concepts contained in EITF 00-21; the other revenue recognition concepts contained in SAB 101 remain unchanged. The issuance of SAB 104 did not have a material impact on our results of operations or financial position.

In April 2004, the EITF reached consensus on EITF Issue No. 03-6, “Participating Securities and the Two Class Method under FASB Statement No. 128” (“EITF 03-6”). EITF 03-6 addresses a number of questions regarding the computation of earnings per share by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the company when, and if, it declares dividends on its common stock. EITF 03-6 also provides further guidance in applying the two-class method of calculating earnings per share, clarifying what constitutes a participating security and how to apply the two-class method of computing earnings per share once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. EITF 03-6 is effective for fiscal periods beginning after March 31, 2004 and requires retroactive restatement of prior earnings per share amounts. The adoption of this standard did not have a material impact on either our operating results or financial position

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
July 31, 2004 and 2003

3. Research and Development Collaborations

Procter & Gamble Pharmaceuticals Collaboration

In January 1999, we and Procter & Gamble Pharmaceuticals ("P&G") entered into an exclusive collaboration to develop and commercialize pexelizumab. We granted P&G an exclusive license to our intellectual property related to pexelizumab, with the right to sublicense. We are recognizing a non-refundable up-front license fee of $10 million related to the P&G collaboration as revenue over 17 years representing the average of the remaining patent lives of the underlying technologies at the time the payment was received in fiscal 1999. We recorded this payment as deferred revenue. The balance at July 31, 2004 and 2003 was $6.8 million and $7.4 million, respectively. Concurrent with the dosing of our first patient in the APEX-AMI trial in the fourth quarter of 2004, we also recognized a $4 million milestone payment from P&G as milestone receivable.

In December 2001, we and P&G entered into a binding memorandum of understanding ("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. Prior to December 2001, under the original collaboration, P&G was generally funding all clinical development and manufacturing costs relating to pexelizumab for the treatment of inflammation associated with cardiopulmonary bypass surgery and heart attack. 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 agreed to bear the first 50% of projected costs associated with the completed Phase III clinical trial (called "PRIMO-CABG") in coronary artery bypass graft surgery ("CABG") and P&G agreed to bear the second 50% as part of our revised collaboration. During the quarter ended October 31, 2003, we and P&G both completed each of our obligations with respect to the originally projected costs. Additional costs incurred over the original projected costs were shared equally by us and P&G. Reimbursements received by us from P&G in connection with P&G's 50% share of our services and related personnel were recorded as a reduction of research and development expense. As part of the revised collaboration per the MOU, P&G funded 100% of the costs for the two acute myocardial infarction ("AMI") Phase II clinical trials in myocardial infarction, or heart attack, 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 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, as per the MOU, 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.

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 $9.8 million.

XOMA Ltd. Collaboration

In December 2003, we and XOMA (U.S.) LLC ("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. The compound was discovered at AAT and is in pre-clinical development. The c-MPL antibody was designed to mimic the activity of human thrombopoietin, a naturally occurring protein responsible for platelet production. The collaboration will initially focus on preclinical, process development and scale-up work in preparation for future clinical testing.

Under the terms of the agreement, we and XOMA will jointly develop and commercialize the c-MPL agonist antibody for chemotherapy-induced thrombocytopenia. We will share development and commercialization expenses, clinical development, manufacturing and marketing costs world-wide, as well as revenues, on generally a 70 – 30 basis, with us retaining the larger portion. In addition, we received a $1.5 million upfront non-refundable payment upon initiation of the collaboration and will receive a similar sized payment upon the achievement of a regulatory milestone. We recorded the payment as deferred research and development payments. The balance at July 31, 2004 and 2003 was $1.4 million and $0, respectively. We are recognizing this payment as a reduction of research and development expenses over 8 years, which represents the estimated length of time to achieve commercial viability. XOMA will be entitled to royalty payments and milestones from Alexion related to its bacterial cell expression technology.

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 Product License Approval (PLA). These agreements require minimum royalty payments based upon sales developed from the applicable technologies, if any.

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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 enrollment 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 9).

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, 2004, for each of the next five years are as follows (amounts in thousands):

Years Ending July 31,	License Agreements	Research & Development Agreements	Clinical & Manufacturing Development Agreements
2005	$ 398	$ 250	$ 70,009
2006	310	63	32,400
2007	358	—	23,870
2008	292	—	23,430
2009	292	—	20,800

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, 2004, these agreements contain milestone payment provisions aggregating approximately $24 million. The agreements also require us to fund certain future costs associated with the filing of patent applications.

4. Property, Plant and Equipment

Property, plant, and equipment is recorded at cost and is depreciated over the estimated useful lives of the assets involved. Depreciation and amortization commences at the time the assets are placed in service and is computed using the straight-line method over the estimated useful lives of the assets. Maintenance and repairs are charged to expense when incurred. Depreciation and amortization of fixed assets was approximately $2,865,000, $3,108,000 and $2,953,000 for the years ended July 31, 2004, 2003 and 2002, respectively.

Asset	Estimated Useful Life
Building and building improvements	15 years
Leasehold improvements	Life of lease
Laboratory equipment	5 years
Furniture and office equipment	3 years

A summary of property, plant and equipment is as follows (amounts in thousand):

	July 31, 2004	July 31, 2003
Land	$ 364	$ 364
Building, building improvements and leasehold improvements	9,897	9,804
Laboratory and support equipment	12,906	11,762
Furniture and office equipment	4,177	3,045
	27,344	24,975
Less: Accumulated depreciation and amortization	(15,558)	(12,699)
	$ 11,786	$ 12,276

During the year ended July 31, 2003, we determined that conditions had arisen which triggered the need to review certain of our long-lived assets for potential impairment (see Note 2). In the quarter ended October 31, 2003 we notified Tyco that the UniGraft xenotransplantation program and CFC activities had been terminated. CFC's assets are pledged as security for a $3.9 million note issued by CFC to Tyco to purchase the assets (see Note 6). CFC is seeking to liquidate itself to fulfill its debt obligation in whole or in part. CFC further notified Tyco that it does not have the funds or assets to satisfy the $3.9 million note and unpaid interest. During the quarter ended January 31, 2004, we and Tyco initiated a plan to sell or liquidate CFC's assets in their present condition. We anticipate that Tyco will retain the proceeds from the sale of CFC's assets and discharge the note and unpaid interest. In August 2004, a written offer of $450,000 was accepted by Tyco for CFC's assets. We used the accepted offer as the basis for determining the fair-market value of CFC's assets and accordingly, we have written down the fair-market value of these assets from $1.2 million to $450,000 as of July 31, 2004. 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".

5. Goodwill

On September 23, 2000, we acquired Prolifaron, Inc. ("Prolifaron"), a privately-held biopharmaceutical company with extensive combinatorial human antibody library technologies and expertise. The acquisition was accomplished when Prolifaron was merged with a wholly owned subsidiary of Alexion and renamed Alexion Antibody Technologies, Inc. The fair value of our common stock and stock options issued at the date of the acquisition was approximately $43.9 million. The Prolifaron acquisition was accounted for as a purchase and, accordingly, the purchase price was allocated to the assets acquired and liabilities assumed based on their estimated fair values at the date of the acquisition. We allocated $21.0 million of the purchase price to in-process

research and development projects. This allocation represented the estimated fair value based on risk-adjusted cash flows related to the incomplete research and development projects. At the date of the acquisition, development of these projects had not yet reached technological feasibility and the research and development in progress has no alternative future use. Accordingly, these costs were expensed as of the acquisition date. At the merger date, Prolifaron was conducting pre-clinical development and testing activities with a goal to develop technologies for antibody discovery and engineering and identify new fully human therapeutic antibodies addressing multiple disease areas. The drug candidates under development represent innovative technologies addressing autoimmune and inflammatory disorders and cancer.

The excess cost over the fair value of the net assets acquired, which amounted to approximately $22.9 million, was reflected as goodwill and was being amortized over approximately 7 years during fiscal 2001. At July 31, 2004 goodwill balance was $20.0 million representing the $2.9 million amortization that was recorded in fiscal 2001 before the adoption of SFAS No. 142 (see Note 2), which required the cessation of amortization of goodwill.

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. The purchase was financed through the issuance by CFC of a $3.9 million note payable to Tyco. Interest on the $3.9 million note payable, at 6% per annum, is payable quarterly by CFC. The xenotransplantation manufacturing assets of CFC that were purchased from Tyco, including the real estate, are pledged as security for this note. The principal balance under the note is due in May 2005. Upon CFC's failure to make its quarterly interest payment due to Tyco in August 2003, CFC defaulted on the note. We continue to recognize CFC's interest expense on the note payable as such obligations have not been discharged.

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. CFC is seeking to liquidate itself to fulfil its debt obligation in whole or in part. CFC further notified Tyco that it does not have the funds or assets to satisfy the $3.9 million note and unpaid interest. During the quarter ended January 31, 2004, we and Tyco initiated a plan to sell or liquidate CFC's assets in their present condition. We anticipate that Tyco will retain the proceeds from the sale of CFC's assets and discharge the note and unpaid interest. In August 2004, a written offer of $450,000 was accepted by Tyco for CFC's assets. We used the accepted offer as the basis for determining the fair-market value of CFC's assets and accordingly, we have written down the fair-market value of these assets from $1.2 million to $450,000 as of July 31, 2004 (see Note 4). Since CFC's assets, consisting of property, plant and equipment, are insufficient to satisfy the $3.9 million note and unpaid interest, and other obligations of CFC, we expect the unpaid amount of the note and interest will be discharged debt, recognized as other income in fiscal 2005 to CFC. As of July 31, 2004 we have classified the property, plant and equipment of CFC as property, plant and equipment held for sale as per the guidelines set forth in SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets"

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7. Accrued Expenses

A summary of accrued expenses is as follows (amounts in thousands):

	July 31,	
	2004	2003
Payroll and employee benefits	$1,689	$1,332
Research and development expenses	276	1,142
Deferred rent and other	1,833	1,838
	$3,798	$4,312

8. Convertible Subordinated Notes

In March 2000, we completed a $120 million private placement of 5.75 percent Convertible Subordinated Notes due March 15, 2007. The notes bear interest payable semi-annually on September 15 and March 15 of each year, beginning September 15, 2000. The holders may convert all or a portion of the notes into common stock at any time on or before March 15, 2007 at a conversion price of $106.425 per share which would result in the issuance of 1,127,554 shares of common stock, in aggregate.

The notes are subordinated to all of our existing and future senior indebtedness and are effectively subordinated to all of the indebtedness and other liabilities (including trade and other payables) of us and our subsidiaries. The indenture governing the notes does not limit the amount of indebtedness, including senior indebtedness, which we may incur.

Noteholders may require us to repurchase their notes upon a repurchase event, as defined by the loan agreement in cash, or, at our option, in common stock, at 105 percent of the principal amount of the notes, plus accrued and unpaid interest.

The notes are not entitled to any sinking fund. At any time or from time to time on or after March 20, 2003 and ending on March 14, 2007, we may elect to redeem, solely at our discretion, some or all the notes on at least 30 days notice as a whole or, from time to time, in part at certain premiums over the principal amount plus accrued interest.

We incurred deferred financing costs related to this offering of approximately $4.0 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. Amortization expense associated with the financing costs was approximately $573,000 for each of the years ended July 31, 2004, 2003 and 2002. Accumulated amortization associated with these costs was approximately $2,470,000 and $1,897,000 as of July 31, 2004 and 2003, respectively.

9. Commitments and Contingencies

Operating Leases

As of July 31, 2004, we lease our headquarters and primary research and development facilities. 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 $80,000, increasing to approximately $104,000 over the term of this lease. We have issued a $200,000 open letter of credit to secure the lease.

We entered into a lease agreement in January 2003 for our pilot manufacturing plant and associated labs and offices, which is used for producing compounds for clinical trials. Monthly fixed rent started at approximately $36,000, increasing to approximately $50,000 over the term of the lease, which expires in 2007. We have the option to extend the lease for an additional three years.

We lease an additional research facility starting at a monthly fixed rent of approximately $35,000 increasing to approximately $90,000 as the facility is expanded. This lease expires in 2012.

Aggregate lease expense for our facilities was $2,176,000, $1,998,000 and $1,373,000 for the years ended July 31, 2004, 2003 and 2002, 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 noncancellable operating leases (including facilities and equipment) are as follows (amounts in thousands):

Years Ended July 31,	
2005	$2,330
2006	2,380
2007	2,520
2008	2,000
2009	1,870
2010 and thereafter	4,080

Purchase Commitments

The Large-Scale Product Supply Agreement dated December 18, 2002 (the “Lonza Agreement”) between Lonza Biologics PLC (“Lonza”) and Alexion Pharmaceuticals, Inc., relating to the manufacture of our product candidate eculizumab, was amended (the “Lonza Amendment”) in April 2004. Per the Lonza Agreement, we remitted cash advances aggregating $10 million through July 31, 2004 for the long-term commercial manufacture of our C5 inhibitor antibody, eculizumab.

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 by us relating to manufacturing yields achieved by Lonza are eliminated. Subsequent to year-end, 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.

The amounts paid to Lonza in consideration of the Lonza Agreement are reflected as prepaid manufacturing costs within the accompanying balance sheet and are recognized as additional manufacturing costs as the batches are manufactured. On a quarterly basis, we evaluate our plans to proceed with production under the agreement which depends upon our clinical development programs' progress as well as commercialization plans. In addition, we evaluate the prepaid manufacturing costs against estimated net realizable value ("NRV"). If estimated NRV were not to be 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, 2004.

10. Common Stock

Fiscal 2004 Common Stock Sales

In September 2003, we sold 3.6 million shares of our common stock at a price of $13.00 per share resulting in net proceeds of approximately $43.9 million, net of underwriting discounts, fees and other expenses of approximately $2.9 million related to the transaction.

In July 2004, we sold 5.5 million shares of our common stock at a price of $15.50 per share resulting in net proceeds of approximately $80.9 million, net of underwriting discounts, fees and other expenses of approximately $4.4 million related to the transaction.

11. Stock Options

Alexion has two stock-based compensation plans, which are described below.

Under the 2000 Stock Option Plan ("2000 Plan"), incentive and nonqualified stock options may be granted for up to a maximum of 3,400,000 shares of common stock to our directors, officers, key employees and consultants. Stock options granted under the 2000 Plan 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. In December 2003, the stockholders approved an amendment to the 2000 Plan to increase the number of shares of common stock available for grant by 1,000,000 to 3,400,000 from 2,400,000. Previously, in December 2002, the stockholders approved amendments to the 2000 Plan which: (1) increased the number of shares of common stock available for grant by 900,000 to 2,400,000 from 1,500,000; (2) prohibited the repricing of options granted pursuant to the 2000 Plan; and (3) prohibited the grant of options pursuant to the 2000 Plan

with an exercise price that is less than the fair market value of common stock on the date of the grant. In December 2000, the stockholders approved the adoption of the 2000 Plan and elected to terminate the previous 1992 Plan. At July 31, 2004, there were 948,921 options available for grant under the 2000 Plan. Under the 1992 Stock Option Plan ("1992 Plan"), which was terminated in December 2000, stock options to acquire 1,911,666 shares of common stock are outstanding as of July 31, 2004.

Under the 1992 Stock Option Plan for Outside Directors ("1992 Outside Directors' Plan"), nonqualified stock options are granted initially (12,000 options) to qualifying directors as well as upon annual re-election (7,500 options) to the board of directors. Options are granted at the fair market value of the common stock on the date of the grant and generally become exercisable in equal proportions over three to four years and remain exercisable for up to ten years after the grant date, subject to certain conditions. In December 2002, the stockholders approved amendments to the 1992 Outside Director's Plan: (1) extending the term of the 1992 Outside Director's Plan by an additional five years to August 26, 2007; and (2) prohibiting the repricing of options granted pursuant to the 1992 Outside Directors' Plan. In December 2000, the stockholders approved an amendment to the 1992 Outside Directors' Plan increasing the initial option grant to qualifying directors to 12,000 options from 7,500 options and additional grants upon annual re-election to the board of directors to 7,500 options from 2,000 options. At July 31, 2004, stock options to acquire 200,067 shares of common stock are outstanding under the 1992 Outside Directors' Plan.

SFAS No. 123, "Accounting for Stock-Based Compensation", as amended by SFAS No. 148, requires the measurement of the fair value of stock options or warrants to be disclosed in the notes to financial statements. We have computed the required pro forma disclosure for options granted using the Black-Scholes option pricing model prescribed by SFAS No. 123. The assumptions used are as follows:

	2004	2003	2002
Risk free interest rate	4.3%	3.7%	4.5%
Expected dividend yield	—	—	—
Expected lives	5 years	5 years	5 years
Expected volatility	82%	92%	92%

Alexion Pharmaceuticals, Inc.
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A summary of the status of our stock option plans at July 31, 2004, 2003 and 2002 and changes during the years then ended is presented in the table and narrative below:

	2004		2003		2002	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at August 1	4,020,810	$ 22.85	3,557,605	$ 25.30	3,561,520	$ 25.12
Granted	972,000	19.88	662,500	11.68	203,855	21.17
Exercised	(199,557)	12.52	(16,650)	9.29	(121,750)	7.27
Cancelled	(251,043)	27.94	(182,645)	31.38	(86,020)	33.87
Outstanding at July 31	4,542,210	$ 22.38	4,020,810	$ 22.84	3,557,605	$ 25.30
Options exercisable at July 31	3,100,091	$ 23.98	2,732,900	$ 22.94	2,163,580	$ 20.25
Weighted-average fair value of options granted during the year		$ 13.25		$ 8.58		$ 15.16

During fiscal 2004, options to purchase 972,000 shares of common stock were granted to our employees and directors at an exercise price equal to the fair value of the stock at the date of grant.

During fiscal 2003, options to purchase 662,500 shares of common stock were granted to employees, directors, and a consultant at exercise prices equal to the fair value of the stock at the date of grant. We are recording compensation expense based upon the fair value of the options granted to the consultant over the vesting term. Compensation expense related to these options was $22,000 and $4,000 for the years ended July 31, 2004 and 2003, respectively. Aggregate compensation expense of approximately $20,000 associated with this option grant is expected to be recognized over the next three years.

During fiscal 2002, options to purchase 203,855 shares of common stock were granted to employees and directors at exercise prices equal to the fair value of the stock at the date of grant.

During fiscal 2001, options to purchase 10,000 shares of common stock were granted to an employee at exercise prices which were less than the fair value of the common stock at the date of grant. Accordingly, we are recording compensation expense based upon this difference over the vesting period associated with these options. Compensation expense associated with these options is $67,000, $65,000 and $65,000 for the years ended July 31, 2004, 2003 and 2002, respectively. Aggregate compensation expense of approximately $5,000 associated with these option grants is expected to be recognized next year. 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 fiscal 2001 to employees and consultants. Compensation expense associated with these options was $17,000, $78,000 and $116,000 for the years ended July 31, 2004, 2003, and 2002, respectively. No further compensation expense associated with these options will be recognized.

The following table presents weighted average price and life information about significant option groups outstanding at July 31, 2004:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Yrs.)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$2.37 - 9.00	594,098	2.1	$ 5.13	594,098	$ 5.13
$9.01 - 20.99	1,959,182	6.5	12.80	1,097,194	11.14
$21.00 - 24.50	1,252,552	7.6	21.86	712,796	21.25
$32.00 - 54.00	153,711	6.2	37.68	126,961	38.17
$61.00 - 87.00	551,167	5.9	67.08	545,042	66.94
$106.00 - 108.00	31,500	5.8	107.88	24,000	107.88
	4,542,210	6.1	$ 22.38	3,100,091	$ 23.98

12. Rights to Purchase 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 a 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, cashflow, 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.

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13. 401(k) Plan

We have a 401(k) plan. Under the plan, employees may contribute up to a maximum of $13,000 per employee in calendar year 2004. We match 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 $330,000, $291,000 and $207,000 for the years ended July 31, 2004, 2003 and 2002, respectively.

14. Contract Research Revenues

Our fiscal 2004 revenue primarily reflects a milestone receivable of $4.0 million from P&G concurrent with the dosing of our first patient in the APEX-AMI clinical trial and the amortization of deferred revenue resulting from cash received from P&G (see Note 3). The prior fiscal year includes deferred revenue from P&G and revenue from government grants.

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 $0.7 million from the National Institutes of Health to fund a specific research project.

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

	Year Ended July 31,		
	2004	2003	2002
Collaboration/Grant Awards			
P&G	$4,588	$673	$4,591
U.S. government grants	21	204	1,745
Other	—	—	200
Total revenues	$4,609	$877	$6,536

15. Income Taxes

At July 31, 2004, we have available for federal tax reporting purposes, net operating loss carryforwards of approximately $319.9 million which expire through 2024 (of which approximately $19.6 million resulted from the exercise of nonqualified stock options as discussed below). We also have federal and state research and development credit carryforwards of approximately $14.6 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 carryforwards in any given year resulting from cumulative changes in ownership interests in excess of 50 percent over a three-year period. We believe we have triggered these limitation provisions.

The State of Connecticut provides companies with the opportunity to exchange certain research and development tax credit carryforwards for cash in exchange for foregoing the carryforward 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, 2004, we plan to file claims to exchange our fiscal 2004 research and tax development credits and, therefore, recognized a state tax benefit of $691,000. The state tax benefit excluded our estimated capital-based state taxes of approximately $113,000 which was recorded as an operating expense.

During the year ended July 31, 2003, we filed claims to exchange our fiscal 2003 and 2002 research and development credits and recognized a state tax benefit of $1,012,000 that excluded our estimated capital-based state taxes of approximately $248,000 which was reclassified as an operating expense. During the year ended July 31, 2002, we had filed a claim to exchange our fiscal 2001 research and development credits and as a result recognized a state tax benefit of $700,000.

We follow SFAS No. 109, "Accounting for Income Taxes." This statement requires that deferred income tax assets and liabilities reflect the impact of "temporary differences" between the amount of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws and regulations.

The components of deferred income tax assets are as follows (amounts in thousands):

	July 31,	
	2004	2003
Deferred tax assets		
Net operating loss carryforwards, federal and state	$ 121,938	$ 93,463
Tax credit carryforwards	12,236	9,486
Deferred revenues	2,635	2,864
Other	2,096	1,624
Total deferred tax assets	138,905	107,437
Less: Valuation allowance for deferred tax assets	(138,905)	(107,437)
	$ —	$ —

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 carryforwards of approximately $19.6 million which can be used to offset future taxable income, if any. If and when realized, the related tax benefits of these net operating loss carryforwards 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:

	Year Ended July 31,		
	2004	2003	2002
Statutory rate	(34) %	(34) %	(34) %
State tax benefit, net of Federal taxes	(5)	(5)	(5)
Research & development credits	(3)	(2)	4
Increase in deferred tax valuation allowance	41	40	34
Effective rate	(1) %	(1) %	(1) %

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We have not yet achieved profitable operations. Accordingly, management believes the tax benefits as of July 31, 2004 do not satisfy the realization criteria set forth in SFAS No. 109 and have recorded a valuation allowance for the entire deferred tax assets.

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16. Unaudited Quarterly Financial Information

The following is condensed quarterly financial information (amounts in thousands, except per share amounts):

	Fiscal 2004			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
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)

	Fiscal 2003			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Contract research revenues	$ 323	$ 220	$ 167	$ 167
Operating expenses	21,918	21,421	19,402	21,730
Operating loss	(21,595)	(21,201)	(19,235)	(21,563)
Net loss applicable to common shareholders	(21,640)	(21,465)	(19,778)	(21,584)
Net loss per common share, basic and diluted	(1.19)	(1.18)	(1.09)	(1.18)

Exhibit 21.1

SUBSIDIARIES OF ALEXION PHARMACEUTICALS, INC.

Columbus Farming Corporation (New York)
100% owned by Registrant

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

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File numbers 333-29617, 333-41397, 333-47645, 333-89343, 333-36738, 333-52886, 333-59702, 333-110828 and 333-114449) and Form S-8 (File numbers 333-24863, 333-52856, 333-69478, 333-71879, 333-71985 and 333-106854) of our report dated September 15, 2004 relating to the consolidated financial statements of Alexion Pharmaceuticals, Inc., which appears in this Form 10-K.

/s/ PriceWaterhouseCoopers, LLP

Hartford, Connecticut
September 24, 2004

Exhibit 31.1

302 CERTIFICATION

I, Leonard Bell, 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)) 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) 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
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
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.

Date: September 23, 2004

/s/ Leonard Bell
Leonard Bell, M.D.
Chief Executive Officer,
Secretary and Treasurer

Exhibit 31.2

302 CERTIFICATION

I, Carsten Boess, 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)) 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) 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
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
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.

Date: September 23, 2004

/s/ Carsten Boess
Carsten Boess
Vice President and
Chief Financial Officer

Exhibit 32.1

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 of Alexion Pharmaceuticals, Inc. (the "Company") on Form 10-K for the fiscal year ended July 31, 2004 as filed with the Securities and Exchange Commission (the "Report"), I, Leonard Bell, Chief Executive Officer, Secretary and Treasurer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(i) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard Bell
Leonard Bell, M.D.
Chief Executive Officer, Secretary and Treasurer
September 23, 2004

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

Exhibit 32.2

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 of Alexion Pharmaceuticals, Inc. (the "Company") on Form 10-K for the fiscal year ended July 31, 2004 as filed with the Securities and Exchange Commission (the "Report"), I, Carsten Boess, 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:

(i) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Carsten Boess
Carsten Boess
Vice-President and Chief Financial Officer
September 23, 2004

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