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

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**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, 2002

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

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**ALEXION PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of  
Incorporation or Organization)

13-3648318

(I.R.S. Employer Identification No.)

352 Knotter Drive, Cheshire Connecticut 06410

(Address of Principal Executive Offices) (Zip Code)

203-272-2596

(Registrant's telephone number, including area code)

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**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.

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 October 24, 2002, was approximately \$176,404,000.

The number of shares of Common Stock outstanding as of October 24, 2002 was 18,204,796.

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**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 THE COMPANY'S INDUSTRY, MANAGEMENT'S BELIEFS AND CERTAIN ASSUMPTIONS MADE BY THE COMPANY'S 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 "RISK FACTORS," ATTACHED HERETO AS EXHIBIT 99.2, AS WELL AS THOSE NOTED IN THE DOCUMENTS INCORPORATED HEREIN BY REFERENCE. UNLESS REQUIRED BY LAW, THE COMPANY UNDERTAKES 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 THE COMPANY FILES 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 aimed at treating patients with a wide array of severe disease states, including cardiovascular, autoimmune and hematologic disorders, inflammation and cancer. Since our incorporation in January 1992, we have devoted substantially all of our resources to drug discovery, research, and product and clinical development. Additionally, through our wholly owned subsidiary, Alexion Antibody Technologies, Inc., or AAT, we are engaged in the discovery and development of a portfolio of additional antibody therapeutics targeting severe unmet medical needs. During the fiscal years ended July 31, 2002, 2001, and 2000, we spent \$60.0 million, \$38.9 million, and \$40.2 million, respectively, on research and development activities, excluding acquisition related non-cash charges for in-process research and development and amortization of goodwill.

Our two lead product candidates are therapeutic antibodies that address specific diseases that arise when the human immune system produces inappropriately activated 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 eight different clinical development programs.

One of our antibody product candidates, pexelizumab, is an antibody fragment being developed in collaboration with Procter & Gamble Pharmaceuticals, or P&G. In January 2002, we commenced enrollment of a

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pivotal Phase III clinical trial of pexelizumab, called PRIMO-CABG, in approximately 3,000 patients undergoing coronary artery bypass graft surgery, or CABG, with cardiopulmonary bypass, or CPB. The Phase III trial will assess the safety and efficacy of pexelizumab in reducing the combined incidence of death or myocardial infarction in this patient population. In September 2000, the United States Food and Drug Administration, or FDA, granted "Fast Track" status for the development of pexelizumab in CPB. Fast Track designation provides for expedited development and application review for approval of a drug through the FDA.

Also in collaboration with P&G, we are conducting two Phase II studies with pexelizumab in acute myocardial infarction or heart attack patients: one study in patients receiving thrombolytic therapy, a procedure for dissolving clots that block heart vessels, and the other in patients receiving angioplasty, a procedure for opening up narrowed or blocked arteries that supply blood to the heart. The thrombolytic study, called COMPLY, completed patient enrollment in January 2002 and the angioplasty study, called COMMA, completed patient enrollment in April 2002. For each of these studies, enrollment completion is followed by completion of all follow-up patient visits, data collection and subsequent data analysis. We expect data from the COMPLY and COMMA trials to be presented at the American Heart Association meeting in November 2002.

Our other lead antibody product candidate, eculizumab, is in clinical development for the treatment of a variety of chronic autoimmune diseases. In rheumatoid arthritis patients, we have completed enrollment in a 12 month extension trial related to our completed Phase IIa rheumatoid arthritis trial. In January 2002, we initiated a Phase IIb study in rheumatoid arthritis patients and enrollment is on-going in a 12 month extension trial related to this study. A separate Phase II study in membranous nephritis, a kidney disease, was completed in September 2002 and enrollment has been completed in a 12 month extension study connected with this trial. We have undertaken separate early stage clinical programs to study eculizumab in several additional diseases. We completed a Phase I pilot safety trial of eculizumab in psoriasis patients which indicated that eculizumab appeared to be safe and well tolerated in these patients. At this time, we are not pursuing psoriasis as a clinical indication. In January 2002, we completed a Phase I pilot safety trial in dermatomyositis, an inflammatory skin and muscle disorder, which indicated that eculizumab appeared to be safe and well tolerated in this patient population. We reviewed the clinical data with the FDA and intend to initiate a Phase II clinical study for eculizumab in this disease. We also initiated a Phase I pilot safety trial in patients with bullous pemphigoid, a severe inflammatory skin disorder. Although there were no apparent safety issues, at this time, we have elected not to pursue this program further in order to more efficiently focus resources on other on-going eculizumab development programs.

In June 2002, we initiated an open-label Phase I pilot safety study of eculizumab in paroxysmal nocturnal hemoglobinuria, or PNH, patients. PNH is a rare, blood disease characterized by severe anemia and risk of blood clotting or thrombosis. Patient enrollment for the Phase I pilot study in PNH was completed in September 2002 and an open-label 12 month extension study to evaluate long-term safety is on-going. Evaluation of the initial pilot study awaits completion of all follow-up patient visits, data collection, and subsequent data analysis. We expect data from this pilot study to be presented at the American Society of Hematology meeting in December 2002.

Through 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 are also seeking to develop therapies employing the transplantation of cells from other species into humans, known as xenotransplantation.

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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, 2002, we had an accumulated deficit of \$180.8 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 and developing a sales and marketing force. 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 with major pharmaceutical companies for product development and commercialization, where we will still play a major role.

### ***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;
- acute myocardial infarction or heart attack;
- unstable angina or painful chest pains associated with an insufficient blood supply to the heart;
- angioplasty or procedures for opening up narrowed or blocked arteries that supply the heart; and
- stroke and other peripheral vascular or blood circulatory diseases.

Autoimmune or hematologic diseases in which the complement cascade is activated include:

- rheumatoid arthritis;
- kidney diseases;
- lupus;
- inflammatory bowel diseases;

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- inflammatory skin and muscle disorders;
- multiple sclerosis; and
- paroxysmal nocturnal hemoglobinuria, or PNH.

**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. Currently available drugs for certain autoimmune, cardiovascular, and hematologic disorders, in which the immune system attacks the patient’s own tissue, broadly suppress the entire immune system, and may also cause potentially severe side effects. 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. Additionally, we are seeking to develop UniGraft xenotransplants or use of non-human cells and tissues for neurologic or nervous systems disorders.

Our product candidates are as follows:

<u>Product candidate</u>	<u>Technology</u>	<u>Indication</u>	<u>Status</u>
Pexelizumab	C5 Inhibitor (single chain antibody)	Coronary Artery Bypass Graft surgery (CABG) with cardiopulmonary bypass (CPB)	Phase III trial ongoing (PRIMO-CABG)
		Myocardial Infarction (1) Thrombolysis(a)  (2) PTCA(b)	Phase II trial enrollment completed (COMPLY) Phase II trial enrollment completed (COMMA)
Eculizumab	C5 Inhibitor (whole antibody)	Rheumatoid Arthritis	Phase IIb trial on-going; extension study on-going
		Membranous Nephritis	Phase II trial enrollment completed; extension study on-going
		Paroxysmal Nocturnal Hemoglobinuria (PNH)	Phase I trial enrollment completed; extension study on-going
		Lupus Nephritis	Phase II trial under review for re-design
UniGraft-SCI	Cell replacement	Dermatomyositis	Phase Ib trial completed
UniGraft-PD	Cell replacement	Spinal Cord Injury	Pre-clinical
		Parkinson’s Disease	Pre-clinical

(a) dissolving clots that block heart vessels

(b) percutaneous transluminal coronary angioplasty or PTCA, a procedure for opening up narrowed or blocked arteries that supply blood to the heart

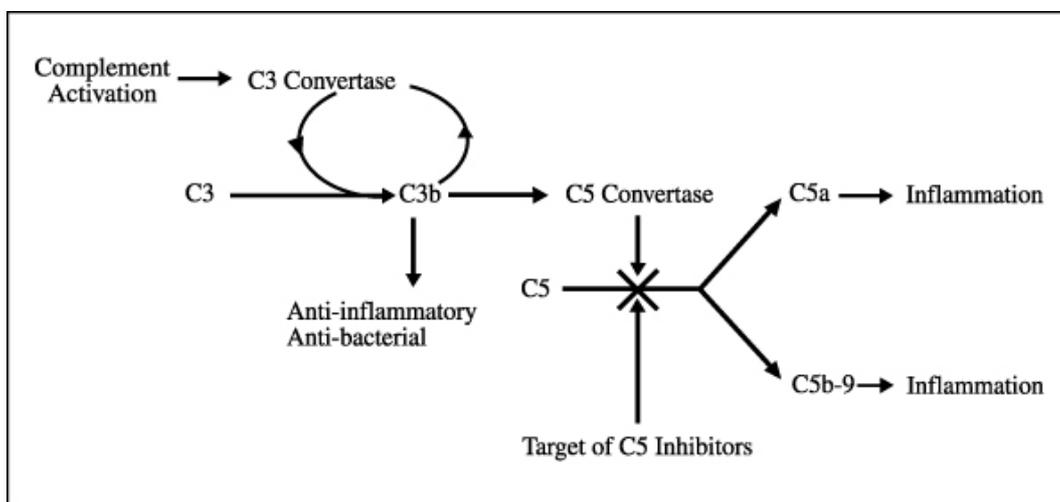
### **C5 Inhibitors**

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 injurious hormones 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; and
- lysis 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; and
- preventing lysis of red blood cells.

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; and
- the incidence of proteinuria or abnormal loss of substantial amounts of protein in a patient's urine in lupus patients.

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

We are developing one of our two lead C5 Inhibitor product candidates, 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, myocardial infarction utilizing thrombolysis, and myocardial infarction utilizing percutaneous transluminal coronary angioplasty or PTCA, a procedure for opening up narrowed or blocked arteries that supply blood to the heart. We are developing our other C5 Inhibitor product candidate, eculizumab, for the treatment of inflammation related to chronic autoimmune disorders and hematologic disorders. The initial indications for which we are pursuing clinical development activities for eculizumab are rheumatoid arthritis, membranous nephritis, lupus nephritis, PNH, and dermatomyositis. 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, pexelizumab and eculizumab have been observed to be safe and well tolerated in completed and ongoing clinical trials in which over 4,500 individuals were treated with either C5 Inhibitor or placebo.

### ***Pexelizumab***

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 thrombolysis or 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, or U.S., development and commercialization costs for pexelizumab, including clinical, manufacturing, marketing, and sales efforts. Also see section “**Strategic Alliance with Procter & Gamble**”. A letter of understanding has been signed relating to the negotiation and completion of an agreement with a third party manufacturer for the large scale commercial manufacture of pexelizumab over 5 years.

### ***Cardiopulmonary Bypass Surgery***

In cardiopulmonary bypass surgery, or CPB, blood is diverted from a patient’s heart and lungs to a cardiopulmonary, heart-lung, bypass machine in the operating room. The machine adds oxygen to the blood and circulates the oxygenated blood to the organs in the patient’s body. Significant side effects of CPB include heart damage and excessive bleeding during and after the procedure. We believe these side effects may result from the activation of the complement cascade when the patient’s blood comes into contact with the plastic lining of the machine. Additionally, these side effects may also result from complement activation that occurs when insufficient blood flows through the heart as a result of the procedure and after blood flow through the heart is reintroduced following completion of the procedure; this combined reaction is sometimes called ischemia-reperfusion injury. Activated complement byproducts may be increased by over 1000% in patients undergoing CPB. The inflammation is also characterized by the activation of leukocytes, a type of white blood cell, and platelets, cells responsible for clotting. We believe that this leukocyte activation is associated with impaired lung, heart, brain and kidney function. We further believe that platelet activation and subsequent platelet dysfunction during the procedure impair a patient’s ability to stop the bleeding that occurs after extensive surgery.

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

- the incidence of death;
- the incidence of heart tissue damage;
- the incidence of stroke or brain tissue damage;
- post-operative or after surgery complications;
- the time spent by patients in the intensive care unit or ICU;
- the scope of required treatments associated with CPB; and
- perioperative bleeding resulting in the need for blood transfusions.

The American Heart Association estimated that in 1999, approximately 600,000 CPB operations were performed in the United States. Currently, products utilized in patients undergoing cardiopulmonary bypass are designed to enhance the coagulation of blood so as 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.

Our pre-clinical studies indicated that C5 Inhibitors can prevent activation of platelets and leukocytes and the subsequent inflammatory response that occurs during the circulation of human blood in a closed-loop cardiopulmonary bypass machine. These pre-clinical studies additionally indicated that administration of a C5 Inhibitor may reduce cardiac damage associated with reduced heart blood flow.

### *Clinical Trials—Coronary Artery Bypass Graft Surgery*

In January 1999, we commenced dosing in a Phase IIb clinical trial with pexelizumab in patients undergoing coronary artery bypass graft surgery, or CABG during CPB, with or without accompanying valve surgery. The objective of this multi-center, double-blinded, randomized, placebo-controlled study was to assess the safety and effectiveness of pexelizumab in these patients. After completion of this trial, preliminary results from this trial were released in January 2001 which suggested that pexelizumab blocked complement, reduced inflammation and appeared to be safe and 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 therapeutic, exploratory 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, the 800 patients who had CABG, without valve surgery, those that received pexelizumab at the highest dose level experienced a significant reduction in larger post-surgical heart attacks.

In January 2002, we commenced initiation of a pivotal Phase III clinical trial of pexelizumab, called PRIMO-CABG, in approximately 3,000 patients undergoing CABG with CPB. The Phase III trial will assess the safety and efficacy of pexelizumab in reducing the combined incidence of death or myocardial infarction in this patient population. Patient enrollment is on-going.

### ***Acute Myocardial Infarction***

Myocardial infarction is an acute cardiovascular disorder in which the coronary arteries, the blood vessels that supply nutrients to the heart muscle, are blocked to such an extent that the flow of blood is insufficient to supply enough oxygen and nutrients to keep the heart muscle alive. With insufficient supply of blood, oxygen, and nutrients, the heart muscle may subsequently infarct or die. 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 associated with subsequent death of heart muscle. Restoration of blood flow is also associated with an additional inflammatory reaction with an accompanying production of activated complement byproducts. This combined reaction is sometimes called ischemia-reperfusion 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, shock, stroke, and death. The American Heart Association estimates that approximately 1.1 million people in the United States will have a heart attack 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 caused by 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*

In October 1998, we commenced dosing subjects in a Phase I clinical trial in healthy individuals that was designed to evaluate dosing regimens for subsequent CPB and myocardial infarction clinical trials. We have used the results of this trial to select dosing regimens for subsequent clinical trials in acute myocardial infarction and CPB patients. The results of this trial indicated that pexelizumab was well tolerated at doses more than three times as high as had been previously administered. We completed patient enrollment in two Phase II clinical trials, each one designed to enroll approximately 900 patients, with our collaborator P&G, that test the safety and effectiveness of pexelizumab for the treatment of acute inflammation in patients suffering an acute myocardial infarction. One study is in patients receiving thrombolytic therapy, a procedure for dissolving clots that block heart vessels, and the other is in patients receiving angioplasty, a procedure for opening up narrowed or blocked arteries that supply blood to the heart. The thrombolytic study completed patient enrollment in January 2002 and the angioplasty study completed patient enrollment in April 2002. Evaluation of each study awaits completion of all follow-up patient visits, data collection and subsequent data analysis. We expect the data analyses to be presented at the American Heart Association meeting in November 2002.

#### ***Eculizumab***

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 autoimmune diseases such as rheumatoid arthritis and nephritis and hematologic disorders such as PNH. Eculizumab is not included in the collaboration with P&G, and we have retained full rights to eculizumab.

#### ***Rheumatoid Arthritis***

Rheumatoid arthritis 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. Diagnostic procedures, which may include obtaining a sample of joint fluid, routinely demonstrate substantial elevations in the levels of activated complement byproducts in the joint fluid of affected rheumatoid arthritis patients. Rheumatoid arthritis is generally believed to be caused by different types of white blood cells, including T-cells, which both directly attack the patient's joints and also activate B-cells, another type of white blood cell, to produce antibodies that activate complement proteins in the joint leading to inflammation with subsequent tissue and joint destruction. It is estimated that more than 2.1 million people are currently affected by rheumatoid arthritis in the United States.

We are developing eculizumab for the treatment of patients with chronic inflammatory diseases, including rheumatoid arthritis. We have performed pre-clinical studies in rodent models of rheumatoid arthritis which have shown that C5 Inhibitor administration, as compared to placebo-treated subjects:

- reduced the swelling in joints;
- prevented the onset of erosion of joints;
- reduced the inflammatory white blood cell infiltration into the joints;
- prevented the spread of disease to additional joints;
- blocked the onset of clinical signs of rheumatoid arthritis; and
- reduced established disease.

Currently, there are a large number of anti-inflammatory drugs under development or on the market for the treatment of patients with rheumatoid arthritis. These drugs include non-steroidal anti-inflammatory drugs, and their more recent analog the COX-2 inhibitors, which generally treat the symptoms of the disease, but do not alter disease progression. There are also several currently available drugs that are disease-modifying agents, but these are associated with undesirable side effects. Recently, tumor necrosis factor, or TNF, inhibitors have been approved or are under development to reduce the inflammatory response. TNF is one of the many injurious substances that may be generated downstream of the complement cascade. In contrast to single agent inhibitors like TNF inhibitors, by acting at C5 of the complement cascade, we expect eculizumab both to block complement activation and reduce the production of many of these downstream harmful substances. Because of this novel mechanism, we believe that eculizumab may provide a more clinically beneficial effect for RA patients.

### *Clinical Trials—Rheumatoid Arthritis*

In December 1997, we filed an Investigational New Drug application or IND with the U.S. Food and Drug Administration or FDA for eculizumab in the treatment of rheumatoid arthritis patients. In our early clinical trials, single doses of eculizumab appeared safe and well tolerated in the study populations as compared to placebo, showed dose-dependent reduction in complement activity in the study subjects, and showed a reduction in C-reactive protein blood levels in the study subjects. C-reactive protein is considered by many physicians to be the most objective component of the American College of Rheumatology's definition of efficacy criteria for rheumatoid arthritis drug trials. Biological and clinical results from our Phase I/II trial demonstrated that 50% of rheumatoid arthritis patients receiving 8.0 mg/kg of eculizumab achieved an ACR 20 score, a measure of clinical benefit, as compared to 10% of placebo-treated patients.

We completed our first Phase IIa clinical trial testing the safety and effectiveness of repetitive dosing of eculizumab in patients with rheumatoid arthritis. 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 suggested a 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, or therapeutic pre-set goal, 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. Our on-going 12 month open label extension studies in RA will help us assess long-term safety.

In January 2002, we initiated a Phase IIb multi-center study in RA patients. The trial is designed to assess safety and efficacy of eculizumab and to confirm the most efficacious dose regimen of the drug. The trial will consist of approximately 300 patients who are being treated concomitantly with disease-modifying anti-rheumatic drugs. Patient enrollment is on-going. We have additionally commenced enrollment in an on-going 12 month open label extension study related to this Phase IIb RA trial.

### ***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. This condition occurs when more than 90% of the kidney is destroyed by disease. Kidney failure is frequently associated with:

- hypertension;
- strokes;
- infections;
- anemia;
- heart, lung and joint inflammation;
- coma; and
- death.

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 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 loss of substantial amounts of protein in the patient's urine; this condition is known as proteinuria and is recognized as an objective measurement of kidney disease. Loss of protein in the urine disturbs the normal control of water in the blood vessels and also is believed to directly further injure the kidney. Moreover, clinical studies by others have shown that the degree of proteinuria is associated with the incidence of subsequent kidney failure. 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.

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Current therapies for membranous nephritis include potentially toxic drugs more frequently used to treat other indications 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, 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.

We have performed pre-clinical studies in rodent models of nephritis and observed that C5 Inhibitor administration, as compared to placebo-treated subjects, substantially reduced:

- scarring of the kidney;
- breakdown of kidney tissue into the urine;
- clogging of the kidney filtering units; and
- proteinuria.

### *Clinical Trials—Membranous Nephritis*

We are developing eculizumab for a group of kidney and kidney-related chronic autoimmune disorders, which include membranous nephritis, lupus nephritis, and lupus. Our strategy is to develop eculizumab in kidney disease by initially obtaining safety data in the more readily available lupus patient population and then to commence efficacy trials in patients with a kidney disorder known as membranous nephritis. We initiated a Phase II trial with eculizumab for the treatment of membranous nephritis patients because of the more uniform clinical presentations of membranous nephritis as compared to other autoimmune renal diseases.

In August 1999, we commenced a Phase II multi-center, double-blinded, randomized, placebo-controlled clinical safety and efficacy trial with multiple doses of eculizumab at two to four week dosing intervals that was intended to enroll approximately 120 membranous nephritis patients.

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 Phase II trial patient enrollment for membranous nephritis was completed in February 2002. Evaluation of the study awaits completion of all follow-up patient visits, data collection and subsequent analysis. We expect the data analyses will be presented at a subsequent scientific meeting before the end of 2002. The on-going 12 month open label extension study in membranous nephritis will help us assess long-term safety.

### ***Lupus***

Lupus is an autoimmune disorder that damages the brain, lungs, heart, joints and especially the kidneys. In lupus, antibodies deposit within particular organs causing complement activation, inflammation and tissue destruction. For decades, clinical studies by others have demonstrated the presence of complement activation in lupus patients undergoing flares. Studies have further shown an abundant deposition of activated complement

proteins with localized inflammation in tissue biopsies from kidney or other tissues in lupus patients. The Lupus Foundation estimates that approximately 1.4 million people in the United States have lupus. Further, up to one-half of individuals estimated to be afflicted with lupus have nephritis. Although lupus may affect people of either gender, women are 10 to 15 times more likely to suffer from the disease than men.

Patients with active lupus may have a broad range of symptoms related to the antibody and activated complement deposition and inflammation. Inflammation of the brain may cause seizures and other neurologic abnormalities. Inflammation of the heart may cause heart failure or sudden death. Lung inflammation causes shortness of breath. Lupus may also cause swollen joints and arthritis. One of the most common complications associated with lupus, however, is kidney disease, which often leads to kidney failure requiring dialysis or transplantation.

Current therapies generally act to suppress broadly the proliferation of many types of cells, including white blood cells. In contrast, 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.

We are developing eculizumab for the prevention and treatment of inflammation in lupus patients. We have performed pre-clinical studies in a rodent model of lupus. In this chronic rodent model that spontaneously develops a disease similar to lupus, substantially more animals treated with a C5 Inhibitor survived as compared to untreated control animals.

#### *Clinical Trials—Lupus*

We filed an IND with the FDA in late December 1997 for eculizumab in the treatment of patients suffering from lupus and began a Phase I clinical trial in lupus patients in July 1998. We announced results of this 24 patient, placebo-controlled clinical study in June 1999. This trial showed that a single dose of eculizumab appeared safe and well tolerated, reduced complement activity in a dose-dependent manner, and a single 8.0 mg/kg dose significantly lowered the incidence of proteinuria.

In June 2001, we announced the commencement of a Phase II eculizumab trial for lupus nephritis. Due to slow enrollment, a re-design of the study has been proposed. There have been no apparent safety issues in this study. Continuation of development depends on the evaluation of the re-design as well as availability of resources relative to other development programs.

#### ***Paroxysmal Nocturnal Hemoglobinuria or PNH, Dermatomyositis, Psoriasis, and Pemphigoid***

In addition to the above disease indications, we commenced Phase I pilot clinical trials with eculizumab in patients afflicted with the chronic hematologic disorder, paroxysmal nocturnal hemoglobinuria, or PNH, and also in the chronic autoimmune disorders dermatomyositis, psoriasis, and bullous pemphigoid. Paroxysmal nocturnal hemoglobinuria, or 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, allowing their own complement system to attack and destroy these red blood cells. According to published reports, the incidence of PNH is estimated to be between 1 per 1 million and 1 per 100,000. Approximately half the patients with PNH die from their disease. Dermatomyositis is an autoimmune disorder in which the immune system attacks the patients' muscles and skin, which may cause extensive rash and

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progressive and severe muscle weakness, pain and fatigue. According to the Muscular Dystrophy Association, approximately 2,000—3,000 new cases of dermatomyositis are diagnosed each year in the U.S., with an estimated prevalence of approximately 5,000—20,000 patients. Psoriasis is life-long autoimmune disorder in which the immune system attacks the patient's skin, which may cause red, painful and disfiguring scaling in the affected areas. Bullous pemphigoid is an autoimmune disorder in which the immune system attacks the patient's skin, which may cause extensive and striking blistering and is associated with one-year mortality rates of between 20—40%.

### *Clinical Trials—PNH, Dermatomyositis, Psoriasis, and Pemphigoid*

In September 2002, we completed patient enrollment in an open-label Phase I pilot study in the United Kingdom in patients with PNH to gather clinical data regarding the safety profile and the biological and clinical effects of eculizumab in this patient population. An open-label 12 month extension study to evaluate long-term safety is on-going. Evaluation of the initial pilot study awaits completion of all follow-up patient visits, data collection, and subsequent data analysis. We intend to review the clinical data with the FDA in order to finalize our clinical plan for eculizumab in this disease. We expect data from this pilot study to be presented at the American Society of Hematology meeting in December 2002.

We completed a Phase I pilot safety trial in dermatomyositis patients with eculizumab. Eculizumab treatment for two months appeared to be safe and well tolerated and associated with an improvement in skin rash in this 13 patient population. There were few adverse events noted, with most common adverse effects being skin rash and headache. Adverse events appeared comparable in placebo and drug populations. In this pilot Phase I trial, exploratory clinical measurements included clinical and laboratory assessments of skin rash and muscle strength. There were consistent trends in improvements with drug administration in subjective and objective measures of skin rash during the two-month trial. While there was little baseline skin inflammation in the placebo group, a majority of drug-treated patients who completed the trial experienced an improvement of 50% or more in their skin rash score. We reviewed the clinical data with the FDA and intend to initiate a Phase II clinical study for eculizumab in this disease. We also expect that data will be presented at a subsequent scientific meeting. In October 2000, we announced that the FDA granted Orphan Drug status for development of eculizumab for the treatment of patients with dermatomyositis. The Orphan Drug designation would provide Alexion with market exclusivity for eculizumab for this indication for seven years from the drug's approval date.

We completed a Phase I clinical trial to investigate the safety of two months of therapy with eculizumab in psoriasis patients. Eculizumab appeared to be safe and well tolerated in this patient population. According to a standard measure of disease activity, eculizumab treatment for two months did not influence the outcome of psoriasis in this trial. At this time, we are not pursuing psoriasis as a clinical indication. We also initiated a Phase I pilot safety trial in patients with bullous pemphigoid, which was subsequently terminated. There were no apparent safety issues, but in view of difficulties in patient enrollment in this very rare disease, we have elected not to pursue this program further in order to more efficiently focus resources on other on-going eculizumab development programs.

## **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

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owned subsidiary, Alexion Antibody Technologies, Inc., or AAT. AAT possesses extensive research expertise and technologies in the area of creating fully human antibodies from libraries containing billions of human antibody genes.

AAT's goal 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 which may be therapeutically effective in different autoimmune or inflammatory disorders, cancer, 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 provide new therapeutic antibodies when the libraries are screened against certain of these new gene targets.

In May 2001, we announced the results of a pre-clinical study of a new class of therapeutic antibodies that accelerated the return to normal platelet levels in an animal model of bone marrow toxicity commonly found in cancer patients. Antibodies in this new class function as agonists that stimulate their cell target, rather than blocking it, and were created using a rational design and selection process utilizing proprietary technology developed at AAT. This new class of antibody agonists is designed to selectively bind to the c-Mpl receptor on the surface of platelet precursors and then to stimulate platelet-specific proliferation and differentiation both in vitro and in vivo. We believe that our c-Mpl agonist has potential use for patients who need treatment related to anti-cancer drug-induced thrombocytopenia, a frequent adverse event that occurs in various types of cancer treatment including leukemia, bone marrow transplantation for various disorders and certain solid tumors.

### **Pre-Clinical Programs**

#### ***UniGraft Xenotransplantation Technologies Program***

Most transplant procedures today are whole organ transplants. We believe that there is a far greater number of patients with medical disorders, such as Parkinson's disease and spinal cord injury, that are caused by the functional loss of highly specialized cells. However, since there are no human donors of such specialized cells, there is currently no available supply of such cells for replacement therapy. Further, the immune system prevents the transplantation of cells from other species, known as xenografts, as they are recognized by the immune system as foreign and they are rejected. We are studying a portfolio of UniGraft anti-rejection technologies designed to permit the therapeutic transplantation, or xenotransplantation, of such cells without rejection.

Although approximately 21,000 people received whole organ transplants in the United States in 1999, there are many times that number of patients who have disorders that may be amenable to cell or tissue transplantation. It is estimated that this broader population includes approximately 200,000 patients suffering from spinal cord injury and 1.0 million individuals with Parkinson's disease. In particular, we believe that use of a safe and effective cell transplantation therapy for patients with spinal cord injury or Parkinson's disease would represent major therapeutic advances.

### ***Neurologic Cell Transplantation***

We have developed methods of blocking the immune system which are designed to permit the replacement of damaged human brain cells and other neurologic cells with potentially highly therapeutic genetically modified porcine or pig cells.

Rejection of non-human tissue by patients is generally believed to occur in two stages:

- the hyperacute phase, which is very rapid, extending from minutes to hours; and
- the acute phase, which is somewhat less rapid, extending from days to months.

Hyperacute rejection is generally believed to be mediated by naturally-occurring antibodies in the patient, most of which target a sugar antigen uniquely present on the surface of non-human tissue but not on the patient's own tissue. After binding to the foreign tissue, these antibodies stimulate the activation of the recipient's inactive complement proteins on the surface of the donor tissue with subsequent destruction of the donor tissue. Subsequently, acute rejection of xenografts is generally believed to be mediated by white blood cells.

We are designing UniGraft cell products to resist complement/antibody-mediated hyperacute rejection. We have commenced pre-clinical studies employing the UniGraft technologies during transplantation of genetically modified and proprietary porcine cells that are resistant to destruction by human complement proteins. We are currently focusing our anti-rejection and molecular engineering technologies primarily on the development of UniGraft cells to treat Parkinson's disease and injuries to the spinal cord. We are currently performing pre-clinical studies in the spinal cord injury and Parkinson's disease programs and optimizing manufacturing methods of the genetically modified pig cells.

As we complete optimization of manufacturing methods for the UniGraft cells/tissue to enable clinical development, we are seeking to collaborate with other parties on this program. If we are unable to secure a collaboration to share in the future funding of the development and clinical trials, we may be unable to maximize the value in this program; and subsequently, may have to reduce our financial commitment to the program. This may cause a delay or termination of our UniGraft program, and impairment to our UniGraft manufacturing assets resulting in a write down of a portion of those assets. As of July 31, 2002, the carrying value of those assets was approximately \$4 million.

### ***Apogen T-Cell Immunotherapeutic Technology and Product Candidates***

#### ***MP4***

MP4 is a recombinant or genetically-modified protein consisting of parts of two brain-derived proteins. These two proteins are believed to be major targets of disease-causing T-cells in patients with multiple sclerosis. MP4 is designed to bind specifically to, and eliminate, the small population of T-cells in multiple sclerosis patients which are responsible for attacking the patient's brain cells, while leaving the vast majority of uninvolved T-cells unaffected.

In February 1998, we filed an IND with the FDA for MP4 for the treatment of patients suffering from multiple sclerosis. The FDA has accepted a plan for a Phase I clinical trial of MP4. We have sought to license our rights to MP4 or to otherwise collaborate with a partner in its development. At this time, we have elected not to

conduct this trial or to pursue this program further in order to more efficiently focus resources on our on-going pexelizumab and eculizumab development programs.

#### **Grants from Advanced Technology Program and National Institute of Standards and Technology**

In October 1998, we were granted our third award from the National Institute of Standards and Technology or NIST under its Advanced Technology Program, a three-year grant supporting product development within our neurologic disorder transplantation program. Through the program, we may receive up to approximately \$2.0 million over three years to support our UniGraft program to develop a spinal cord injury product within our neurologic disorder xenotransplantation program. As of December 31, 2001 this award has been completed. Through July 31, 2002, we had received approximately \$1.9 million under this award.

In November 1999, we were granted our fourth award under the NIST program, a three-year grant supporting product development within our UniGraft program. Through the program, we may receive up to approximately \$2.0 million over three years to support our production of UniGraft products. Through July 31, 2002, we had received approximately \$1.2 million under this award.

#### **Strategic Alliance with Procter & Gamble**

We and Procter & Gamble Pharmaceuticals, or P&G, entered into an exclusive collaboration in January 1999 to develop and commercialize pexelizumab. We granted P&G an exclusive license to our intellectual property related to pexelizumab, with the right to sublicense. P&G agreed to fund generally all clinical development and manufacturing costs relating to pexelizumab for the treatment of inflammation caused by cardiopulmonary bypass surgery, heart attack, and angioplasty. Additionally, P&G agreed to pay us up to \$95 million in payments, which included a non-refundable up-front \$10 million license fee, milestone payments (including up to \$33 million in milestone payments for achievement of certain sales thresholds), and research and development support payments. We were also to receive royalties on worldwide sales of pexelizumab, if any, for all indications. We retained a preferred position relative to third-party manufacturers to manufacture pexelizumab worldwide. We shared co-promotion rights with P&G to sell, market and distribute pexelizumab in the United States or U.S., and granted P&G the exclusive rights to sell, market and distribute pexelizumab outside of the U.S.

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, or 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. Per the MOU, our revised collaboration with P&G provides for us and P&G to 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 each firm will receive an approximate equal share of the gross margin on U.S. sales, if any. P&G agreed to retain responsibility and costs for future development and commercialization outside the U.S., with us receiving a royalty on sales to the rest of the world, 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, but will not receive previously agreed sales milestones and will generally forego further research and development support payments from P&G.

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As part of the revised collaboration per the MOU, P&G agreed to continue to fund 100% of the costs to complete the two on-going Phase II clinical trials in myocardial infarction or heart attack patients that recently completed enrollment. We have agreed to bear the first 50% of projected costs associated with the coronary artery bypass graft surgery, or CABG, Phase III clinical trial and P&G will bear the second 50%, with a final adjustment to make even the 50% sharing of costs. We and P&G have agreed that each will share concurrently 50% of the on-going U.S. pre-production and development manufacturing costs of pexelizumab as well as any future AMI Phase III clinical trial costs. A letter of understanding has been signed relating to the negotiation and completion of an agreement with a third party manufacturer for the large scale commercial manufacture of pexelizumab over five years.

P&G has the right to terminate the collaboration at any time. If P&G terminates prior to incurring its 50% of the CABG-Phase III clinical trial costs, then P&G will not be required to contribute towards its approximately equal share of the U.S. CABG-Phase III clinical trial costs and P&G will be released from its future funding obligations. In addition, P&G would offer to assign any pexelizumab third party manufacturing agreements and we could be obligated to assume all future costs thereunder and reimburse P&G for its prior payments thereunder. If P&G terminates, all rights and the exclusive license to our intellectual property related to pexelizumab will revert back to us and we will be entitled to all future pexelizumab revenues, if any, without any sharing of revenues, if any, with P&G. If we were to continue development of pexelizumab, our costs would increase significantly as we would need to fund development and commercialization of pexelizumab on our own or identify a new collaboration partner.

### **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 fermentation and purification of certain of our recombinant compounds for clinical studies. Our pilot plant has the capacity to manufacture under cGMP or current good manufacturing practices regulations. We have also secured the production of clinical supplies of certain other recombinant products 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 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 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 which will be given consideration when making the determination of which products will be manufactured internally and which 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.

### **Sales and Marketing**

We currently have no sales, marketing, or distribution capabilities. We will need to establish or contract these capabilities to commercialize successfully any of our drug candidates. We may promote our products in

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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. Of our owned and licensed patents and patent applications as of July 31, 2002, 19 relate to technologies or products in the C5 Inhibitor program, 8 relate to other technologies, 33 relate to the UniGraft program, 25 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 the commercial manufacture and sale of our expected 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, recombinant human single-chain antibodies, and genetically engineered animals. 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, and other products are tissues from animals. 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. With respect to certain of these patents which we believe are relevant for the expeditious development and commercialization of certain of our products as currently contemplated, we have acquired licenses. 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 in 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 prevented.

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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 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. At the present time, we believe that our currently anticipated products will be regulated by the FDA as therapeutic biologics. In September 2002, the FDA announced that review of most therapeutic biologics will move to the Center for Drug Evaluation and Research, or CDER, from the Center of Biologics Evaluation and Research or CBER. It is unclear what changes, if any, will result from this announcement.

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

- (1) pre-clinical laboratory tests and *in vivo*, or within a living organism, pre-clinical studies;
- (2) the submission to the FDA of an IND 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 biologics license application or BLA; and
- (5) FDA review and approval of such application.

The testing and approval process requires substantial time, effort and financial resources. Prior to and following approval, if granted, the establishment or establishments where the product is manufactured are subject to inspection by the FDA and must comply with cGMP requirements enforced by the FDA through its facilities inspection program. Manufacturers of biological materials also may be subject to state regulation.

Pre-clinical studies include animal studies to evaluate the mechanism of action of the product, 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 and compounds used for clinical trials must be produced according to applicable cGMP requirements. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an 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 requests an extension to review or raises concerns about the conduct of the trials as outlined in the application. In such latter case, the sponsor of the

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application 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 a qualified principal investigator. Clinical trials are conducted in accordance with protocols that detail many items, including:

- the objectives of the study;
- the parameters to be used to monitor safety; and
- the efficacy criteria to be evaluated.

Each protocol must be submitted to the FDA as part of the IND. Further, 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 tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmacodynamics and pharmacokinetics. 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 products being tested by a sponsor. 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.

The results of the pre-clinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, are submitted to the FDA as part of a BLA requesting approval for the marketing of the product. The FDA will occasionally convene an Advisory Panel of experts to review and recommend a non-binding course of action regarding a sponsor's BLA requests. The FDA may deny approval of the application if applicable regulatory criteria are not satisfied, or if additional testing or information is required. Post-marketing testing and surveillance to monitor the safety or efficacy of a product may be required. FDA approval of any application may include many delays or never be granted. Moreover, if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which it may be marketed. Finally, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. Among the conditions for approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to cGMP requirements. These requirements must be followed at all times in the manufacture of the approved product. In complying with these requirements, manufacturers must continue to expend time, monies and effort in the area of production and quality control to ensure full compliance.

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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. Violations of regulatory requirements at any stage, including the pre-clinical and clinical testing process, the review process, or at any time afterward, including after approval, may result in various adverse consequences, including the FDA's delay in approving or refusal to approve a product, withdrawal of an approved product from the market, and/or the imposition of criminal penalties against the manufacturer and/or the BLA holder. In addition, later discovery of previously unknown problems may result in restrictions on a product, its manufacturer, or the BLA holder, including withdrawal of the product from the market. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

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.

No xenotransplantation-based therapeutic product has been approved for sale by the FDA. The FDA has not yet established definitive regulatory guidelines for xenotransplantation, but has proposed interim guidelines in an attempt to reduce the risk of contamination of transplanted organ and cellular products with infectious agents. Definitive guidelines in the United States may never be issued. Current companies involved in this field, including ourselves, may not be able to comply with any final and definitive federal guidelines that may be issued.

### **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

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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, and xenotransplantation.

Each of Avant Immunotherapeutics, Inc., Millennium Pharmaceuticals, Inc., Tanox, Inc., Abbott Laboratories, Baxter International Inc., Gliatech Inc., Neurogen Corporation, and Biocryst Pharmaceuticals Inc. has publicly announced intentions to develop complement inhibitors to treat diseases related to trauma, inflammation or certain brain or nervous system disorders. Avant has concluded limited clinical trials for a proposed complement inhibitor to treat acute respiratory distress syndrome, myocardial infarction, lung transplantation, and in infants and adults undergoing heart and/or lung bypass procedures. Neurogen has also announced a human study. We are aware that Pfizer, Inc., GlaxoSmithKline plc, and Merck & Co., 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 Bayer AG, Amgen Inc.(which acquired Immunex Corp.), Pharmacia & Upjohn Inc.(acquired by Pfizer, Inc.) and Rhone-Poulenc SA (merged to form Aventis S.A.) sells a product which is used clinically to reduce surgical bleeding during cardiopulmonary bypass surgery, but has little beneficial effect on other significant inflammatory morbidities associated with cardiopulmonary bypass surgery. 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 cardiopulmonary bypass surgery, 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 that blocks ion transport.

Nextran Inc., a subsidiary of Baxter International Inc., and Imutran Ltd., a wholly-owned subsidiary of Novartis Pharma AG, are seeking to develop pig cell xenograft technology. Novartis Pharma AG is also collaborating with Biotransplant Inc. to commercially develop xenograft organs in a joint venture known as Immerge, Inc. We are aware that Diacrin Inc. is working in this field.

Each of Cambridge Antibody Technology, PLC, MorphoSys AG, and Dyax Corporation 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. have 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 October 1, 2002, we had 172 full-time employees, of which 146 were engaged in research, development, manufacturing, and clinical development, and 26 in administration and finance. Doctorates are held by 42 of our employees. Each of our employees has signed a confidentiality agreement.

**Item 2. Properties.****Facilities**

We lease our headquarters and research and development facilities in Cheshire, Connecticut, where we relocated in November 2000. The lease has an initial term of ten years and six months. 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 incurred initial leasehold improvements aggregating approximately \$5.7 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 30,000 square feet of labs and offices. We are on a month-to-month rental and we are currently negotiating a longer-term arrangement for this facility. We believe our research and development facilities and our pilot manufacturing facility will be adequate for our on-going current clinical activities. Alexion Antibody Technologies, Inc. leases approximately 12,000 square feet of labs and office space in San Diego, California. The lease has an initial term of ten years.

**Item 3. Legal Proceedings.**

We are not a party to any material legal proceeding.

**Item 4. Submission of Matters to a Vote of Security Holders.**

None.

**EXECUTIVE OFFICERS AND KEY EMPLOYEES OF THE COMPANY**

The executive officers and key employees of the Company and their respective ages and positions with the Company as of October 1, 2002 were as follows:

<u>Name</u>	<u>Age</u>	<u>Position with Alexion</u>
*Leonard Bell, M.D.	44	Chief Executive Officer, Secretary, Treasurer, Director
*David W. Keiser	51	President and Chief Operating Officer, Director
*Stephen P. Squinto, Ph.D.	46	Executive Vice President and Head of Research
*Katherine S. Bowdish, Ph.D.	45	Senior Vice President, Antibody Discovery, and President, Alexion Antibody Technologies
*Scott A. Rollins, Ph.D.	39	Senior Vice President, Drug Development and Project Management
Samuel S. Chu, Ph.D.	52	Vice President, Manufacturing and Process Sciences
*Thomas I.H. Dubin, J.D.	40	Vice President and General Counsel
Paul W. Finnegan, M.D., M.B.A.	42	Vice President, Commercial Operations and Development
*Barry P. Luke	44	Vice President, Finance and Administration, Assistant Secretary
*Christopher F. Mojcik, M.D., Ph.D.	42	Vice President, Clinical Development
*Nancy C. Motola, Ph.D.	49	Vice President, Regulatory and Quality
Russell P. Rother, Ph.D.	41	Vice President, Discovery Research
Daniel N. Caron	39	Senior Director, Operations and Engineering

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

**Leonard Bell, M.D.** is the principal founder of Alexion, and has been a director of Alexion since February 1992 and the Company's President and Chief Executive Officer, Secretary and Treasurer from January 1992 to April 2002. 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 a director of The Medicines Company and Connecticut United for Research Excellence, Inc. 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 and 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 has also served as a Director of the BRDC since 1997. 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 1997 to 1998, 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 1998 to 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.

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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.

**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.

**Samuel S. Chu, Ph.D.** has been Vice President, Manufacturing and Process Sciences since September 2000. Before joining Alexion Dr. Chu was Director of the Biotech Development and Pilot Plant, Bio-Chemistry Division operations at Bristol-Meyers Squibb Company from 1993 to 2000. From 1990 to 1993, Dr. Chu was an Associate Director of Product Development and Scale-up at Lederle-Praxis Biologicals, a division of American Cyanamid. From 1985 to 1990 Dr. Chu was the Associate Director of Product Development and Scale-up at Praxis Biologics. Dr. Chu received his B.S. from National Chung-Hsing University, M.S. from Illinois Institute of Technology, and Ph.D. degree from the University of Toronto.

**Thomas I.H. Dubin, J.D.** joined the Company in January 2001 as Vice President and General Counsel. 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, pharmaco-economics, strategic planning and business 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

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

**Christopher F. Mojcik, M.D., Ph.D.** has been Vice President, Clinical Development since August 2000. 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 NIAID at the NIH. 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 Vice President, Regulatory and Quality since 1998. 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 and 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.

**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 Senior Director, Operations and Engineering since 1998. After joining the Company in 1992, Mr. Caron was Operations Manager from 1992 to 1993, Senior Operations Manager from 1993 to 1996, and Director of Operations from 1996 to 1998. Mr. Caron has been responsible for managing the engineering, build-out, validation and maintenance 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.

**PART II****Item 5. Market for Registrant's Common Equity and Related Stockholder Matters.**

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, 1999.

<b>Fiscal 2000</b>	<b>High</b>	<b>Low</b>
First Quarter (August 1, 1999 to October 31, 1999)	\$ 16.25	\$ 10.00
Second Quarter (November 1, 1999 to January 31, 2000)	\$ 50.13	\$ 12.75
Third Quarter (February 1, 2000 to April 30, 2000)	\$ 119.88	\$ 34.81
Fourth Quarter (May 1, 2000 to July 31, 2000)	\$ 84.50	\$ 30.50
<b>Fiscal 2001</b>	<b>High</b>	<b>Low</b>
First Quarter (August 1, 2000 to October 31, 2001)	\$ 118.63	\$ 64.00
Second Quarter (November 1, 2000 to January 31, 2001)	\$ 112.00	\$ 42.75
Third Quarter (February 1, 2001 to April 30, 2001)	\$ 54.50	\$ 16.88
Fourth Quarter (May 1, 2001 to July 31, 2001)	\$ 29.99	\$ 18.50
<b>Fiscal 2002</b>	<b>High</b>	<b>Low</b>
First Quarter (August 1, 2001 to October 31, 2001)	\$ 20.05	\$ 14.01
Second Quarter (November 1, 2001 to January 31, 2002)	\$ 25.00	\$ 16.74
Third Quarter (February 1, 2002 to April 30, 2002)	\$ 26.69	\$ 17.30
Fourth Quarter (May 1, 2002 to July 31, 2002)	\$ 18.24	\$ 10.66

As of October 24, 2002, we had 150 stockholders of record of our common stock and an estimated 4,000 beneficial owners. The closing sale price of our common stock on October 25, 2002 was \$9.58 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.

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In October 2000, we filed a shelf registration statement to offer up to \$300 million of equity securities. On November 1, 2000, we sold 2.3 million shares of common stock at a price of \$90.75 per share resulting in net proceeds of approximately \$208.5 million, net of fees and other expenses of approximately \$201,000 related to the transaction.

### 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.

	Fiscal Year Ended July 31,				
	2002	2001	2000	1999	1998
	(in thousands, except per share data)				
<b>Consolidated Statements of Operations Data:</b>					
Contract research revenues	\$ 6,536	\$ 11,805	\$ 21,441	\$ 18,754	\$ 5,037
Operating expenses:					
Research and development	60,005	38,871	40,187	23,710	12,323
General and administrative	7,993	7,135	4,175	2,953	2,666
In-process research and development (IPRD)	—	21,000	—	—	—
Amortization of goodwill (GW)	—	2,901	—	—	—
Total operating expenses	67,998	69,907	44,362	26,663	14,989
Operating loss	(61,462)	(58,102)	(22,921)	(7,909)	(9,952)
Other income, net	4,220	10,177	2,694	1,514	2,087
State tax benefit	700	—	—	—	—
Loss before cumulative effect of SAB 101	(56,542)	(47,925)	(20,227)	(6,395)	(7,865)
Cumulative effect of adoption of SAB 101	—	(9,118)	—	—	—
Net loss	\$ (56,542)	\$ (57,043)	\$ (20,227)	\$ (6,395)	\$ (7,865)
Preferred stock dividends	—	—	—	—	(900)
Net loss applicable to common shareholders	\$ (56,542)	\$ (57,043)	\$ (20,227)	\$ (6,395)	\$ (8,765)
Basic and diluted net loss per common share	\$ (3.12)	\$ (3.28)	\$ (1.45)	\$ (0.57)	\$ (0.87)
Shares used in computing net loss per common share	18,146	17,371	13,914	11,265	10,056
	As of July 31,				
	2002	2001	2000	1999	1998
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents, and marketable securities	\$ 308,584	\$ 355,274	\$ 174,529	\$ 28,328	\$ 37,494
Total current assets	310,784	362,747	180,080	35,662	37,840
Total assets	354,069	400,259	192,702	44,374	42,085
Notes payable, less current portion	3,920	3,920	3,920	4,383	832
Convertible subordinated notes	120,000	120,000	120,000	—	—
Total stockholders' equity	205,478	260,408	61,604	33,301	39,190

**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 "Risk Factors" attached hereto as Exhibit 99.2.

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

Our two lead product candidates are antibodies that address specific diseases that arise when the human immune system attacks the human body itself and produces undesired inflammation. 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, pexelizumab and eculizumab, in eight different clinical development programs.

Through 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 are also developing therapies employing the transplantation of cells from other species into humans, known as xenotransplantation.

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, 2002, we had an accumulated deficit of \$180.8 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 and developing a sales and marketing force 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 with major pharmaceutical companies for product development and commercialization, where we will stay play a major role.

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, or U.S., development and commercialization costs for pexelizumab, including clinical, manufacturing, marketing, and sales efforts. Prior to December 2001,

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P&G was generally funding all clinical development and manufacturing costs for pexelizumab. Per the MOU, our revised collaboration with P&G provides for us and P&G to 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 each firm will receive an approximate equal share of the gross margin on U.S. sales, if any. P&G agreed to retain responsibility and costs for future development and commercialization outside the U.S., with us receiving a royalty on sales to the rest of the world, 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, but will not receive previously agreed sales milestones and will generally forego further research and development support payments from P&G.

As part of the revised collaboration per the MOU, P&G agreed to continue to fund 100% of the costs to complete the two on-going Phase II clinical trials in myocardial infarction or heart attack patients that recently completed enrollment. We have agreed to bear the first 50% of projected costs associated with the CABG-Phase III clinical trial and P&G will bear the second 50%, with a final adjustment to make even the 50% sharing of costs. We and P&G have agreed that each will share concurrently 50% of the on-going U.S. pre-production and development manufacturing costs of pexelizumab as well as any future AMI-Phase III clinical trial costs. A letter of understanding has been signed relating to the negotiation and completion of an agreement with a third party manufacturer for the large scale commercial manufacture of pexelizumab over five years.

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent liabilities. On an on-going basis, we evaluate our estimates, including those related to intangible assets; collaborative, royalty and license arrangements; and other contingencies. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

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. 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. Unbilled reimbursable contract costs as shown on our consolidated balance sheets represent reimbursable costs incurred in connection with research contracts which have not yet been billed. We bill these costs and recognize the costs and related revenues in accordance with the terms of the contracts. Deferred revenue results from cash received or amounts receivable in advance of revenue recognition under research and development contracts.

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*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, depreciation and amortization of lab facilities and leasehold improvements, building and utilities costs related to research space and lab supplies.

*Goodwill*—At July 31, 2002, we carry \$20.0 million of goodwill, net, acquired in connection with our acquisition of Prolifaron (see Financial Note No.3 ), 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.

## **Results of Operations**

### *Fiscal Years Ended July 31, 2002, 2001, and 2000*

We earned contract research revenues of \$6.5 million, \$11.8 million, and \$21.4 million for the fiscal years ended July 31, 2002, 2001, and 2000, respectively. The decrease in revenues in fiscal year 2002 as compared to 2001 was primarily due to decreased research payments from Procter & Gamble Pharmaceuticals, or P&G, resulting from: (1) our December 2001 agreement per a binding memorandum of understanding, or MOU, to revise our 1999 collaboration agreement with P&G and (2) the completion of the Phase II pexelizumab CPB study. The decrease in revenues in fiscal year 2001 as compared to 2000 was primarily due to the lower research payments resulting from our completion of the Phase II pexelizumab CPB study.

During fiscal year 2002, we incurred research and development expenses of \$60.0 million. For fiscal years 2001 and 2000, we incurred research and development expenses of \$38.9 million and \$40.2 million, respectively. The increase in research and development expenses for fiscal year 2002 as compared to 2001 was attributable to higher clinical trial costs associated primarily with the Phase III pexelizumab PRIMO-CABG trial as a result of the revised collaboration agreement with P&G which required us to share in the pexelizumab development costs and greater clinical manufacturing costs associated with our two lead product candidates—pexelizumab and eculizumab. The decrease in research and development expenses for fiscal 2001 as compared to 2000 was primarily attributable to lower clinical manufacturing and clinical trial costs associated with the completion of Phase II pexelizumab CPB study. These lower costs were offset by increased costs from clinical trials, manufacturing development, and manufacturing of other lead C5 Inhibitor product candidate, eculizumab, and the consolidated on-going research and development costs of AAT which was formed through the September 2000 acquisition from Prolifaron.

The acquisition of Prolifaron in fiscal 2001 resulted in a one-time, non-cash charge of \$21 million allocated to in-process research and development projects. In addition, the Company recognized approximately \$23 million of the purchase price as goodwill which was being amortized over the seven years following purchase. The amortization of this goodwill resulted in a charge of \$2.9 million in the twelve months ended July 31, 2001. Effective August 1, 2001, the Company's adoption of SFAS No. 142 caused the amortization of goodwill to cease.

Our general and administrative expenses were \$8.0 million, \$7.1 million and \$4.2 million for fiscal years 2002, 2001, and 2000, respectively. The increase in general and administrative expenses in fiscal year 2002 as

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compared to 2001 was principally due to higher payroll related costs. The increase in fiscal year 2001 as compared to 2000 was principally due to increased personnel and professional fees, as well as higher facilities expenses resulting from our relocation and expansion of our operations to support our growth, including our acquisition of Prolifaron.

Total operating expenses were \$68.0 million, \$69.9 million, and \$44.4 million for fiscal years 2002, 2001, and 2000, respectively. Total operating expenses in the twelve months ended July 31, 2001 included the one-time non-cash in-process research and development charge and the non-cash amortization of goodwill.

Other income, net, was \$4.2 million, \$10.1 million, and \$2.7 million for fiscal years 2002, 2001, and 2000, respectively. The decrease in fiscal year 2002 as compared to 2001 was due to decreased interest income from lower cash balances and lower market interest rates. The increase in fiscal year 2001 as compared to 2000 was due to increased interest income from higher cash balances resulting primarily from the \$208.5 million of net proceeds received from the sale of common stock in November 2000. A state tax benefit of \$0.7 million was recognized in fiscal year 2002 resulting from the Company's exchange of its fiscal 2001 incremental research and development tax credit.

During fiscal year 2001, we recorded a \$9.1 million non-cash charge that is related to the cumulative change in accounting principle per the adoption of Staff Accounting Bulletin No. 101 or SAB 101. We adopted SAB 101 in fiscal year 2001 and therefore changed our revenue recognition policy for up front non-refundable payments from immediate recognition to deferral of the revenue with the up front fee amortized into revenue over the life of the agreement. We recognized the non-cash cumulative effect adjustment of \$9.1 million as of August 1, 2000. Included in each of fiscal years 2002 and 2001 were contract revenues of \$0.6 million related to the SAB 101 amortization of the up front, non-refundable payment over the life of the agreement.

As a result of the above factors, we incurred a net loss of \$56.5 million, \$57.0 million, and \$20.2 million or \$3.12, \$3.28, and \$1.45 basic and diluted net loss per share for fiscal years ended July 31, 2002, 2001, and 2000, respectively. Shown below are our statements of operations for fiscal years ended 2002, 2001, and 2000. Excluding the impact of the non-cash charges resulting from our acquisition of Prolifaron and the cumulative effect of SAB 101, we incurred a pro forma net loss of \$24.0 million or \$1.38 basic and diluted net loss per share for fiscal year ended July 31, 2001.

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The following table displays the results of our operations, as well as on a pro forma basis relative to our 2001 results. The pro forma 2001 results exclude non-cash charges for in-process research and development, amortization of goodwill, and cumulative effect of adoption of SAB 101.

	Twelve months ended July 31,			
	2002	2001	2001	2000
		<b>pro forma(a)</b>		
		(\$ in thousands, except per share data)		
Contract Research Revenues	\$ 6,536	\$ 11,805	\$ 11,805	\$ 21,441
Operating Expenses:				
Research and development	60,005	38,871	38,871	40,187
General and administrative	7,993	7,135	7,135	4,175
In process research development (IPRD)	—	—	21,000	—
Amortization of goodwill (GW)	—	—	2,901	—
Total operating expenses	67,988	46,006	69,907	44,362
Operating loss	(61,462)	(34,201)	(58,102)	(22,921)
Other income, net	4,220	10,177	10,177	2,694
State tax benefit	700	—	—	—
Loss before cumulative effect of SAB 101	(56,542)	(24,024)	(47,925)	(20,277)
Cumulative effect of adoption of SAB 101	—	—	(9,118)	—
Net loss	\$ (56,542)	\$ (24,024)	\$ (57,043)	\$ (20,227)
Basic and diluted net loss per share	\$ (3.12)	\$ (1.38)	\$ (3.28)	\$ (1.45)

(a) excludes non-cash IPRD, Amortization of GW, and Cumulative effect of adoption of SAB 101

### 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, 2002, our cash, cash equivalents, and marketable securities totaled \$308.6 million compared to \$355.3 million as of July 31, 2001. At July 31, 2002, our cash and cash equivalents consisted of \$47.6 million that we hold in short-term highly liquid investments with original maturities of less than three months. The decrease in cash, cash equivalents and marketable securities as compared to July 31, 2001 was due to the use of funds to fund our operations and capital equipment investments. As of July 31, 2002, we have invested \$24.7 million in property and equipment to support our research and development efforts. We anticipate our research and development expense will increase significantly 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. This should also provide us adequate funding for the clinical testing of our C5 Inhibitor product candidates and support our broad research and development of our additional product candidates.

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Our contractual obligations and commercial commitments consist principally of our \$120 million of convertible subordinated notes, a \$3.9 million note payable, our 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 lease in Cheshire, Connecticut. We have no outstanding capital leases. We have cancelable research and development and clinical and manufacturing development cost commitments along with anticipated supporting arrangements, subject to certain limitations and cancellation clauses, aggregating \$58.8 million over the next three years. And, if and when we achieve specified contractual milestones related to product development and product license applications and approvals, additional payments would be required if we elect to continue and maintain our licenses with our licensors, aggregating up to \$24.2 million.

The following table summarizes our contractual obligations, commercial commitments, and anticipated supporting arrangements—subject to certain limitations and cancellation clauses—and the effect such obligations are expected to have on our liquidity and cash flow in future periods (\$ amounts in millions):

	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008 and thereafter</u>
<b>Contractual obligations:</b>						
Subordinated convertible notes	\$ —	\$ —	\$ —	\$ —	\$ 120.0	\$ —
Note payable	—	—	3.9	—	—	—
Operating leases	1.6	2.0	2.0	2.0	2.1	9.4
<b>Total contractual obligations</b>	<b>\$ 1.6</b>	<b>\$ 2.0</b>	<b>\$ 5.9</b>	<b>\$ 2.0</b>	<b>\$ 122.1</b>	<b>\$ 9.4</b>
<b>Commercial commitments and anticipated supporting arrangements:</b>						
Clinical and manufacturing development	\$ 47.1	\$ 7.2	\$ 1.2	\$ 0.1	\$ 0.1	\$ —
Licenses	0.5	0.5	0.5	0.5	0.5	—
Research and development	1.0	0.4	0.4	0.3	0.4	—
<b>Total commercial commitments</b>	<b>\$ 48.6</b>	<b>\$ 8.1</b>	<b>\$ 2.1</b>	<b>\$ 0.9</b>	<b>\$ 1.0</b>	<b>\$ —</b>

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.

Interest on our \$3.9 million note payable due in May 2005, bearing interest at 6.0% per annum, is payable quarterly. This note payable was used to finance certain manufacturing assets acquired in February 1999, principally land, buildings and laboratory equipment, for the xenograft program developed by Tyco Healthcare, formerly known as U.S. Surgical Corporation. The principal balance under the note is due in May 2005. Security for this term note is the manufacturing assets that we purchased. We are looking to leverage our opportunities in this program as we complete optimization of manufacturing methods for the UniGraft cells/tissue to enable clinical development. If we are unable to secure a collaboration to share in the future funding of the development and clinical trials, we may be unable to maximize the value in this program; and subsequently, may have to reduce our financial commitment to the program. This may cause a delay or termination of our UniGraft program, and impairment to our UniGraft manufacturing assets resulting in a write down of a portion of those assets. As of July 31, 2002, the carrying value of those assets was approximately \$4 million.

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We lease our headquarters and research and development facility in Cheshire, Connecticut that we relocated to in November 2000. The lease has an initial term of ten years and six months, 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 initial leasehold improvements aggregating approximately \$5.7 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 30,000 square feet of labs and offices. We are on a month-to-month rental and are currently negotiating a longer-term arrangement for the facilities in New Haven, Connecticut. We believe our research and development facilities and our pilot manufacturing facility will be adequate for our current ongoing activities. Alexion Antibody Technologies, Inc., our wholly-owned subsidiary, leases approximately 12,000 square feet of labs and office space in San Diego, California. The lease has a term of ten years, expiring in August 2012.

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 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 for us and P&G to 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 each firm will receive an approximate equal share of the gross margin on U.S. sales, if any. P&G agreed to retain responsibility and cost for future development and commercialization outside the U.S., with us receiving a royalty on sales to the rest of the world, 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, but will not receive previously agreed sales milestones and will generally forgo further research and development support payments from P&G.

As part of the revised collaboration per the MOU, P&G agreed to continue to fund 100% of the costs to complete the two on-going Phase II clinical trials in myocardial infarction or heart attack patients that recently completed enrollment. We have agreed to bear the first 50% of projected costs associated with the CABG-Phase III clinical trial and P&G will bear the second 50%, with a final adjustment to make even the 50% sharing of costs. We and P&G have agreed that each will share concurrently 50% of the on-going U.S. pre-production and development manufacturing costs of pexelizumab as well as any future AMI-Phase III clinical trial costs. The parties have agreed to secure commercial manufacturing capacity for pexelizumab. A letter of understanding has been signed relating to the negotiation and completion of an agreement with a third party manufacturer for large scale commercial production.

P&G has the right to terminate the collaboration at any time. If P&G terminates prior to incurring its 50% of the CABG-Phase III clinical trial costs, then P&G will not be required to contribute towards its approximately equal share of the U.S. CABG-Phase III clinical trial costs and P&G will be released from its future funding obligations. In addition, P&G would offer to assign any pexelizumab third party manufacturing agreements and we could be obligated to assume all future costs there under and reimburse P & G for its prior payments thereunder. If P&G terminates, all rights and the exclusive license to our intellectual property related to pexelizumab will revert back to us and we will be entitled to all future pexelizumab revenues, if any, without any sharing of revenues, if any, with P&G. If we were to continue development of pexelizumab, our costs would increase significantly as we would need to fund development and commercialization of pexelizumab on our own or identify a new collaboration partner.

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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 and continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. Our operating expenses will depend on many factors, including:

- the progress, timing and scope of our research and development programs;
- the progress, timing and scope of our preclinical studies and clinical trials;
- the time and cost necessary to obtain regulatory approvals;
- the time and cost necessary to further develop manufacturing processes, arrange for contract manufacturing or build manufacturing facilities and obtain the necessary regulatory approvals for those facilities;
- the time and cost necessary to develop sales, marketing and distribution capabilities;
- changes in applicable governmental regulatory policies; and
- any new collaborative, licensing and other commercial relationships that we may establish.

We expect to incur substantial additional costs for research, pre-clinical and clinical testing, manufacturing process development, additional capital expenditures related to personnel and facilities expansion, clinical and commercial manufacturing requirements, secure commercial contract manufacturing capacity, and marketing and sales in order to commercialize our products currently under development. Furthermore, we will owe royalties to parties we have licensed intellectual property from, or may in the future license intellectual property from, in connection with the development, manufacture or sale of our products.

In addition to milestone payments we may receive from our collaboration with P&G and our interest and investment income that are subject to market interest rate fluctuations, we will need to raise or generate substantial additional funding in order to complete the development and commercialization of all of our product candidates. Furthermore, the development or expansion of our business or any acquired business or companies may require a substantial capital investment by us. Our additional financing may include 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. There can be no assurance that funds will be available on terms acceptable to us, if at all, or that discussions with potential strategic or collaborative partners will result in any agreements on a timely basis, if at all. The unavailability of additional financing when and if required could require us to delay, scale back or eliminate certain research and product development programs or to license third parties to commercialize products or technologies that we would otherwise undertake ourselves, any of which could have a material adverse effect.

For tax reporting purposes, as of July 31, 2002, we had approximately \$162.6 million of federal net operating loss carryforwards, which expire through 2022 (of which approximately \$ 18.0 million resulted from the exercise of nonqualified stock options) and \$9.6 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 June 2002, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 146, “Accounting for Costs Associated with Exit or Disposal Activities” (“SFAS 146”). This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, “Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring).” The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. We believe the adoption of this new standard will not have a material impact on either the operating results or financial position of the Company.

In April 2002, the FASB issued SFAS No. 145, “Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections”. This Statement rescinds SFAS No. 4, “Reporting Gains and Losses from Extinguishment of Debt”, SFAS No. 44, “Accounting for Intangible Assets of Motor Carriers” and SFAS No. 64, “Extinguishments of Debt Made to Satisfy Sinking-Fund Requirements”. This statement also amends SFAS No. 13, “Accounting for Leases” and makes various technical corrections to existing pronouncements. Those corrections are not substantive in nature. The provisions of SFAS No. 145 were effective as of May 15, 2002. The adoption of the new standard had no impact on the operating results or the financial position of the Company.

In August 2001, the FASB issued SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets.” SFAS No. 144 modifies the rules for accounting for the impairment or disposal of long-lived assets and supercedes SFAS No. 121. The new rules become effective for fiscal years beginning after December 15, 2001, with earlier application encouraged. The adoption of this standard on August 1, 2002 did not have a material impact on the operating results or financial position of the Company.

In August 2001, the FASB issued SFAS No. 143, “Accounting for Obligations Associated with the Retirement of Long-Lived Assets”. The objective of SFAS No. 143 is to provide accounting guidance for legal obligations associated with the retirement of long-lived assets. The retirement obligations included within the scope of this pronouncement are those that an entity cannot avoid as a result of either the acquisition, construction or normal operation of a long-lived asset. Components of larger systems also fall under this pronouncement, as well as tangible long-lived assets with indeterminable lives. The provisions of SFAS No. 143 are effective for financial statements issued for fiscal years beginning after June 15, 2002. The adoption of this standard on August 1, 2002 did not have a material impact on the operating results or the financial position of the Company.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

We account for our marketable securities in accordance with Statement of Financial Accounting Standards No. 115, “Accounting for Certain Investments in Debt and Equity Securities” (“SFAS 115”). All of the cash equivalents and marketable securities are treated as available-for-sale under SFAS 115.

Investments in fixed rate interest earning instruments carry a degree of interest rate risk. Fixed rate securities may have their fair market value adversely impacted due to a rise in interest rates. Due in part to these factors, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have seen a decline in market value due to changes in

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interest rates. Our marketable securities are held for purposes other than trading and we believe that we currently have no material adverse market risk exposure. The marketable securities as of July 31, 2002, had maturities of less than two years. The weighted-average interest rate on marketable securities at July 31, 2002 and 2001 was 2.4% and 4.2%, respectively. The fair value of marketable securities held at July 31, 2002 was \$261.0 million.

At July 31, 2002, we had aggregate fixed rate debt of approximately \$124 million. If interest rates associated with this debt were increased 10%, a corresponding increase in our annual interest expense of approximately \$700,000 would occur.

### **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 14(a)(1).

### **Item 9. *Changes In and Disagreements with Accountants on Accounting and Financial Disclosure.***

The Board of Directors, based upon a recommendation of its Audit Committee, dismissed Arthur Andersen LLP (“Arthur Andersen” or “AA”) as the Company’s independent public accountants on May 31, 2002. We engaged PricewaterhouseCoopers LLP as our independent auditors to audit our consolidated financial statements for the year ended July 31, 2002. PricewaterhouseCoopers commenced its engagement on May 31, 2002 with the review of the Company’s financial statements for the fiscal third quarter ended April 30, 2002.

Arthur Andersen’s reports on our consolidated financial statements for each of the years ended July 31, 2001 and 2000 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles.

During the years ended July 31, 2001 and 2000 and through May 31, 2002, there were no disagreements between us and Arthur Andersen on any matter of accounting principle or practice, financial statement disclosure, or auditing scope or procedure which, if not resolved to Arthur Andersen’s satisfaction, would have caused it to make reference to the subject matter in connection with its report on our consolidated financial statements for such years; and there were no reportable events as defined in Item 304(a)(1)(v) of Regulation S-K. Arthur Andersen submitted a letter, dated May 31, 2002, stating its agreement with our statements filed on Form 8-K dated May 31, 2002 related to our change in public accountants.

During the two most recent fiscal years ended July 31, 2001 and 2000 and through May 31, 2002, we have not consulted with PricewaterhouseCoopers LLP regarding either (i) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on our consolidated financial statements, and neither a written report was provided to us or oral advice was provided that PricewaterhouseCoopers LLP concluded was an important factor considered by us in reaching a decision as to the accounting, auditing, or financial reporting issue; or (ii) any matter that was either the subject of a disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K, or a reportable event, as that term is defined in Item 304(a)(1)(v) of Regulation S-K.

**PART III****Item 10. Directors, Executive Officers and Key Employees.**

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

<u>Name</u>	<u>Age</u>	<u>Position with Alexion</u>
John Fried, Ph.D. <sup>(1)(2)(3)</sup>	72	Chairman of the Board of Directors
Leonard Bell, M.D. <sup>(4)</sup>	44	Chief Executive Officer, Secretary, Treasurer, Director
David W. Keiser <sup>(4)</sup>	51	President and Chief Operating Officer, Director
Stephen P. Squinto, Ph.D. <sup>(4)</sup>	46	Executive Vice President and Head of Research
Katherine S. Bowdish, Ph.D. <sup>(4)</sup>	45	Senior Vice President, Antibody Discovery, and President, Alexion Antibody Technologies
Scott A. Rollins, Ph.D. <sup>(4)</sup>	39	Senior Vice President, Drug Development and Project Management
Samuel S. Chu, Ph.D.	52	Vice President, Manufacturing and Process Sciences
Thomas I.H. Dubin, J.D. <sup>(4)</sup>	40	Vice President and General Counsel
Paul W. Finnegan, M.D., M.B.A.	42	Vice President, Commercial Operations and Development
Barry P. Luke <sup>(4)</sup>	44	Vice President, Finance and Administration, Assistant Secretary
Christopher F. Mojcik, M.D., Ph.D. <sup>(4)</sup>	42	Vice President, Clinical Development
Nancy Motola, Ph.D. <sup>(4)</sup>	49	Vice President, Regulatory and Quality
Russell P. Rother, Ph.D.	41	Vice President, Discovery Research
Daniel N. Caron	39	Senior Director, Operations and Engineering
Jerry T. Jackson <sup>(2)</sup>	61	Director
Max Link, Ph.D. <sup>(1)(2)(3)</sup>	62	Director
Joseph A. Madri, Ph.D., M.D.	56	Director
R. Douglas Norby <sup>(1)</sup>	67	Director
Alvin S. Parven <sup>(2)</sup>	62	Director

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

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

(3) Member of our Nominating 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. Drs. Bell and Bowdish are each a party to an employment agreement with us.

**John H. Fried, Ph.D.** has been the Chairman of our board of directors since April 1992. Since 1992, Dr. Fried has been President of Fried & Co., Inc., a health technology venture firm. Dr. Fried was a director of Syntex Corp., a life sciences and health care company, from 1982 to 1994 and he served as Vice Chairman of Syntex from 1985 to January 1993 and President of the Syntex Research Division from 1976 to 1992. Dr. Fried has originated more than 200 U.S. Patents and has authored more than 80 scientific publications. Dr. Fried received his B.S. in Chemistry and Ph.D. in Organic Chemistry from Cornell University.

Biographical details of the following persons are incorporated by reference herein to the section of this Report in Part I, Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS, entitled

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“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., Scott A. Rollins, Ph.D., Samuel S. Chu, Ph.D., Thomas I.H. Dubin, J.D. Paul W Finnegan, M.D., M.B.A., Barry P. Luke, Christopher F. Mojcik, M.D., Ph.D., Nancy Motola, Ph.D., Russell P. Rother, Ph.D., and Daniel N. Caron.

**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 Global Edge, Inc., IntraBiotics Pharmaceuticals, Inc., and Myogen, Inc. He received his B.A. from University of New Mexico.

**Max Link, Ph.D.** has been a director of Alexion since April 1992. In July 2002, Dr. Link became Chief Executive Officer 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 also a director of Access Pharmaceuticals, Inc., Discovery Labs, Inc., Protein Design Labs, Inc., Human Genome Sciences, Inc., CytRx Corporation, and Cell Therapeutics, Inc., each a publicly held pharmaceutical company, as well as Celsion Corporation and Sulzer Medica, Ltd. Dr. Link holds a Ph.D. in economics from University of St. Gallen (Switzerland).

**Joseph A. Madri, Ph.D., M.D.** is a founder of Alexion and has been a director of Alexion since February 1992. Since 1980, Dr. Madri has been on the faculty of the Yale University School of Medicine and is currently a Professor of Pathology. Dr. Madri serves on the editorial boards of numerous scientific journals and he is the author of over 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.

**R. Douglas Norby** has been a director of Alexion since September 1999. Since March 2002, Mr. Norby has been Chief Financial Officer of Zambeel, Inc., a data storage company. From January 2001 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. From September 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 Pharmedix 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

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Vice President and Chief Financial Officer of Syntex Corporation, a pharmaceutical 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 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 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 by reference to our Proxy Statement.

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**Item 12. Security Ownership of Certain Beneficial Owners and Management.**

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of October 1, 2002, 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 Alexion as a group.

Name and Address of Beneficial Owner (1)	Number of Shares Beneficially Owned (2)	Percentage of Outstanding Shares of Common Stock
OppenheimerFunds, Inc. 498 Seventh Avenue New York, NY 10018 <sup>(3)</sup>	2,000,000	11.0%
Fidelity Management & Research Company 82 Devonshire Street Boston, MA 02109 <sup>(4)</sup>	1,809,740	9.9%
OrbiMed Advisors, LLC 41 Madison Avenue, 40th Floor New York, NY 10010 <sup>(5)</sup>	1,000,000	5.2%
Leonard Bell, M.D. <sup>(6)</sup>	821,836	4.4%
David W. Keiser <sup>(7)</sup>	256,358	1.4%
Stephen P. Squinto, Ph.D. <sup>(8)</sup>	250,778	1.4%
John H. Fried, Ph.D. <sup>(9)</sup>	113,836	*
Joseph Madri, Ph.D., M.D. <sup>(10)</sup>	71,300	*
Christopher F. Mojcik, M.D., Ph.D. <sup>(11)</sup>	52,389	*
Max Link, Ph.D. <sup>(12)</sup>	39,323	*
Thomas I.H. Dubin, J.D. <sup>(13)</sup>	26,874	*
Jerry T. Jackson <sup>(14)</sup>	18,000	*
R. Douglas Norby <sup>(15)</sup>	18,000	*
Alvin S. Parven <sup>(16)</sup>	16,900	*
All directors and executive officers as a group (15 persons) <sup>(17)</sup>	1,979,926	10.1%

\* 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) This figure is based upon information set forth in Schedule 13F dated June 30, 2002.

(4) This figure is based upon information set forth in Schedule 13F dated June 30, 2002.

(5) This figure is based upon information set forth in Schedule 13F dated June 30, 2002.

(6) Includes 602,391 shares of common stock that may be acquired upon the exercise of options within 60 days of October 1, 2002 and 300 shares, in aggregate, held in the names of Dr. Bell's three children.

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Excludes 97,464 shares obtainable through the exercise of options, granted to Dr. Bell, which are not exercisable within 60 days of October 1, 2002 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.

- (7) Includes 214,058 shares of common stock which may be acquired upon the exercise of options within 60 days of October 1, 2002 and 300 shares, in aggregate, held in the names of Mr. Keiser's three children. Excludes 44,942 shares obtainable through the exercise of options, granted to Mr. Keiser, which are not exercisable within 60 days of October 1, 2002. Mr. Keiser disclaims beneficial ownership of the shares held in the names of his minor children.
- (8) Includes 200,078 shares of common stock which may be acquired upon the exercise of options within 60 days of October 1, 2002; 6,106 shares held in trust for the benefit of Dr. Squinto's three minor children of which Dr. Squinto's spouse is the trustee; and 9,012 shares held in a charitable remainder trust of which Dr. Squinto and his spouse are the trustees and income beneficiaries. Excludes 36,422 shares obtainable through the exercise of options, granted to Dr. Squinto, which are not exercisable within 60 days of October 1, 2002. Dr. Squinto disclaims beneficial ownership of the shares held in the names of his minor children and the foregoing trusts.
- (9) Includes 11,167 shares of common stock, which may be acquired upon the exercise of options that are exercisable within 60 days of October 1, 2002. Excludes 16,500 obtainable through the exercise of options granted to Dr. Fried, which are not exercisable within 60 days of October 1, 2002.
- (10) Includes 21,300 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of October 1, 2002. Excludes 16,500 obtainable through the exercise of options granted to Dr. Madri, which are not exercisable within 60 days of October 1, 2002.
- (11) Includes 52,389 shares of common stock, which may be acquired upon the exercise of options within 60 days of October 1, 2002. Excludes 30,611 shares obtainable through the exercise of options granted to Dr. Mojcik, which are not exercisable within 60 days of October 1, 2002.
- (12) Includes 11,167 shares of common stock which may be acquired upon the exercise of options within 60 days of October 1, 2002. Excludes 16,500 shares obtainable through the exercise of options granted to Dr. Link, which are not exercisable within 60 days of October 1, 2002.
- (13) Includes 26,874 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of October 1, 2002. Excludes 44,126 shares obtainable through the exercise of options granted to Mr. Dubin, which are not exercisable within 60 days of October 1, 2002.
- (14) Includes 18,000 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of October 1, 2002. Excludes 16,500 shares obtainable through the exercise of options granted to Mr. Jackson, which are not exercisable within 60 days of October 1, 2002.
- (15) Includes 18,000 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of October 1, 2002. Excludes 16,500 shares obtainable through the exercise of options granted to Mr. Norby, which are not exercisable within 60 days of October 1, 2002.
- (16) Includes 16,900 shares of common stock which may be acquired on the exercise of options that are exercisable within 60 days of October 1, 2001. Excludes 16,500 shares obtainable through the exercise of options granted to Mr. Parven, which are not exercisable within 60 days of October 1, 2002.
- (17) Consists of shares beneficially owned by Drs. Bell, Fried, Link, Madri, Mojcik, and Squinto and Messrs. Dubin, Jackson, Keiser, Norby and Parven, and certain other officers. Includes 1,422,860 shares of common stock, which may be acquired upon the exercise of options within 60 days of October 1, 2002.

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### 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, 2002.

<u>Plan Category</u>	<u>Number of shares of common stock to be issued upon exercise of outstanding options</u>	<u>Weighted-average exercise price of outstanding options</u>	<u>Number of shares of common stock remaining available for future issuance under equity compensation plans</u>
Equity compensation plans approved by stockholders <sup>(1)</sup>	3,519,020	\$ 25.08	310,324
Equity compensation plans not approved by stockholders <sup>(2)</sup>	—	—	—

- (1) Reflects aggregate options outstanding and available for issuance, if applicable, under our 1992 Stock Option Plan, 1992 Stock Option Plan for Outside Directors, and 2000 Stock Option Plan.
- (2) Does not include 38,585 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 average exercise price of \$45.24 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. 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. *Exhibits, Financial Statement Schedules, and Reports on Form 8-K.*

#### (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.

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### (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.\*(2)
- 3.2 Bylaws.\*(2)
- 4.1 Specimen Common Stock Certificate.\*(2)
- 10.1 Employment Agreement, dated April 1, 2000, between the Company and Dr. Leonard Bell.\*(3)
- 10.2 Employment Agreement, dated September 21, 2000, between the Company and Dr. Katherine S. Bowdish.\*(1)
- 10.3 Administrative, Research and Development Facility Lease, dated May 9, 2000, between the Company and WE Knotter L.L.C.\*(6)
- 10.4 Company's 1992 Stock Option Plan, as amended.\*(7)
- 10.5 Company's 2000 Stock Option Plan.\*(8)
- 10.6 Company's 1992 Outside Directors Stock Option Plan, as amended.\*(9)
- 10.7 Exclusive License Agreement dated as of June 19, 1992 among the Company, Yale University and Oklahoma Medical Research Foundation.\*(3)
- 10.8 License Agreement dated as of September 30, 1992 between the Company and Yale University, as amended July 2, 1993.\*(2)†
- 10.9 License Agreement dated as of August 1, 1993 between the Company and Biotechnology Research and Development Corporation ("BRDC"), as amended as of July 1, 1995.\*(2)†
- 10.10 License Agreement dated January 25, 1994 between the Company and The Austin Research Institute.\*(2)†
- 10.11 Exclusive Patent License Agreement dated April 21, 1994 between the Company and the National Institutes of Health.\*(2)†
- 10.12 License Agreement dated July 22, 1994 between the Company and The Austin Research Institute.\*(2)†
- 10.13 License Agreement dated as of January 10, 1995 between the Company and Yale University.\*(2)†
- 10.17 License Agreement dated as of May 27, 1992 between the Company and Yale University, as amended September 23, 1992.\*(2)†
- 10.18 Agreement to be Bound by Master Agreement dated as of August 1, 1993 between the Company and BRDC.\*(2)
- 10.19 License Agreement dated March 27, 1996 between the Company and Medical Research Council.\*(10)†
- 10.20 License Agreement dated May 8, 1996 between the Company and Enzon, Inc.\*(10)†
- 10.21 Asset Purchase Agreement date as of February 9, 1999 between the Company and United States Surgical Corporation.\*(11)
- 10.22 Collaboration Agreement dated January 25, 1999 between the Company and the Procter & Gamble Company, as amended.\*(11)†

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10.23	Letter agreement dated September 14, 1999 between the Company and Leonard Bell.*(11)
10.24	Binding Memorandum of Understanding dated December 11, 2001 between the Company and the Procter & Gamble Company.††
10.25	Research and Development Facility lease, dated February 1, 2002, between the Company and PMSI SRF L.L.C.*(12)
21.1	Subsidiaries of Alexion Pharmaceuticals, Inc.
23.1	Consent of PricewaterhouseCoopers LLP.
99.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.2	Risk Factors.
99.3	Copy of a report previously issued by Arthur Andersen LLP and has not been reissued by Arthur Andersen LLP.

\* Previously filed

- (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 Quarterly Report on Form 10-Q for the quarter ended April 30, 2000.
  - (4) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended July 31, 2000.
  - (5) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended July 31, 1997.
  - (6) Incorporated by reference to our Registration Statement on Form S-3 (Reg. No. 333-36738) filed on May 10, 2000.
  - (7) Incorporated by reference to our Registration Statement on Form S-8 (Reg. No. 333-71879) filed on February 5, 1999.
  - (8) Incorporated by reference to our Registration Statement on Form S-8 (Reg. No. 333-69478) filed on September 14, 2001.
  - (9) Incorporated by reference to our Registration Statement on Form S-8 (Reg. No. 333-71985) filed on February 8, 1999.
  - (10) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended July 31, 1996.
  - (11) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended July 31, 1999.
  - (12) Incorporated by reference to our Quarterly report Form 10-Q for the quarter ended January 31, 2002.
- † Confidential treatment was granted for portions of such document.
- †† A request for confidential treatment was filed for certain portions of the indicated document. Confidential portions have been omitted and filed separately with the Commission as required by Rule 24b-2.

(b) Reports on Form 8-K

Current report on Form 8-K filed on June 3, 2002 on the adopting of policy allowing directors and officers of the Company to effect sales of the Company's securities under the Securities and Exchange Commission Rule 10b5-1.

Current report on the form 8-K/A filed on June 21, 2002 to replace Arthur Andersen, LLP as the Company's independent public accountants with PricewaterhouseCoopers, LLP effective May 31, 2002

(c) Exhibits

See (a) (3) above.

(d) Financial Statement Schedules

See (a) (2) above.



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<u>Signature</u>	<u>Title</u>	<u>Date</u>
<hr/> <p>/s/ R. DOUGLAS NORBY</p> <hr/> <p><b>R. Douglas Norby</b></p>	Director	October 24, 2002
<hr/> <p>/s/ ALVIN S. PARVEN</p> <hr/> <p><b>Alvin S. Parven</b></p>	Director	October 24, 2002

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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 annual 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 annual report; and
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual report.

Date: October 24, 2002

/s/ LEONARD BELL

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**Leonard Bell, M.D.**  
**Chief Executive Officer**

I, David W. Keiser, certify that:

1. I have reviewed this annual report on Form 10-K of Alexion Pharmaceuticals, Inc.;
2. Based on my knowledge, this annual 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 annual report; and
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual report.

Date: October 24, 2002

/s/ DAVID W. KEISER

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**David W. Keiser**  
**President and Chief Operating Officer**  
**(Principal Financial Officer)**

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ALEXION PHARMACEUTICALS, INC.

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## Report of Independent Accountants

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

In our opinion, the accompanying consolidated balance sheet as of July 31, 2002 and the related consolidated statements of operations, of stockholders' equity and comprehensive loss and of cash flows present fairly, in all material respects, the financial position of Alexion Pharmaceuticals, Inc. and its subsidiaries at July 31, 2002, and the results of their operations and their cash flows for the year then ended 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 the financial statements based on our audit. We conducted our audit of these statements in accordance with auditing standards generally accepted in the United States of America, which 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 audit provides a reasonable basis for our opinion. The financial statements of the Company as of July 31, 2001, and for each of the two years in the period ended July 31, 2001, were audited by other independent accountants who have ceased operations. Those independent accountants expressed an unqualified opinion on those financial statements before the revisions described in Note 2 in their report dated August 31, 2001.

As discussed above, the financial statements of Alexion Pharmaceuticals, Inc. as of July 31, 2001, and for each of the two years in the period ended July 31, 2001, were audited by other independent accountants who have ceased operations. As described in Note 2, these financial statements have been revised to include the transitional disclosures required by Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets", which was adopted by the Company as of August 1, 2001. We audited the transitional disclosures described in Note 2. In our opinion, the transitional disclosures for 2001 and 2000 in Note 2 are appropriate. However, we were not engaged to audit, review, or apply any procedures to the 2001 or 2000 financial statements of the Company other than with respect to such disclosures and, accordingly, we do not express an opinion or any other form of assurance on the 2001 or 2000 financial statements taken as a whole.

As discussed in Note 4 to the consolidated financial statements, the Company changed its method of revenue recognition relating to non-refundable upfront licensing fees in accordance with Staff Accounting Bulletin No. 101 in fiscal 2001.

/s/ PRICEWATERHOUSECOOPERS LLP

Hartford, Connecticut  
October 18, 2002

ALEXION PHARMACEUTICALS, INC.

Consolidated Balance Sheets  
(in thousands)

	July 31,	
	2002	2001
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 47,574	\$ 135,188
Marketable securities	261,010	220,086
Reimbursable contract costs		
Billed	863	2,974
Unbilled	—	4,006
Prepaid expenses and other current assets	1,337	493
	<hr/>	<hr/>
Total current assets	310,784	362,747
PROPERTY, PLANT AND EQUIPMENT, net	14,874	13,731
GOODWILL	19,954	20,270
DEFERRED FINANCING COSTS, net of accumulated amortization of \$1,324 and \$751 at July 31, 2002 and 2001, respectively	2,692	3,265
OTHER ASSETS	5,765	246
	<hr/>	<hr/>
Total assets	\$ 354,069	\$ 400,259
	<hr/>	<hr/>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 9,843	\$ 1,722
Accrued expenses	4,303	2,271
Accrued interest	2,627	2,646
Deferred revenue	546	1,351
	<hr/>	<hr/>
Total current liabilities	17,319	7,990
DEFERRED REVENUE, less current portion included above	7,352	7,941
NOTE PAYABLE	3,920	3,920
CONVERTIBLE SUBORDINATED NOTES	120,000	120,000
COMMITMENTS AND CONTINGENCIES (Notes 9, 11, and 14)		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, \$.0001 par value; 5,000 shares authorized; no shares issued or outstanding	—	—
Common stock, \$.0001 par value; 145,000 shares authorized; 18,241 and 18,119 shares issued at July 31, 2002 and 2001, respectively	2	2
Additional paid-in capital	385,197	384,091
Accumulated deficit	(180,799)	(124,257)
Other comprehensive income	1,678	572
Treasury stock, at cost, 37 and 12 shares at July 31, 2002 and 2001, respectively	(600)	—
	<hr/>	<hr/>
Total stockholders' equity	205,478	260,408
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 354,069	\$ 400,259
	<hr/>	<hr/>

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

**ALEXION PHARMACEUTICALS, INC.**

**Consolidated Statements Of Operations**  
**(in thousands, except per share amounts)**

	For the Years Ended July 31,		
	2002	2001	2000
CONTRACT RESEARCH REVENUES	\$ 6,536	\$ 11,805	\$ 21,441
<b>OPERATING EXPENSES</b>			
Research and development	60,005	38,871	40,187
General and administrative	7,993	7,135	4,175
In-process research and development (Note 3)	—	21,000	—
Amortization of goodwill (Goodwill, Note 2)	—	2,901	—
Total operating expenses	67,998	69,907	44,362
Operating loss	(61,462)	(58,102)	(22,921)
<b>OTHER INCOME AND EXPENSE</b>			
Investment income	11,920	17,975	5,833
Interest expense	(7,700)	(7,798)	(3,139)
Loss before state tax benefit and cumulative effect of adoption of Staff Accounting Bulletin No. 101 (SAB 101)	(57,242)	(47,925)	(20,227)
STATE TAX BENEFIT	700	—	—
Loss before cumulative effect of adoption of SAB 101	(56,542)	(47,925)	(20,227)
CUMULATIVE EFFECT OF ADOPTION OF SAB 101 (Note 4)	—	(9,118)	—
Net loss	\$ (56,542)	\$ (57,043)	\$ (20,227)
<b>BASIC AND DILUTED PER SHARE DATA</b>			
Loss before cumulative effect of adoption of SAB 101	\$ (3.12)	\$ (2.76)	\$ (1.45)
Cumulative effect of adoption of SAB 101	—	(0.52)	—
Net loss	\$ (3.12)	\$ (3.28)	\$ (1.45)
<b>PRO FORMA AMOUNTS ASSUMING ADOPTION OF SAB 101 APPLIED RETROACTIVELY</b>			
Pro forma operating loss	\$ (61,462)	\$ (58,102)	\$ (22,333)
Pro forma net loss	\$ (56,542)	\$ (47,925)	\$ (19,639)
Pro forma basic and diluted net loss per common share	\$ (3.12)	\$ (2.76)	\$ (1.41)
<b>SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS PER COMMON SHARE AND PRO FORMA NET LOSS PER COMMON SHARE</b>			
	18,146	17,371	13,914

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

ALEXION PHARMACEUTICALS, INC.

Consolidated Statements of Stockholders' Equity and Comprehensive Loss  
(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, 1999	11,304	\$ 1	\$ 80,291	\$ (46,987)	\$ (4)	12	\$ —	\$ 33,301	
Issuance of common stock from exercise of options	225	—	1,697	—	—	—	—	1,697	
Noncash compensation expense related to grant of stock options	—	—	430	—	—	—	—	430	
Issuance of common stock from exercise of warrants	202	—	1,998	—	—	—	—	1,998	
Issuance of common stock, net of issuance costs of \$3.391	3,415	1	44,420	—	—	—	—	44,421	
Net change in unrealized losses on marketable securities	—	—	—	—	(16)	—	—	(16)	\$ (16)
Net loss	—	—	—	(20,227)	—	—	—	(20,227)	(20,227)
Comprehensive loss	—	—	—	—	—	—	—	—	\$ (20,243)
BALANCE, July 31, 2000	15,146	\$ 2	\$ 128,836	\$ (67,214)	\$ (20)	12	\$ —	\$ 61,604	
Issuance of common stock from exercise of options	299	—	2,199	—	—	—	—	2,199	
Noncash compensation expense related to grant of stock options	—	—	408	—	—	—	—	408	
Issuance of common stock from exercise of warrants	18	—	179	—	—	—	—	179	
Issuance of common stock, net of issuance costs of \$201	2,300	—	208,524	—	—	—	—	208,524	
Issuance of common stock and stock options to acquire all outstanding equity of Prolifaron	356	—	43,945	—	—	—	—	43,945	
Net change in unrealized gains (losses) on marketable securities	—	—	—	—	592	—	—	592	\$ 592
Net loss	—	—	—	(57,043)	—	—	—	(57,043)	(57,043)
Comprehensive loss	—	—	—	—	—	—	—	—	\$ (56,451)
BALANCE, July 31, 2001	18,119	\$ 2	\$ 384,091	\$ (124,257)	\$ 572	12	\$ —	\$ 260,408	

ALEXION PHARMACEUTICALS, INC.

Consolidated Statements of Stockholders' Equity and Comprehensive Loss (Continued)  
(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 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	

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

**ALEXION PHARMACEUTICALS, INC.**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	For the Years Ended July 31,		
	2002	2001	2000
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net loss	\$ (56,542)	\$ (57,043)	\$ (20,227)
Adjustments to reconcile net loss to net cash used in operating activities			
In-process research and development	—	21,000	—
Cumulative effect of adopting SAB 101	—	9,118	—
Amortization of goodwill	—	2,901	—
Depreciation and amortization	3,562	2,620	1,769
Gain on sale of marketable securities	(1,891)	—	—
Compensation expense related to grant of stock options	180	408	430
Changes in assets and liabilities			
Reimbursable contract costs	6,117	(1,842)	1,767
Prepaid expenses	(844)	270	16
Other assets	(5,519)	—	—
Accounts payable	8,121	(789)	(1,444)
Accrued expenses	2,008	845	(1,026)
Accrued interest	(19)	(84)	2,657
Deferred revenue	(1,394)	(576)	300
Net cash used in operating activities	(46,221)	(23,172)	(15,758)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchases of marketable securities	(533,117)	(561,940)	(93,065)
Proceeds from maturity or sale of marketable securities	495,190	425,117	14,468
Purchases of property, plant and equipment	(4,096)	(7,021)	(2,229)
Investments in patents and licensed technology	(36)	(65)	(40)
Net cash received (paid) in acquisition of Prolifaron	340	(464)	—
Net cash used in investing activities	(41,719)	(144,373)	(80,866)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Net proceeds from issuance of common stock	326	210,902	48,116
Net proceeds from issuance of convertible subordinated notes	—	—	116,063
Repayments of notes payable	—	(369)	(462)
Other	—	342	527
Net cash provided by financing activities	326	210,875	164,244
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	(87,614)	43,330	67,620
CASH AND CASH EQUIVALENTS, beginning of year	135,188	91,858	24,238
CASH AND CASH EQUIVALENTS, end of year	\$ 47,574	\$ 135,188	\$ 91,858
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION</b>			
Cash paid for interest expense	\$ 7,077	\$ 7,316	\$ 296
<b>SUPPLEMENTAL DISCLOSURE OF NONCASH FINANCING ACTIVITIES</b>			
Exercise of stock options through tendering of mature common stock	\$ 600	\$ —	\$ —
Acquisition of Prolifaron through issuance of common stock and stock options	\$ —	\$ 43,945	\$ —

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

**ALEXION PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Operations**

Alexion Pharmaceuticals, Inc. (“Alexion” or the “Company”) was organized in 1992 and is engaged in the development of therapeutic products for the treatment of a wide array of severe diseases, including cardiovascular and autoimmune disorders and cancer. The Company’s two lead product candidates are antibodies that address specific diseases that arise when the human immune system attacks the human body itself and produces undesired inflammation.

The Company has incurred consolidated losses since inception and has made no product sales to date. The Company will continue to seek financing to obtain regulatory approvals for its product candidates, fund operations losses, and if deemed appropriate, establish manufacturing, sales, marketing and distribution capabilities. The Company expects to incur substantial expenditures in the foreseeable future for the research and development and commercialization of its products. The Company 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.

**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 (“Columbus”). Results of operations of AAT are included in the Company’s consolidated statements of operations since September 23, 2000, the effective date of the Prolifaron acquisition (see Note 3). Columbus was formed on February 9, 1999 to acquire certain manufacturing assets from Tyco Healthcare. All significant inter-company balances and transactions have been eliminated in consolidation.

**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**

The Company invests in marketable debt securities of highly rated financial institutions and investment-grade debt instruments and limits the amount of credit exposure with any one entity.

The Company has classified its marketable securities as “available for sale” and, accordingly, carries such securities at aggregate fair value. Unrealized gains or losses are included in other comprehensive income (loss) as a component of stockholders’ equity. During the year ended July 31, 2002, the Company realized a gain on sales of marketable securities of approximately \$1.9 million. No significant realized gains or losses were recorded during the years ended July 31, 2001 and 2000. The Company utilizes the specific identification method in computing realized gains and losses. At July 31, 2002, the Company’s marketable securities had a maximum

## ALEXION PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

maturity of less than two years with an average of approximately twelve months. The weighted average interest rate associated with these marketable debt securities was 2.4% and 4.2% as of July 31, 2002 and 2001, respectively.

The following is a summary of marketable securities at July 31, 2002 and 2001 (amounts in thousands):

	Amortized Cost	Unrealized Gains	Fair Value
Federal agency obligations	\$ 159,827	\$ 1,228	\$ 161,055
Corporate bonds	81,496	405	81,901
Certificates of deposit	17,950	12	17,962
Other	59	33	92
<b>Total marketable securities at July 31, 2002</b>	<b>\$ 259,332</b>	<b>\$ 1,678</b>	<b>\$ 261,010</b>
Federal agency obligations	123,022	387	123,409
Corporate bonds	96,492	185	96,677
<b>Total marketable securities at July 31, 2001</b>	<b>\$ 219,514</b>	<b>\$ 572</b>	<b>\$ 220,086</b>

**Goodwill**

In July 2001, the FASB issued SFAS No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets", which together significantly change the accounting and disclosures required for these activities and related assets. The primary changes resulting from these standards consist of the cessation of the "pooling of interests" method of accounting and how goodwill and intangible assets will be segregated, amortized (or not amortized), reviewed for impairment (if any), and disclosed within the footnotes to financial statements.

The Company adopted SFAS No. 142 effective August 1, 2001. The adoption of SFAS No. 142 caused the amortization as it relates to the \$22.9 million of goodwill acquired in connection with the acquisition of Prolifaron (see Note 3) to cease effective August 1, 2001. Prior to the adoption of this standard, this annual amortization was expected to be approximately \$3.3 million annually over a seven-year period. On a prospective basis, this goodwill is subject to annual impairment reviews, and, if conditions warrant, interim reviews based upon its estimated fair value. 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. Changes in goodwill during fiscal 2002 resulted primarily from adjustments related to tax benefits generated by Prolifaron prior to the acquisition.

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

A reconciliation of reported net loss to adjusted net loss before amortization of goodwill is as follows (dollars in thousands, except per share amounts):

	Year Ended July 31,		
	2002	2001	2000
Reported net loss	\$ (56,542)	\$ (57,043)(a)	\$ (20,227)
Amortization of goodwill	—	2,901	—
Adjusted net loss	\$ (56,542)	\$ (54,142)(a)	\$ (20,227)
Basic and diluted loss per share:			
Reported net loss	\$ (3.12)	\$ (3.28)(b)	\$ (1.45)
Amortization of goodwill	—	.16	—
Adjusted net loss	\$ (3.12)	\$ (3.12)(b)	\$ (1.45)

(a) Includes the noncash charge for IPRD of \$21,000 and Cumulative Effect of Adoption of SAB 101 of \$9,118.

(b) Includes the noncash charges for IPRD of \$1.21 and Cumulative Effect of Adoption of SAB 101 of \$0.52.

**Long-Lived Assets**

The Company accounts for its investments in long-lived assets in accordance with Statement of Financial Accounting Standard (SFAS) No. 121, "Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to be Disposed of". SFAS No. 121 requires a company to review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company has reviewed its long-lived assets and has determined that no impairments exist.

**Revenue Recognition**

Contract research revenues recorded by the Company consist of research and development support payments and license fees under collaborations with third parties and amounts received under various government grants.

As a result of the Company's adoption of SAB 101 (see Note 4), up-front, non-refundable license fees received in connection with a collaboration are deferred and amortized into revenue based upon the terms of each collaborative arrangement.

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.

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Unbilled reimbursable contract costs as shown on the accompanying consolidated balance sheets represent reimbursable costs incurred in connection with research contracts which have not yet been billed. The Company bills these costs and recognizes the costs and related revenues in accordance with the terms of the contracts.

Deferred revenue results from cash received or amounts receivable in advance of revenue recognition under research and development contracts (see Notes 4 and 10).

**Research and Development Expenses**

Research and development expenses are expensed when 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, depreciation and amortization of lab facilities and leasehold improvements, building and utilities costs related to research space and lab supplies.

**Comprehensive Income (Loss)**

The Company reports and presents comprehensive income (loss) in accordance with SFAS No. 130 "Reporting Comprehensive Income," which establishes standards for reporting and display of comprehensive income (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 (loss)). The Company's other comprehensive income (loss) arises from net unrealized gains (losses) on marketable securities. The Company has elected to display comprehensive income (loss) as a component of the statements of stockholders' equity and comprehensive loss.

**Stock Options**

The Company accounts for stock options granted to employees in accordance with Accounting Principles Board Opinion No. 25. The Company accounts 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". The Company recognizes compensation cost associated with stock option grants, if any, over the applicable vesting term.

**Net Loss Per Common Share**

The Company computes and presents 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 shares equivalents outstanding during the period. Common share equivalents represent dilutive stock options, and convertible subordinated debt. These outstanding stock options, warrants and convertible subordinated debt entitled holders to acquire 4,685,160, 4,689,075 and 3,829,887 shares of common stock at July 31, 2002, 2001 and 2000, 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.

**ALEXION PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The pro forma net loss per share as reported in the accompanying statements of operations for the years ended July 31, 2002, 2001 and 2000, assumes the retroactive adoption of SAB 101 (see Note 4).

**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. The Company has determined that it operates in only one segment. In addition, all revenues are generated from United States ("U.S.") entities, and all long-lived assets are maintained in the U.S.

**Fair Value of Financial Instruments**

Financial instruments include cash and cash equivalents, marketable securities, reimbursable contract costs, accounts payable, notes payable and convertible subordinated notes. Cash and cash equivalents and marketable securities are carried at fair value. Reimbursable contract costs, accounts payable, notes payable and convertible subordinated notes are carried at cost. Management believes reimbursable contract costs, accounts payable and notes payable approximate fair value. The carrying value of convertible subordinated notes exceeded fair value by approximately \$47.7 million based upon trading values reported at July 31, 2002.

**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 June 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. Management believes the adoption of this new standard will not have a material impact on either the operating results or financial position of the Company.

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections". This Statement rescinds SFAS No. 4, "Reporting Gains and Losses from Extinguishment of Debt", SFAS No. 44, "Accounting for Intangible Assets of

**ALEXION PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

Motor Carriers” and SFAS No. 64, “Extinguishments of Debt Made to Satisfy Sinking-Fund Requirements”. This statement also amends SFAS No. 13, “Accounting for Leases” and makes various technical corrections to existing pronouncements. Those corrections are not substantive in nature. The provisions of SFAS No. 145 were effective as of May 15, 2002. The adoption of the new standard had no impact on the operating results or the financial position of the Company.

In August 2001, the FASB issued SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets.” SFAS No. 144 modifies the rules for accounting for the impairment or disposal of long-lived assets and supercedes SFAS No. 121. The new rules become effective for fiscal years beginning after December 15, 2001, with earlier application encouraged. The adoption of this standard on August 1, 2002 did not have a material impact on the operating results or financial position of the Company.

In August 2001, the FASB issued SFAS No. 143, “Accounting for Obligations Associated with the Retirement of Long-Lived Assets”. The objective of SFAS No. 143 is to provide accounting guidance for legal obligations associated with the retirement of long-lived assets. The retirement obligations included within the scope of this pronouncement are those that an entity cannot avoid as a result of either the acquisition, construction or normal operation of a long-lived asset. Components of larger systems also fall under this pronouncement, as well as tangible long-lived assets with indeterminable lives. The provisions of SFAS No. 143 are effective for financial statements issued for fiscal years beginning after June 15, 2002. The adoption of this standard on August 1, 2002 did not have a material impact on the operating results or the financial position of the Company.

**3. Alexion Antibody Technologies, Inc.**

On September 23, 2000, the Company 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. In consideration thereof, the Company issued 355,594 shares of the Company’s common stock and fully vested options to purchase 44,364 shares of the Company’s common stock at a weighted average exercise price of \$44.35 per share, in exchange for all of the outstanding equity of Prolifaron including fully vested options under their stock option plan. The fair value of the Company’s 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. The Company 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 uses. 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.

## ALEXION PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The drug candidates under development represent innovative technologies addressing autoimmune and inflammatory disorders and cancer.

As of the acquisition date, Prolifaron had incurred approximately \$5.7 million of expenses on development projects since its inception in 1998, and expected to spend approximately \$8.5 million over the next seven years to complete animal testing of the developmental drug candidates. Management anticipates the in-process projects would, if successful, be marketed in the U.S. in five to nine years.

In making its purchase price allocation, management considered present value calculations of income, an analysis of project accomplishments and remaining outstanding items, an assessment of overall contributions, as well as technological and regulatory risks. The value assigned to purchased in-process technology was determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting net cash flows from the projects, and discounting the net cash flows to their present value. The revenue projection used to value the in-process research and development was based on estimates of relevant market sizes and growth factors, expected trends in technology, and nature and expected timing of new product introductions by Prolifaron and its competitors.

The rates utilized to discount the net cash flows to their present value were based on estimated cost of capital calculations. Due to the risks associated with the projected cash flow forecast, a discount rate of 40 percent was considered appropriate for the in-process research and development. The selected rate reflects the inherent uncertainties surrounding the successful development of the purchased in-process technology, the useful life of such technology, and the uncertainty of technological advances that are unknown at this time.

If these projects are not successfully developed, the sales and profitability of the combined companies may be adversely affected in future periods. Additionally, the value of other acquired intangible assets may become impaired. The research and development projects acquired in connection with the acquisition of Prolifaron are expected to continue in line with the estimates described above.

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 (see Goodwill, Note 2). The following table summarizes the allocation of the purchase price to the net assets acquired (amounts in thousands):

Cash and cash equivalents acquired	\$	771
Reimbursable contract costs		43
Prepaid expenses and other current assets		623
Property, plant and equipment		493
Other		3
Goodwill		22,855
In-process research and development		21,000
Accounts payable and accrued expenses		(540)
Accrued transaction costs		(1,303)
		<hr/>
Total fair value of equities issued	\$	43,945
		<hr/>

## ALEXION PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following unaudited pro forma condensed consolidated information has been prepared to give effect to the acquisition as if such transaction had occurred at the beginning of the period presented. The historical results have been adjusted to reflect: i) elimination of the one-time charge to operations for the purchase of acquired in-process research and development, ii) amortization of goodwill arising from the transaction, and iii) elimination of income tax benefits or expenses that would not have been realized on a combined basis (amounts in thousands, except per share amounts).

	Year Ended July 31,	
	2001 Pro Forma	2000 Pro Forma
Contract research revenues	\$ 12,926	\$ 24,019
Net loss before cumulative effect of adoption of SAB 101	\$ (27,724)	\$ (23,955)
Net loss	\$ (36,842)	\$ (23,955)
Basic and diluted net loss per common share	\$ (2.11)	\$ (1.68)
Shares used in computing basic and diluted net loss per common share	17,423	14,270

Had SAB 101 been retroactively applied (see Note 4) to the above pro forma information for the year ended July 31, 2000, contract revenues would increase and net loss would decrease by \$588,000. Basic and diluted net loss per share would be reduced to \$(1.64) per share for that year.

The unaudited pro forma condensed consolidated financial information is not necessarily indicative of what actual results would have been had the transaction occurred on the dates indicated and do not purport to indicate the results of future operations.

#### 4. Cumulative Effect of Accounting Change

In December 1999, the Securities and Exchange Commission staff issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101). SAB 101 summarized certain of the staff's views in applying generally accepted accounting principles to revenue recognition in financial statements and specifically addressed revenue recognition in the biotechnology industry for non-refundable up-front fees. Prior to the implementation of SAB 101, non-refundable license fees received upon execution of license agreements were recognized as revenue immediately. The Company adopted SAB 101 in fiscal 2001 and therefore changed its revenue recognition policy for up-front non-refundable payments from immediate recognition to deferral of the revenue with the up-front fee amortized into revenue over the life of the agreement.

In fiscal 1999 the Company recognized \$10 million of revenue from a non-refundable up-front licensing fee received from Procter & Gamble Pharmaceuticals ("P&G") (see Note 10). With the adoption of SAB 101, the Company is now required to recognize this \$10 million license fee as revenue over the average of the remaining patent lives of the underlying technologies (17 years) as the agreement with P&G provided for ongoing collaborative services and the funding of specified clinical development and manufacturing costs of the Company's pexelizumab product candidate. The license is being recognized over the lives of the patents, as the agreement does not have a specified contractual term. As part of the change to the accounting method, the Company recognized a non-cash cumulative effect adjustment of \$9.1 million as of August 1, 2000. There were no income tax effects related to this accounting change.

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The Company has provided pro forma operating loss, net loss and net loss per share information as if the Company had adopted SAB 101 for all periods presented.

**5. 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 \$2,953,000, \$2,095,000 and \$1,429,000 for the years ended July 31, 2002, 2001 and 2000, respectively.

<u>Asset</u>	<u>Estimated Useful Life</u>
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,	
	2002	2001
Land	\$ 364	\$ 364
Building, building improvements and leasehold improvements	10,302	9,088
Laboratory and support equipment	11,644	9,338
Furniture and office equipment	2,428	1,852
	<u>24,738</u>	<u>20,642</u>
Less: Accumulated depreciation and amortization	(9,864)	(6,911)
	<u>\$ 14,874</u>	<u>\$ 13,731</u>

**6. Accrued Expenses**

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

	July 31,	
	2002	2001
Payroll and employee benefits	\$ 1,365	\$ 1,121
Research and development expenses	1,445	398
State taxes	591	—
Accrued rent	475	452
Other	427	300
	<u>\$ 4,303</u>	<u>\$ 2,271</u>

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

**7. Note Payable**

The Company has a term note payable to Tyco Healthcare (formerly U.S. Surgical Corporation) bearing interest at 6% per annum, payable quarterly. The principal balance of \$3.92 million under the note matures in May 2005. The note payable is collateralized by certain assets of Columbus with a net book value of approximately \$2.84 million as of July 31, 2002.

**8. Convertible Subordinated Notes**

In March 2000, the Company completed a \$120 million private placement of 5.75% 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 resulting in the issuance of 1,127,555 shares of common stock, in aggregate.

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

Noteholders may require the Company to repurchase their notes upon a repurchase event, as defined by the loan agreement in cash, or, at the option of the Company, in common stock, at 105% 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, the Company may elect to redeem, solely at its 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.

The Company 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 \$570,000 for each of the years ended July 31, 2002 and 2001.

**9. License and Research and Development Agreements**

The Company has entered into a number of license and research and development agreements since its inception. These agreements have been made with various research institutions, universities, and government agencies in order to advance and obtain technologies management believes important to the Company's 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,

## ALEXION PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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.

Research and development agreements generally provide for the Company to fund future project research and clinical trials. Based upon these agreements, the Company 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 the Company to fund manufacturing development and on-going clinical trials.

In order to maintain its rights under these agreements, the Company may be required to provide a minimum level of funding or support. The Company may elect to terminate these arrangements. Accordingly, the Company recognizes the expense related to these arrangements over the period of performance.

The minimum fixed payments (assuming non-termination of the above agreements) as of July 31, 2002, for each of the next five years are as follows (amounts in thousands):

<u>Years Ending July 31,</u>	<u>License Agreements</u>	<u>Research &amp; Development Agreements</u>	<u>Clinical &amp; Manufacturing Development Agreements</u>
2003	\$517	\$1,021	\$15,373
2004	472	388	813
2005	477	438	121
2006	477	296	97
2007	477	363	48

Should the Company 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, 2002, these agreements contain milestone payment provisions aggregating approximately \$24.2 million. The agreements also require the Company to fund certain future costs associated with the filing of patent applications.

**10. Contract Research Revenues**

During the three years ended July 31, 2002 the Company recorded contract research revenues from research and development support payments and license fees under collaboration with third parties and amounts received from various government grants.

The Company and P&G entered into an exclusive collaboration in January 1999 to develop and commercialize pexelizumab. The Company granted P&G an exclusive license to the Company's intellectual property related to pexelizumab, with the right to sublicense. P&G originally agreed to fund generally all clinical development and manufacturing costs relating to pexelizumab for the treatment of inflammation caused by

**ALEXION PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

cardiopulmonary bypass surgery, heart attack and angioplasty (see below). Additionally, P&G agreed to pay the Company up to \$95 million in payments, which included a non-refundable up-front \$10 million license fee (see Note 4), milestone payments (including up to \$33 million in milestone payments for achievement of certain sales thresholds), and research and development support payments. The Company was also to receive royalties on worldwide sales of pexelizumab, if any, for all indications. The Company was to retain a preferred position relative to third-party manufacturers to manufacture pexelizumab worldwide. The Company was to share co-promotion rights with P&G to sell, market and distribute pexelizumab in the U.S., and grant P&G the exclusive rights to sell, market and distribute pexelizumab outside of the U.S.

In December 2001, the Company and P&G entered into a binding memorandum of understanding (“MOU”) pursuant to which they revised their January 1999 collaboration. Under the revised structure per the MOU, the Company 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 the Company 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 each firm will receive an approximate equal share of the gross margin on U.S. sales, if any. The Company has agreed to bear the first 50% of projected costs associated with the U.S. coronary artery bypass graft surgery (“CABG”) – Phase III clinical trial costs and P&G will bear the second 50%, with a final adjustment to make even the 50% sharing of costs. The Company and P&G have agreed that each will share concurrently 50% of the ongoing U.S. pre-production and development manufacturing costs of pexelizumab. P&G agreed to retain responsibility for future development and commercialization costs outside the U.S., with the Company receiving a royalty on sales to the rest of the world, if any. The Company is responsible for royalties on certain third party intellectual property worldwide, if such intellectual property is necessary. Additionally, as part of the MOU, the Company will receive milestone payments for achieving specified development steps, regulatory filings and approvals, but not receive previously agreed sales milestones and will generally forego further research and development support payments from P&G.

P&G has the right to terminate the collaboration at any time. If P&G terminates prior to incurring its 50% of the CABG-Phase III clinical trial costs, then P&G will not be required to contribute towards its approximately equal share of the U.S. CABG-Phase III clinical trial costs and P&G will be released from its future funding obligations. In such circumstance, all rights and the exclusive license to the Company’s intellectual property related to pexelizumab will revert back to the Company and the Company will be entitled to all future pexelizumab revenues, if any, without any sharing of revenues, if any, with P&G.

As part of the revised collaboration per the MOU, P&G agreed to continue to fund 100% of the costs to complete the two acute myocardial infarction (“AMI”) Phase II clinical trials in myocardial infarction (“heart attack”) patients that recently completed enrollment. The Company and P&G have agreed that each will share concurrently 50% of any future AMI-Phase III clinical trial costs.

The Company has been awarded various grants by agencies of the U.S. government to fund specific research projects. Based upon costs incurred under these projects as of July 31, 2002, the Company has up to approximately \$200,000 of additional funding available under these grants.

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

	Year Ended July 31,		
	2002	2001	2000
Collaboration/Grant Awards			
P&G	\$ 4,591	\$ 9,728	\$ 19,708
U.S. government grants	1,745	1,677	1,733
Other	200	400	—
	<u>6,536</u>	<u>11,805</u>	<u>21,441</u>
Pro forma revenue as if SAB 101 was retroactively adopted (Note 4)	—	—	588
	<u>—</u>	<u>—</u>	<u>588</u>
Total pro forma revenues	\$ 6,536	\$ 11,805	\$ 22,029

**11. Commitments**

As of July 31, 2002, the Company leases its headquarters and primary research and development facilities. The lease commenced in August 2000 and has a term of ten years and six months. The Company is 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. The Company has issued a \$200,000 open letter of credit to secure the lease.

The pilot manufacturing plant, which is used for producing compounds for clinical trials, has a monthly fixed rent of approximately \$16,700. The Company is currently leasing the facility on a month to month basis. The Company leases 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 the Company's facilities was \$1,373,000, \$1,536,000 and \$694,000 for the years ended July 31, 2002, 2001 and 2000, respectively. Lease expense is being recorded on a straight-line basis over the applicable rental 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,	
	<u>2003</u>	\$1,550
	2004	2,007
	2005	2,022
	2006	1,989
	2007	2,086
	2008 and thereafter	9,418

## ALEXION PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

**12. Common Stock***Fiscal 2001 Common Stock Sale*

In October 2000, the Company filed a shelf registration statement to offer up to \$300 million of equity securities. In November 2000, the Company sold 2.3 million shares of common stock at a price of \$90.75 per share resulting in proceeds of approximately \$208.5 million, net of fees and other expenses of approximately \$201,000 related to the transaction.

*Fiscal 2000 Common Stock Sale*

In November 1999, the Company sold 3.415 million shares of common stock at a price of \$14 per share in a follow-on public offering resulting in net proceeds of approximately \$44.4 million net of fees and other expenses of \$3.4 million related to the transaction.

**13. Stock Options and Warrants***Stock Options*

During fiscal 2001, the stockholders of the Company approved the adoption of the 2000 Stock Option Plan (“2000 Plan”) and elected to terminate the previous 1992 Plan. As of July 31, 2002, stock options to acquire 2,164,588 shares of common stock are outstanding under the 1992 Plan. Under the 2000 Plan, incentive and nonqualified stock options may be granted for up to a maximum of 1,500,000 shares of common stock to directors, officers, key employees and consultants of the Company. As July 31, 2002, there were 273,990 options available for grant under the 2000 Plan. During fiscal 2001, the stockholders of the Company approved an amendment to the 1992 Stock Option Plan for Outside Directors. This amendment increased the number of stock options granted initially to qualifying directors as well as upon annual re-election to the board of directors. Options 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.

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

	2002	2001	2000
Risk free interest rate	4.5%	4.7%	6.0%
Expected dividend yield	—	—	—
Expected lives	5 years	5 years	5 years
Expected volatility	92%	101%	85%

Had compensation cost for the Company’s stock option plans been determined based on the fair value at the grant dates of awards under these plans consistent with the method of SFAS No. 123, the Company’s net loss and

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

pro forma net loss per common share would have been increased to the pro forma amounts indicated below (amounts in thousands, except per share amounts):

	2002	2001	2000
Net loss			
As reported	\$ (56,542)	\$ (57,043)	\$ (20,227)
Pro forma	(72,454)	(69,470)	(22,887)
Net loss per common share:			
As reported	\$ (3.12)	\$ (3.28)	\$ (1.45)
Pro forma	(3.99)	(4.00)	(1.64)

A summary of the status of the Company's stock option plans at July 31, 2002, 2001 and 2000 and changes during the years then ended is presented in the table and narrative below:

	2002		2001		2000	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at August 1	3,561,520	\$ 25.12	2,684,215	\$ 21.09	2,348,587	\$ 8.10
Granted	203,855	21.17	1,275,164	30.05	644,800	63.18
Exercised	(121,750)	7.27	(299,525)	7.34	(225,083)	7.56
Cancelled	(86,020)	33.87	(98,334)	33.20	(84,089)	17.34
Outstanding at July 31	3,557,605	\$ 25.30	3,561,520	\$ 25.12	2,684,215	\$ 21.09
Options exercisable at July 31	2,163,580	\$ 20.25	1,622,164	\$ 14.65	1,443,554	\$ 7.26
Weighted-average fair value of options granted during the year		\$ 15.16		\$ 25.70		\$ 45.02

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 1,220,800 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. The weighted average exercise price of these options was \$29.16 per share. The weighted average fair value of these options at the date of grant was \$22.40 per option. In addition, options to purchase 10,000 shares of common stock were granted to employees at exercise prices which were less than the fair value of the common stock at the date of grant. Accordingly, the Company is recording compensation expense based upon this difference over the vesting period associated with these options. Compensation expense associated with these options is \$65,000 and \$121,000 for the years ended July 31, 2002 and 2001, respectively. Aggregate compensation expense of approximately \$138,000 associated with these option grants is expected to be recognized over the next two years. 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.

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

During fiscal 2001, in connection with acquisition of Prolifaron (see Note 3), the Company also issued fully vested options to purchase 44,364 shares of common stock at a weighted average exercise price of \$44.35 per share. The weighted average fair value of these options at the date of grant was \$101.46 per option. The value of these options was included as a component of the purchase price of Prolifaron at the date of acquisition.

During fiscal 2000, options to purchase 644,800 shares of common stock were granted to employees, directors and consultants of the Company at an exercise price equal to the fair value of the stock at the date of grant. The Company is recording compensation expense based upon the fair value of the options granted to consultants over the vesting term. Compensation expense related to these options was \$12,000, \$93,000 and \$239,000 for the years ended July 31, 2002, 2001 and 2000, respectively.

The Company also records compensation expense on certain options to purchase common stock granted prior to fiscal 2000 to employees. These options were subject to shareholders approving an increase in total shares available to be granted under the plan. The exercise price of these options was less than the fair value of the stock at the date of shareholder approval. Accordingly, the Company is recording compensation expense based upon this difference over the vesting period associated with these options. Compensation expense associated with these options is \$104,000, \$194,000 and \$191,000 for the years ended July 31, 2002, 2001 and 2000, respectively. Aggregate compensation expense of approximately \$36,000 associated with these option grants is expected to be recognized over the next year.

The following table presents weighted average price and life information about significant option groups outstanding at July 31, 2002:

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	639,887	4.0	\$ 5.31	636,637	\$ 5.31
\$ 9.01 – \$ 20.99	1,004,685	5.5	10.79	857,785	10.47
\$ 21.00 – \$ 24.50	1,072,198	8.8	21.24	248,823	21.03
\$ 32.00 – \$ 54.00	167,085	8.1	37.65	78,210	40.24
\$ 61.00 – \$ 87.00	633,750	7.8	66.88	332,125	66.23
\$106.00 – \$108.00	40,000	8.1	107.88	10,000	107.88
	<u>3,557,605</u>	<u>6.8</u>	<u>\$ 25.30</u>	<u>2,163,580</u>	<u>\$ 20.25</u>

*Warrants*

In connection with the Company's initial public offering in 1996, the Company sold to its underwriter, for nominal consideration, warrants to purchase 220,000 shares of common stock. These warrants were exercisable at a price of \$9.90 per share for a period of forty-two (42) months commencing on August 27, 1997. During fiscal 2000, warrants to purchase 201,883 shares were exercised resulting in proceeds of \$2.0 million to the Company. During fiscal 2001, the remaining warrants to purchase 18,117 shares were exercised resulting in proceeds of approximately \$179,000 to the Company.

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

**14. Rights to Purchase Preferred Stock**

In February 1997, the Board of Directors of the Company 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% or more of the Company's common stock or after commencement or public announcement to make a tender offer for 20% or more of the Company's common stock. The rights, which do not have voting rights, expire on March 6, 2007, and may be redeemed by the Company at a price of \$0.01 per right at any time prior to their expiration or the acquisition of 20% or more of the Company's 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, the Board of Directors of the Company 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 the Company is acquired in a merger, other business combination transaction, or 50% or more of its 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.

**15. 401(k) Plan**

The Company has a 401(k) plan. Under the plan, employees may contribute up to 15 percent of their compensation with a maximum of \$11,000 per employee in calendar year 2001. The Company matches contributions at a rate of \$0.50 for each dollar deferred up to the first 6% of compensation. The Company made matching contributions of approximately \$207,000, \$177,000 and \$127,000 for the years ended July 31, 2002, 2001 and 2000, respectively.

**16. Income Taxes**

At July 31, 2002, the Company has available for federal tax reporting purposes, net operating loss carryforwards of approximately \$162.6 million which expire through 2022 (of which approximately \$18.0 million resulted from the exercise of nonqualified stock options as discussed below). The Company also has federal and state research and development credit carryforwards of approximately \$9.6 million which begin to expire commencing in fiscal 2008. The Tax Reform Act of 1986 contains certain provisions that limits the

## ALEXION PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Company's 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% over a three-year period. The Company believes it has triggered these limitation provisions.

As a result of recent legislation, 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 credit. The program provides for such exchange of the research and development credits at a rate of 65% of the annual incremental research and development credits, as defined. During the year ended July 31, 2002, the Company had filed a claim to exchange their fiscal 2001 incremental research and development credit and as a result recognized a state tax benefit of \$700,000.

The Company follows 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,	
	2002	2001
Deferred tax assets		
Net operating loss carryforwards, federal and state	\$ 61,830	\$ 36,870
Tax credit carryforwards	9,640	9,990
Deferred revenues	3,100	3,350
Other	230	—
Total deferred tax assets	74,800	50,210
Less: Valuation allowance for deferred tax assets	74,800	50,210
	\$ —	\$ —

The exercise price of nonqualified stock options gives rise to compensation which is included in the taxable income of the applicable employees and deducted by the Company for federal and state income tax purposes. As a result of the exercise of nonqualified stock options, the Company has related net operating loss carryforwards of approximately \$18.0 million which can be used to offset future taxable income, if any. When realized, the related tax benefits of these net operating loss carryforwards will be credited directly to paid in capital.

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The reconciliation of the statutory Federal income tax rate to the Company's effective income tax rate is as follows:

	Year Ended July 31,		
	2002	2001	2000
Statutory rate	(34)%	(34)%	(34)%
State tax benefit, net of Federal taxes	(5)	(5)	(5)
In-process research and development	—	14	—
Amortization of goodwill	—	2	—
Research & development credits	4	(5)	(11)
Increase in deferred tax valuation allowance	34	28	50
Effective rate	(1)%	— %	— %

The Company has not yet achieved profitable operations. Accordingly, management believes the tax benefits as of July 31, 2002 do not satisfy the realization criteria set forth in SFAS No. 109 and has recorded a valuation allowance for the entire deferred tax assets.

**17. Unaudited Quarterly Financial Information**

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

	Fiscal 2002			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Contract research revenues	\$ 1,860	\$ 3,380	\$ 539	\$ 757
Operating expenses	11,270	16,879	18,338	21,511
Operating loss	(9,410)	(13,499)	(17,799)	(20,754)
Net loss applicable to common shareholders	(7,789)	(10,810)	(17,105)	(20,838)
Net loss per common share, basic and diluted	(0.43)	(0.60)	(0.94)	(1.15)

	Fiscal 2001			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Contract research revenues	\$ 3,399	\$ 3,174	\$ 1,960	\$ 3,272
Operating expenses	33,650	12,248	11,125	12,884
Operating loss	(30,251)	(9,074)	(9,165)	(9,612)
Net loss before cumulative effect of adopting SAB 101	(29,441)	(4,486)	(6,462)	(7,536)
Cumulative effect of adopting SAB 101	(9,118)	—	—	—
Net loss applicable to common shareholders	(38,559)	(4,486)	(6,462)	(7,536)
Net loss per common share, basic and diluted	(2.52)	(0.25)	(0.36)	(0.42)

## MEMORANDUM OF UNDERSTANDING

## Revised P&amp;GP / Alexion Pexelizumab Collaboration

This Memorandum represents a summary of the Parties' interests in renegotiating their current Collaboration and it is binding as set forth in the final paragraph hereof.

## OVERVIEW AND MANAGEMENT OF THE COLLABORATION

Scope: P&GP and Alexion propose to revise the Collaboration Agreement (the "Collaboration Agreement") dated January 25, 1999 in accordance with this Memorandum. P&GP and Alexion agree to negotiate in good faith to restate the Collaboration Agreement (the "Restatement") in accordance with this Memorandum.

Collaboration Agreement. Except as specifically set forth herein, all terms of the Collaboration Agreement shall continue with full force and effect following the execution and delivery of this Memorandum.

Definitions. Capitalized terms used but not defined herein have the meanings set forth in the Collaboration Agreement.

Decisions - R&D, Health Registrations and Supply Issues: Alexion and P&GP will have equal decision-making authority for all R&D, Health Registration and Product Supply/Process Development issues. Such issues will be addressed and resolved through the R&D Steering Committee. Either party may refer an issue for further review and resolution to the President of Alexion and the President of Procter & Gamble Pharmaceuticals (the "Presidents"). Action will be delayed until such meeting or discussion between the Presidents. If the Presidents cannot resolve the issue within [\*\*\*\*\*] business days of such reference (or longer period mutually agreed by the Presidents), the matter will be submitted to a neutral arbitrator (the "Neutral") within [\*\*\*\*\*]

business days thereafter. Both Parties agree to select a Neutral with experience in the U.S. pharmaceutical industry and to use their best efforts promptly to cooperate with any investigations and deliberations of the Neutral. The Parties will present to the Neutral their respective issues with proposed solutions for the Neutral to make a determination. The Neutral's determination will be limited to either Party's solution. The Neutral's determination will be final and binding on the Parties. The fees and costs of the Neutral will be shared equally between the Parties. The Parties agree to identify and engage a mutually acceptable Neutral promptly after execution of the Restatement, to avoid delay in the event the Neutral's determinations become necessary.

Decisions - Commercialization Issues: The Parties shall form a Commercialization Steering Team (the "CST"), that will analyze, discuss and agree on all commercialization strategies, plans and budgets for commercialization of the product in the U.S. This team will have equal membership from both P&GP and Alexion. The CST will establish an annual commercialization plan, which shall be binding on the Parties. The CST will resolve all commercialization issues, including but not limited to Marketing, Promotion, Labeling, Phase IIIb/IV studies, Scientific Exchange and Education. Either party may refer a commercialization issue for further review and resolution to the Presidents. Action will be delayed until such meeting or discussion between the Presidents. If the Presidents cannot resolve the issue within [\*\*\*\*\*] business days of such meeting or discussion, the matter will be resolved by [\*\*\*\*\*].

The development and execution of all commercialization strategies and plans in the ROW will remain the sole responsibility of P&GP.

Executorial Responsibilities:

The executorial responsibility of each Party for clinical programs is outlined on Schedule I which is attached and incorporated herein. While an individual Party has lead executorial responsibility, the Parties agree there will be no unilateral decision-making by either Party on any aspect of the clinical program's execution. Both Parties will as soon as practical but in no event later than within [\*\*\*\*\*], share all significant information relating to the development of pexelizumab received from any Third Party related to the project, including but not limited to, FDA, CROs, clinical sites, or suppliers, about the programs. All other information relating to the development

of pexelizumab will be shared at weekly updates. Prior to meeting with any such Third Party regarding the development of pexelizumab, each Party will give the other Party adequate advance notice and full ability to meaningfully participate. Unless otherwise agreed by the Parties, the executional teams, including the Clinical Strategy Team and Clinical Execution Team, will meet at a minimum of every week to discuss issues, including but not limited to, any executional changes to the protocol or plan, the status on any budgetary or spending changes, the status on recruitment rates, IRB approvals, etc. When a study is unblinded, each Party will participate equally in developing a consistent interpretation of the data. A senior management team consisting of Vice Presidents or Directors with senior authority for a function, will meet quarterly to review, resolve issues as necessary and comment on the status of the various clinical and product supply/ process development executional teams, including but not limited to, spending versus budget and progress against project milestones.

[\*\*\*\*\*] will have full responsibility for management of the preparation of the global marketing applications with input from [\*\*\*\*\*]. [\*\*\*\*\*] will lead interactions with FDA regarding the BLA preparation (e.g., pre-BLA meetings). [\*\*\*\*\*] will be responsible for supplying global modular documents with input from [\*\*\*\*\*] to use in completing the CMC section of the global marketing applications. [\*\*\*\*\*] will have full responsibility for preparation, content and maintenance of the Product's labeling, subject to [\*\*\*\*\*] prior review and opportunity to comment.

Clinical Databases: Clinical databases for CABG and AMI will continue to use P&GP systems and specifications and remain under P&GP control and ownership, in accordance with the Collaboration Agreement. P&GP will give Alexion current access to all such databases. Both Parties must agree prior to granting access to any portion of the database to a Third Party. In the event P&GP exercises the Opt Out option and the Collaboration Agreement is terminated, P&GP will without further consideration promptly transfer ownership of such databases to Alexion, and will provide Alexion other access reasonably needed by Alexion, including but not limited to, introducing Alexion to database vendors that P&GP license from and providing Alexion licenses to P&GP owned software exclusively for use in connection with the CABG and AMI clinical database, so Alexion is able to assume control of and to exploit the databases to the same extent as P&GP had been capable of internally.

## RESEARCH AND DEVELOPMENT PLAN

U.S. R&D Funding: P&GP will continue to control AMI Phase II and fund all out-of-pocket costs and in-house FTE costs for work performed pursuant to the R&D Plan for the AMI Phase II program. Alexion and P&GP will each pay 50% of all pre-agreed out-of-pocket costs to Third Parties for work performed pursuant to the R&D Plan for the AMI Phase III U.S. program and the CABG Phase III U.S. program, plus mutually agreed Alexion and P&GP FTE costs in connection therewith. Prior to commencement of a program an overall budget ("Budget") must be pre-agreed in writing by the Parties. This Budget will be updated no less than every 6 months and all changes must be agreed to in writing. Out-of-pocket costs include any mutually agreed-to payments to Third Parties. Studies conducted outside the United States that are used to support either Phase III U.S. program shall be considered U.S. program costs. Any expenses incurred by either Party that were not pre-agreed to in writing as part of the Budget process will be the sole responsibility of the Party that incurred the expense.

CABG. Alexion agrees to pay the first 50% of the total pre-agreed estimated costs in respect of the CABG Phase III U.S. program (i.e., \$[\*\*\*\*\*]). For clarity, P&GP's previous expenditure for CABG Phase III, the amount of which will be agreed as set forth below, will not be counted as part of Alexion's first 50% of costs. Unless agreed otherwise by the Parties in writing as part of the establishment of the Budgets, Alexion will pay the first \$[\*\*\*\*\*] of such costs, P&GP will pay the second \$[\*\*\*\*\*] of such costs, and the Parties will simultaneously, evenly pay any additional mutually-agreed costs. Upon completion or jointly agreed termination of the CABG Phase III U.S. program, if either Party has paid more than the other Party in connection therewith, the Party having paid less will promptly make a reconciliation payment to the other Party, such that each party has paid 50% of the total of such mutually-agreed costs. Each Party acknowledges that the other has incurred costs directly related to the CABG Phase III program prior to execution of this Memorandum. Accordingly, each Party will be credited with having already spent such amounts in evening the total costs to be absorbed by the Parties. A full accounting will be completed upon signing this Memorandum to itemize the specific CABG Phase III costs incurred by the Parties as of that date.

AMI. Alexion and P&GP will determine a structure to result in their paying their respective 50% of AMI Phase III costs simultaneously.

Clinical Supply Costs. All clinical supply costs incurred prior to initiation of the CABG Phase III program shall be expensed on initiation of the trial, and further such costs will be expensed when incurred.

ROW R&D Funding: P&GP is free to re-use, outside the U.S., any data or information generated from any study performed for U.S. Health Registration, without incurring any additional expense. Alexion is free to use, within the U.S., any data or information generated by P&GP from any study performed solely for a ROW Health Registration, without incurring any additional expense. P&GP may elect to include ROW sites in U.S. led Phase IIIb and Phase IV studies. In the event ROW sites are included in such studies, P&GP will pay for the expenses specifically associated with patients enrolled solely for the ROW needs. If pre-agreed Phase IIIb and Phase IV studies are used in the U.S. and ROW for new marketing or labeling claims, P&GP will pay [\*\*\*\*\*] of the cost and Alexion will pay [\*\*\*\*\*]. All additional R&D expenses specifically and uniquely required for the Health Registration or commercialization of pexelizumab outside of the U.S. will be the responsibility of P&GP.

P&GP OPT-OUT OPTION: P&GP may terminate ("Opt-Out") the Collaboration in its sole discretion by providing six months notice following [\*\*\*\*\*] and no later than the earlier of (i) 30 days after receipt of [\*\*\*\*\*] and (ii) [\*\*\*\*\*].

In the event P&GP elects to exercise its Opt-Out option, P&GP has no responsibility for CABG Phase III expense other than (i) the mutually agreed expenses incurred prior to exercise of the Opt-Out that otherwise would be payable by P&GP pursuant to "CABG", above, and (ii) CABG Phase III amounts paid by P&GP prior to execution of this Memorandum. By way of example, if P&GP exercises the Opt-Out option and \$[\*\*\*\*\*] has been expended on CABG Phase III, and it is determined that P&GP paid \$[\*\*\*\*\*] prior to execution of this agreement in connection with CABG Phase III, Alexion would have paid \$[\*\*\*\*\*] and P&GP [\*\*\*\*\*]. During the six month notice period, P&GP will continue to provide continuing executional support for AMI and CABG Phase

III hereunder but will have no financial liability for any AMI or CABG Phase III expenses, other than in-house P&GP FTE costs, to be paid 100% by P&GP, provided such FTE costs and expenses are consistent with pre-agreed Budgets and provided the work will be transferred to Alexion as soon as practicable.

In the event P&GP elects to exercise its Opt-Out option, Alexion agrees to purchase from P&GP all mutually pre-agreed pexelizumab related manufacturing assets at current book value and to reimburse P&GP for all [\*\*\*\*\*] including but not limited to, [\*\*\*\*\*]. Alexion will also agree to assume any mutually pre-agreed [\*\*\*\*\*] including, but not limited to, [\*\*\*\*\*]. All asset transfers, contract assignments, and payments must be complete prior to the end of the [\*\*\*\*\*] notice period. This paragraph shall apply only to [\*\*\*\*\*] of P&GP's assets, and commitments and fees, if within [\*\*\*\*\*] of P&GP's Opt-Out exercise Alexion certifies that it too [\*\*\*\*\*].

**PRODUCT SUPPLY AND PROCESS DEVELOPMENT:**

PS/PDC. The Parties will form a Product Supply / Process Development Committee (PS/PDC) with equal representation from each Party. The PS/PDC will be sponsored by the R&D Steering Committee. The PS/PDC will analyze, discuss and agree on decisions related to process development, clinical and commercial product supply, including but not limited to, choice of supplier(s), capital expenditures and product development activities. The PS/PDC will be responsible for and have decision-making authority for process development and production of Product for the R&D Plan and for commercialization. If the PS/PDC cannot reach agreement on a product supply issue, either Party may refer the issue to the R&D Steering Committee. If the R&D Steering Committee does not reach agreement within five business days of the referral, the matter will be addressed through the R&D Steering Committee Dispute Resolution process established above. The PS/PDC will develop and agree in writing to a Process Development Plan ("PDP") and a Product Supply Sourcing Plan ("PSSP") for the U.S. P&GP and Alexion will jointly share project leadership for execution of the Product Supply Sourcing Plan, and P&GP will be the primary vendor contact to provide a single and focused point of contact to leverage existing relationships and corporate purchasing scale; Alexion will provide input on the vendor contacts on a co-equal basis. Alexion and P&GP will jointly share project leadership for process development. The process development execution will be conducted consistent with P&GP and Alexion

requirements. Alexion will perform bulk drug development and characterization and P&GP will provide input on a co-equal basis. P&GP will take the lead on vialing and other supply chain activities and Alexion will provide input on a co-equal basis. All U.S. process development and product supply agreements will be mutually agreed. P&GP will be sole signatory on all process development and product supply agreements. Within [\*\*\*\*\*] of the PS/PDC agreeing upon a viable source of commercial supply for pexelizumab, the PS/PDC will agree to the Product Supply Sourcing Plan. The PSSP will include, among other items, detail on validation timing, launch readiness requirements and longer-term forecasted volumes.

The Parties acknowledge that certain vendors may support supply for both the U.S. and ROW. In such cases, the PS/PDC will ensure that vendor costs for U.S. and ROW supply are equal on a unit basis.

In the event that supplies are insufficient for worldwide demand forecasted as of launch, [\*\*\*\*\*] will be [\*\*\*\*\*]. P&GP will provide Alexion the ROW product sourcing plan for review and input. Following launch, if supply is insufficient to meet total demand, available supply will be allocated based on the past [\*\*\*\*\*] volume. In the event of a likely shortage of product in [\*\*\*\*\*], P&GP agrees not to [\*\*\*\*\*]. Unless otherwise agreed by the Parties, the PS/PDC will strive to meet these non-binding objectives of the PS/PDC that include but are not limited to: (i) the primary commercial source(s) of pexelizumab shall be validated in accordance with all relevant regulations [\*\*\*\*\*] before the currently anticipated first BLA filing date and (ii) [\*\*\*\*\*] of commercial supply shall be ready for sale before the currently anticipated United States launch date. Meeting these non-binding objectives will be balanced against technical and commercial feasibility and required investment.

Capital. Capital expenditures will be [\*\*\*\*\*]. P&GP will purchase all capital as agreed to by the PS/PDC in the PSSP and all assets will be maintained on P&GP's ledgers. Until the first launch of pexelizumab, [\*\*\*\*\*] of the annual capital depreciation will be charged to Alexion. Following the first launch, depreciation will be charged to the [\*\*\*\*\*]. Alexion will thereby be charged [\*\*\*\*\*]. Assets will be depreciated based on P&GP's corporate accounting policy, which includes a determination of useful life on an asset-by-asset basis. In the event that P&GP is required to write

down pexelizumab assets due to project failure, etc. (not including assets related to [\*\*\*\*\*]), Alexion will reimburse P&GP for [\*\*\*\*\*] expense associated with the write down.

Supplier Advances. Until the first launch of pexelizumab, all supplier advances that are required to be expensed due to cancellations (other than ROW cancellations), will be [\*\*\*\*\*] between the Parties. Following the first launch, all expensed supplier advances will be [\*\*\*\*\*].

Expenses. All other outside expense pre-agreed in writing that is associated with process development and production, including but not limited to all validation and test run costs, will be [\*\*\*\*\*] insofar as the same are uniquely and specifically required to support production capacity for U.S. commercialization, including in-house FTE costs for process development and product supply work conducted under the R&D Plan. A process development and product supply Budget must be pre-agreed in writing by the Parties. This Budget must be established in conjunction with PS/PDC agreement to the Process Development Plan and Product Supply Sourcing Plan. This Budget will be updated no less than every 6 months and all changes must be agreed to in writing. Any expenses incurred by either Party that were not pre-agreed to in writing as part of the Budget process will be the sole responsibility of the Party that incurred the expense. Any expense that is uniquely and specifically required to support production capacity for ROW commercialization shall be borne by [\*\*\*\*\*] and not reimbursed by [\*\*\*\*\*], and if such expense supports both U.S. and ROW commercialization, P&GP will pay [\*\*\*\*\*] and Alexion will pay [\*\*\*\*\*] of the expense.

#### HEALTH REGISTRATIONS:

Sponsorship. Within the U.S., Alexion will be the Sponsor of the IND for CABG and P&GP will be the Sponsor of the IND for AMI. Both Parties will jointly plan, prepare for, and participate in all FDA interactions. All meetings with FDA will be led by the Sponsor. The Parties agree to adhere to the protocol for involving each other as outlined in Schedule II, which is attached and hereby incorporated by reference. P&GP will sponsor the BLA and all subsequent sBLAs and be responsible for filing, prosecuting and all FDA interactions concerning the BLA or any subsequent sBLAs. In order for P&GP to prepare for filing the BLA, Alexion agrees to transfer the IND for CABG to P&GP no later than practically required before the expected filing of the BLA, but in no event later than the pre-BLA meeting. Outside of the U.S., P&GP will be the sponsor of all Health

Registrations. In the event P&GP exercises the Opt Out option and the Collaboration is terminated, P&GP will without further consideration promptly transfer sponsorship of its INDs and BLAs throughout the world to Alexion or its nominated agent(s), and will provide Alexion access reasonably needed by Alexion to assume control of and to exploit such INDs and BLAs to the same extent as P&GP had been capable of internally.

Funding. All mutually agreed out-of-pocket and in-house FTE costs associated with filing or maintaining the U.S. Health Registration will [\*\*\*\*\*]. All out of pocket and in-house FTE costs associated with filing or maintaining Health Registrations outside of the U.S. will be borne by P&GP.

#### MARKETING AND PROMOTION:

Commercialization Costs. P&GP and Alexion agree to [\*\*\*\*\*] all mutually agreed out-of-pocket and FTE costs associated with the commercialization of the Product [\*\*\*\*\*]. [\*\*\*\*\*] shall be responsible for all such costs [\*\*\*\*\*]. The CST will establish an annual U.S. commercialization plan and Budget agreed to in writing on or before July 1 of each year. Any expenses incurred by either Party that were not pre-agreed to in writing as part of the Budget process will be the sole responsibility of the Party that incurred the expense. All mutually agreed out-of-pocket and internal Alexion and P&GP FTE U.S. costs shall include but are not limited to the following:

1. costs for marketing, market research, advertising, sampling, and promoting the Product, such as advertising agency fees, advertising development costs, sales materials, development costs, training materials and public communication costs, speaker programs and conferences and other scientific education and exchange program (SEEP) costs incurred prior to and following Product approval;
2. costs related to creating and distributing any communication notice mandated by a government authority (e.g. Dear Doctor letters);
3. costs associated with manufacturing, distributing and shipping the Product samples to Third Parties and the handling and disposing of return shipments;
4. costs associated with obtaining, maintaining or enforcing Product related trademarks and logos;

5. costs for Phase IIIb, Phase IV and grant studies mutually agreed by the parties;
6. epidemiological modeling and pharmacoeconomic study costs; and
7. costs associated with effecting any Product recall (i.e., communication, shipping and reimbursement costs).

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1. P&GP will [\*\*\*\*\*]. P&GP will discuss all matters related to [\*\*\*\*\*] with Alexion and provide Alexion an opportunity to comment thereon; provided that the final decisions on all such matters shall be made by Procter & Gamble in its sole discretion. Alexion will be notified of and invited to all meetings [\*\*\*\*\*]. Each party will bear its own internal costs, and P&GP will bear all P&GP outside costs and expense [\*\*\*\*\*], in connection with [\*\*\*\*\*]. Alexion has the right [\*\*\*\*\*]. If [\*\*\*\*\*], P&GP and Alexion [\*\*\*\*\*]. [\*\*\*\*\*] agrees to grant [\*\*\*\*\*] a sublicense [\*\*\*\*\*] necessary to carry out the Agreement. [\*\*\*\*\*] shall reimburse [\*\*\*\*\*] all amounts [\*\*\*\*\*], except that (i) subject to Clause 2 below, [\*\*\*\*\*] shall be responsible for [\*\*\*\*\*] in respect of [\*\*\*\*\*] in the United States, [\*\*\*\*\*] and (ii) [\*\*\*\*\*] shall be responsible [\*\*\*\*\*] in respect of [\*\*\*\*\*] outside the United States. [\*\*\*\*\*] will not be entitled to amend or otherwise modify [\*\*\*\*\*] without the prior, written consent of [\*\*\*\*\*].
2. Notwithstanding Clause 1 above, [\*\*\*\*\*] shall be responsible for [\*\*\*\*\*] of United States [\*\*\*\*\*] under the [\*\*\*\*\*] until the difference between the amount payable under this Clause 2 and the amount otherwise payable under Clause 1 above exceeds the lesser of (i) [\*\*\*\*\*] in respect of United States [\*\*\*\*\*] and (ii) [\*\*\*\*\*]. Thereafter, this Clause 2 shall no longer apply.
3. The [\*\*\*\*\*] in the United States and outside the United States will be identical under [\*\*\*\*\*], and all [\*\*\*\*\*] shall be apportioned [\*\*\*\*\*] between [\*\*\*\*\*] in the United States and [\*\*\*\*\*] outside the United States, respectively.
4. All other [\*\*\*\*\*] (other than as set forth in [\*\*\*\*\*] of the Collaboration Agreement) related to [\*\*\*\*\*] in the United States shall be handled pursuant to Section [\*\*\*\*\*] of the

Collaboration Agreement (i.e., [\*\*\*\*\*] will [\*\*\*\*\*]). All other [\*\*\*\*\*] (other than as set forth in [\*\*\*\*\*]) related to [\*\*\*\*\*] Product outside the United States shall be handled pursuant to Section [\*\*\*\*\*] of the Collaboration Agreement (i.e., [\*\*\*\*\*] will [\*\*\*\*\*]).

5. [\*\*\*\*\*]

6. Example. Following is an example of the operation of this [\*\*\*\*\*] provision:

Assuming:

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Then:

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Sales Efforts. It is expected that each Party [\*\*\*\*\*] selling efforts in the U.S., including but not limited to, the efforts of liaisons and hospital representatives as mutually agreed. The Parties will each pay their own sales force and liaison costs (salaries, benefits, autos, bonuses or other incentive program costs, etc.). In the event [\*\*\*\*\*] selling effort would not be possible, the Party assigned more than [\*\*\*\*\*] will be reimbursed for the extra costs borne by that Party.

One year before launch of the Product, the Parties will enter into a Marketing Services Agreement (MSA). The MSA will describe but not be limited to, terms on budgeting, forecasting, co-promotion services (including requirements for accounting for requisite Details or other calls on target prescribers, coordination of sales effort, compliance with laws and applicable authorities,

etc.), sales penalties, penalties for under performance, responsibilities and procedures for Product returns and recalls.

ROYALTIES AND MILESTONES:

U.S. Contribution: Alexion shall receive [\*\*\*\*\*]% of U.S. Contribution (Contribution is defined as Net Sales minus COGS ) on sales of pexelizumab in the United States. Sections 8.2(a), 8.2(b) and 8.2(c) of the original Agreement are eliminated.

ROW Return: Alexion will receive [\*\*\*\*\*]% of ROW Net Sales.

Milestones: All milestones in the Collaboration Agreement are eliminated and replaced by the following non-refundable, non-creditable one-time milestone payments. Each of these milestones is contingent upon P&GP not having terminated the Collaboration prior to achievement of the milestone event.

MILESTONE

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AMOUNT

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(U.S. \$ Million)

PRE-HEALTH REGISTRATION EVENTS

At initiation of dosing of CABG Phase III clinical trial program which the Research & Development Steering Committee agreed would constitute a pivotal trial for approval of a Product for a CABG Indication

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At initiation of dosing of AMI Phase III clinical trial program which the Research & Development Steering Committee agreed would constitute a pivotal trial for approval of a Product for an AMI Indication

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U.S. HEALTH REGISTRATION EVENTS

On FDA acceptance for filing of the first U.S. Health Registration of a Product for an AMI Indication [\*\*\*\*\*]

On first U.S. Health Registration approval of a Product for a CABG Indication [\*\*\*\*\*]

On first U.S. Health Registration approval of a Product for an AMI Indication [\*\*\*\*\*]

FOREIGN HEALTH REGISTRATION EVENTS (European Union filing/approval means in any country of the European Union.)

On first filing for European Union Health Registration of a Product for a CABG Indication [\*\*\*\*\*]

On first filing for European Union Health Registration of a Product for an AMI Indication [\*\*\*\*\*]

On first European Union Health Registration approval of a Product for a CABG Indication [\*\*\*\*\*]

On first European Union Health Registration approval of a Product for an AMI Indication [\*\*\*\*\*]

MISCELLANEOUS

FTE Funding. The cost of each internal FTE will be calculated at \$[\*\*\*\*\*], multiplied by the percentage of such employee's time devoted to the Collaboration. The R&D Steering Committee will determine FTE effort of each Party in respect of R&D, Health Registration and Supply issues.

The Parties will mutually agree on all other FTE efforts, and the categories of employee chargeable to the Collaboration.

Term: The term of the Collaboration Agreement will continue in each country of the world until pexelizumab is no longer sold in such country.

Termination by P&GP: In addition to both Parties rights to terminate under the original Agreement, as amended hereby, P&GP has the right to exercise the Opt-Out option.

Publicity: The Parties will jointly prepare and agree upon the public announcement of execution of this Memorandum and the Restatement. Thereafter, each Party agrees to publish or otherwise disclose the material, non-public results of the R&D Plan or of development studies or of the commercialization plan (a "Disclosure") only upon prior written approval of the other Party, not to be unreasonably withheld or delayed. In the event either Party is aware of an upcoming Disclosure, the Party will strive to provide the other Party [\*\*\*\*] advance notice of the Disclosure and its content. If specific wording is not available at a minimum the Party proposing the Disclosure will provide the other Party information on the general content and key messages proposed. The Parties agree whenever possible to provide press releases containing any Disclosure [\*\*\*\*] prior to proposed release. Notwithstanding the foregoing, this restriction does not prohibit a party from making Disclosures required by, or highly advisable under, law or government regulation (as determined by opinion of counsel of the party proposing such Disclosure). If a Party decides, upon the advice of counsel that a Disclosure is required or highly advisable, the Party will, insofar as is reasonably practical, notify the other Party of the decision and provide the other Party an advance copy for review and comment.

Indemnification: Section 12.1 (b), "Indemnification for Marketing", in the Collaboration Agreement remains in full force. Notwithstanding the above, P&GP will not indemnify and hold harmless Alexion from and against any losses to the extent due to Alexion's gross negligence or willful or intentional misconduct. In the event that the Collaboration is terminated, Alexion agrees to provide an indemnification to P&GP in respect of Product commercialized by Alexion after termination, consistent with "Indemnification for Marketing" Section 12.1(b) in the Collaboration Agreement.

## CHANGE IN CONTROL

1. Change in Control. Except as set forth in this provision ("Change in Control"), neither Party's consent is necessary to a Change in Control of the other Party, and the Collaboration Agreement shall be binding upon and inure to the benefit of either Party's successors in interest following any such Change in Control transaction. Section 13.7(a), (b) 13.9 (c) of the Collaboration Agreement are deleted.
2. Notice. At any time during the Term, either P&GP or Alexion (the "Acquired Party") may notify (the "Notice") the other Party (the "Continuing Party") that it is contemplating a Change of Control transaction with a Third Party Company. All information provided in the Notice and otherwise provided in connection with the proposed Change of Control shall be maintained by the Continuing Party in the strictest confidence, including the fact that a Change of Control has been discussed and the name of the relevant Third Party Company, and the Continuing Party will restrict knowledge of such matters only to those of its employees who have a need to know the same.
3. Valuation Election. Within [\*\*\*\*\*] following receipt of the Notice, the Continuing Party may elect in writing (the "Election") delivered to the Acquired Party to cause a valuation to be made of the Acquired Company's entire interest in the Collaboration Agreement (the "Acquired Company's Agreement Interest") and the Continuing Company's entire interest in the Collaboration (the "Continuing Company's Agreement Interest", and together with the Acquired Company's Agreement Interest, the "Agreement Interest(s)"). Failure of the Continuing Party to provide such notice shall constitute waiver of its rights under this provision ("Change in Control"), and consent for the Change in Control to occur.
4. Valuation Process. Within [\*\*\*\*\*] of receipt of the Election, the Acquired Party and the Continuing Party shall each retain an internationally recognized investment banking firm to determine the value of the Agreement Interests (the "Prices"). If either Party fails to deliver notice to the other Party of its selection of an investment banking firm within such period, the Price determinations shall be rendered by the single investment banking firm so selected. If the

Continuing Party has elected to cause the valuation to be made, it shall pay all fees and expenses of the investment bank(s). The investment banking firms selected in accordance with the foregoing procedure shall each determine the values of the Agreement Interests and submit their determinations of such values to the Parties within seven days following their selection. The values of Alexion's Agreement Interest and P&GP's Agreement Interest will be determined as set forth in Clause 9 below. The Price of each Party's Agreement Interest shall be the sum of the relevant values determined by each firm therefor, divided by two; provided, however, that if there is more than a [\*\*\*\*\*] percent ([\*\*\*\*\*]%) difference between the two such values for either or both such Agreement Interests, then within [\*\*\*\*\*] of when they have determined such values, the first two firms shall select a third internationally recognized investment banking firm to determine the Price of the Agreement Interest(s) that diverged more than [\*\*\*\*\*] (which shall be determined by such firm [\*\*\*\*\*] of selection, and in no event be outside the range determined by the first two investment banking firms).

5. Put/Call Election. Within [\*\*\*\*\*] ([\*\*\*\*\*]) [\*\*\*\*\*] following determination of the Price, the Continuing Party will irrevocably elect to (i) allow the Change in Control to occur, (ii) require the Third Party Company to purchase the Continuing Party's Agreement Interest at the relevant price, (iii) purchase the Acquired Party's Agreement Interest at the relevant price.
6. Purchase Consummation. Any purchase and sale of an Agreement Interest effected pursuant to this provision ("Change in Control") shall be consummated at a closing at the offices of the Continuing Party on a business day within [\*\*\*\*\*] following the determination of the relevant Price upon at least [\*\*\*\*\*] notice by the Third Party Company to the other parties to the transaction; or the earliest time thereafter following receipt of necessary governmental or regulatory approvals with respect to such transaction and the Change in Control transaction contemplated by Clause 2 above. At such closing, the Third Party Company (or its designee) or the Continuing Party (or its designee), as the case may be, shall pay the relevant Price by certified check or wire transfer of funds. In no event will such purchase and sale of an Agreement Interest occur unless and until the Third Party Company identified under Clause 2 above consummates the Change in Control transaction with the Acquired Company contemplated by the Notice.

7. Purchase Documentation. Upon the closing of the transactions contemplated by Clause 6 above, the Parties and the Third Party Company shall execute such customary instruments of transfer, licenses and other agreements as are necessary to transfer all of the relevant Agreement Interest to assure that the party acquiring such interest shall be able to enjoy the benefits thereof. The Party whose Agreement Interest is acquired shall license or sublicense all of its intellectual property necessary for the manufacture, use or sale of Products in the Field, and the party acquiring such Agreement Interest shall assume all obligations, including payment obligations, to any Third Party from whom the party whose Agreement Interest is acquired licenses such intellectual property. All other necessary agreements (e.g., supply) will also be transferred; or if not transferable, the benefits thereof will otherwise be provided.
8. Third Party Company. "Third Party Company" shall mean, in the case of P&GP, the five companies listed by it on Schedule III (together with their majority owned, direct or indirect subsidiaries), and in the case of Alexion, the five companies listed by it on Schedule III (together with their majority owned, direct or indirect subsidiaries). Each Party shall supply its initial list to the other following execution and delivery of this Memorandum. Either Party may revise its list by written notice to the other delivered within [\*\*\*\*\*] on or after [\*\*\*\*\*] and [\*\*\*\*\*] during the Term. Within [\*\*\*\*\*] on or after [\*\*\*\*\*] and [\*\*\*\*\*] during the Term, Alexion agrees to provide P&GP a written reminder of P&GP's rights under this Section. Neither Party shall have the right to amend its list of 5 companies after the Acquired Party publicly announces, or confidentially notifies the Continuing Party, that it proposes a Change of Control transaction with a company that is not on the list.
9. Agreement Interests. The retained investment banks shall be instructed to value P&GP's Agreement Interest at the amount that, on the basis of market and other conditions prevailing at such time could reasonably be expected to be paid by a third party in an arm's-length transaction for [\*\*\*\*\*]. The retained investment banks shall be instructed to value Alexion's Agreement Interest at the amount that, on the basis of market and other conditions prevailing at such time is the difference between what could reasonably be expected to be paid by a third party in (i) an arm's-length transaction for [\*\*\*\*\*].

10. Closing Condition. Consummation of any Change In Control transaction will require that the Third Party Company agree to be bound by the terms of this provision ("Change in Control").

SUBSTANTIAL STOCK ACCUMULATION: Section 13.8 of the Collaboration Agreement applies only to accumulation in the equity of one Party hereto by a Third Party Company listed by the other Party hereto. Further, Section 13.8 has no force or effect in regard to a Third Party following a Change of Control involving such Third Party.

EXECUTION OF THIS MEMORANDUM OF UNDERSTANDING: Upon execution, the terms of this Memorandum will be in full force and effect. The Parties agree to diligently negotiate the terms of the Restatement. Prior to the Restatement being executed, in the event an issue is not addressed in this Memorandum but is in the Collaboration Agreement, the Parties will operate under the Collaboration Agreement on the issue. Prior to the Restatement being executed, the Parties agree Section 13.2 of the Collaboration Agreement, "Termination", remains in full force; provided, however, Section 13.2(a) of the Collaboration Agreement is deleted, and replaced by the following: "Procter & Gamble may terminate the Agreement upon six (6) months prior written notice to Alexion."

IN WITNESS WHEREOF, the Parties have signed this Memorandum as of  
December 11, 2001.

ALEXION PHARMACEUTICALS, INC.

By: /s/ David W. Keiser

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Name:  
Title:

PROCTER & GAMBLE PHARMACEUTICALS, INC.

By: /s/ Mark A. Collar

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Name:  
Title:

SCHEDULE 1

Executorial Responsibilities: Clinical Programs

Task	CABG Phase III Program		AMI Phase III Program	
	R	I	R	I
Project Leadership*	Shared	Shared	Shared	Shared
Program Physician-Global/NA	[*****]	[*****]	[*****]	[*****]
Program Physician-Europe/ROW	[*****]	[*****]	[*****]	[*****]
CRO/Vendor Contracts, Bids and Scope Changes	[*****]	[*****]	[*****]	[*****]
Site Contracts and Budgets	[*****]	[*****]	[*****]	[*****]
Statistics and Biometrics including DSMB data flow	[*****]	[*****]	[*****]	[*****]
Clinops-NA	[*****]	[*****]	[*****]	[*****]
CRO Interaction-NA	[*****]	[*****]	[*****]	[*****]
Vendor (e.g., Core Labs) Interaction	[*****]	[*****]	[*****]	[*****]
Site Interaction-NA	[*****]	[*****]	[*****]	[*****]
Clinops-Europe/ROW	[*****]	[*****]	[*****]	[*****]
CRO/Vendor Interaction- Europe/ROW	[*****]	[*****]	[*****]	[*****]
Site Interaction- Europe/ROW	[*****]	[*****]	[*****]	[*****]
Clinical Supplies	[*****]	[*****]	[*****]	[*****]
Clinical QA	[*****]	[*****]	[*****]	[*****]
Pharmacovigilance NA ***	[*****]	[*****]	[*****]	[*****]

Pharmacovigilance EU	[*****]	[*****]	[*****]	[*****]
PK and PD	[*****]	[*****]	[*****]	[*****]
Pharmacoeconomics	[*****]	[*****]	[*****]	[*****]
Regulatory U.S.	[*****]	[*****]	[*****]	[*****]
Regulatory ROW	[*****]	[*****]	[*****]	[*****]
Clinical Data Management	[*****]	[*****]	[*****]	[*****]
Medical Writing	[*****]	[*****]	[*****]	[*****]
Global Marketing Application Prep/Mgmt	[*****]	[*****]	[*****]	[*****]

Abbreviations: R = Responsibility; I = Input; P = P&GP; A = Alexion

\* Each company will appoint a project leader.

\*\* [\*\*\*\*\*] to have ability to set up initial site budget and contract in select cases

\*\*\* [\*\*\*\*\*] will have global responsibility for collecting and analyzing adverse events and will own the database. Sponsor will be responsible for filing the information with all regulatory authorities.

## SCHEDULE II

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This document provides some expectations for involvement of the partner company in FDA interactions (Alexion for BB IND 8651 [AMI] and P&GP for BB IND 6592 [CPB]). These expectations apply to all aspects of the project, including CMC.

The primary expectation is that the partner should be involved in all FDA interactions where strategic and executional issues are discussed, unless both partners have agreed in advance that it is not necessary.

Both partners should be involved in all scheduled FDA interactions, unless there is an agreement in advance. When possible, the Regulatory Affairs Managers in both companies should discuss and anticipate FDA interactions and reach agreements about the need for involvement in advance of the FDA interaction. In the event of an unscheduled FDA interaction, both partners agree to use best efforts to involve the other partner. Unscheduled FDA interactions with a Sponsor company should be communicated immediately to the non-Sponsor company. Strategic decisions should not be made with FDA unless both companies are present in the conversation, or an agreement to make such decisions has been made by both companies in advance.

Partner involvement is not expected for administrative FDA interactions which include discussions about scheduling of interactions, response to FDA requests for additional copies of IND submissions, response to FDA requests for updates on status of DSMB review, etc.

Nearly all FDA interactions should be easily managed in one of these ways. It is recognized that in rare instances an "informal" interaction may occur where FDA's willingness to share perspective could be hampered by a delay or by the presence of additional participants in the interaction. In those rare instances it is expected that the partner company will be contacted immediately following the interaction and fully informed in writing as to the content of the discussion. Strategic decisions should not be made with FDA unless both companies are present in the conversation or an agreement to make such decisions has been made by both companies in advance. It is also expected that every effort will be made to keep

those advantageous informal discussions separate from the formal interactions where partner presence is desired.

Each Party maintains the right to directly contact FDA, other regulatory agencies, or other clinically responsible third parties (e.g., investigators, IRBs, ) on any urgent safety or other medically significant concerns; provided, however, that a non-Sponsor Party must first provide the Sponsor all information regarding such concern and allow the Sponsor to be the Party that contacts the FDA or such other agencies or third parties. If the Sponsor does not address the non-Sponsor's concerns, and the non-Sponsor deems there is a regulatory or legal requirement for reporting, the non-Sponsor reserves the right to directly contact FDA, other regulatory agencies or other clinically responsible third parties on the urgent safety or other medically significant concern. Prior to making any third party contact the non-Sponsor will inform the Sponsor of its decision.

SCHEDULE III

CHANGE IN CONTROL - THIRD PARTY COMPANIES

Companies selected by Alexion:	Companies selected by P&GP:
1. [*****]	1. [*****]
2. [*****]	2. [*****]
3. [*****]	3. [*****]
4. [*****]	4. [*****]
5. [*****]	5. [*****]

[Each party to provide the other its list following execution and delivery of this Memorandum]

SUBSIDIARIES OF ALEXION PHARMACEUTICALS, INC.

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

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

Consent of Independent Accountants

We hereby consent to the incorporation by reference in the Registration Statements File numbers 333-19905, 333-24863, 333-29617, 333-36738, 333-41397, 333-47594, 333-47645, 333-52856, 333-52886, 333-59702, 333-69478, 333-71879 and 333-71985 of our report dated October 18, 2002 relating to the consolidated financial statements of Alexion Pharmaceuticals, Inc., which appear in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Hartford, Connecticut  
October 24, 2002

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 year ended July 31, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leonard Bell, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 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

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Leonard Bell, M.D.  
Chief Executive Officer  
October 24, 2002

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 year ended July 31, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David W. Keiser, President and Chief Operating Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 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/ David W. Keiser

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David W. Keiser  
President and Chief Operating Officer  
October 24, 2002

## RISK FACTORS

The following risk factors should be carefully considered in evaluating our Company and our business because these risk factors have a significant impact on our business, operating results, financial condition, and cash flows. If any of these risks actually occurs, our business, financial condition, operating results and/or cash flows could be harmed.

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, 2002, we had an accumulated deficit of approximately \$180.8 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.

If we do not obtain regulatory approval for our drug products, we will not be able to sell our drug products.

We cannot sell or market our drugs without regulatory approval. If we do not obtain regulatory approval for our products, the value of our company and our results of operations will be harmed. In the United States, we must obtain approval from the U.S. Food and Drug Administration, or 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 of any of our product candidates, if ever, for at least the next several years.

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 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.

We have announced the completion of a Phase IIb trial of pexelizumab, one of our two lead antibody product candidates, for the treatment of complications in patients after cardiopulmonary bypass surgery, including the reduction of the frequency and severity of myocardial infarctions, or heart attacks and frequency of death. The primary therapeutic exploratory 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, the 800 patients who had coronary artery bypass graft surgery without valve surgery, those that received pexelizumab at the highest dose level experienced a significant reduction in larger post-surgical heart attacks. Based on these results, in January 2002, we commenced enrollment of a pivotal Phase III clinical trial of pexelizumab in approximately 3,000 patients undergoing coronary artery bypass graft surgery with cardiopulmonary bypass operations. The Phase III trial will assess the safety and efficacy of pexelizumab in reducing the combined incidence of death or myocardial infarction in this patient population. We cannot assure you that this trial will be successful or that any of the endpoints of the trial will be achieved.



We have also announced the completion of a Phase II trial of eculizumab, our other lead antibody product candidate, for the treatment of rheumatoid arthritis. The primary endpoint, or therapeutic pre-set goal, for this trial was met by the group of patients who received the 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.

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.

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;
- . 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 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 nor may they be readily 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 your ownership interest in our company.



On September 22, 2000, we purchased all of the capital stock and other outstanding securities of Prolifaron, Inc., a privately held biopharmaceutical company that is developing therapeutic antibodies addressing multiple diseases, including cancer, for approximately 400,000 shares of our outstanding capital stock. The business of Prolifaron, now our wholly-owned subsidiary, Alexion Antibody Technologies, Inc., or AAT, is subject to many of the same risks that our business is subject to. We cannot assure you that AAT will successfully develop any products or that we will realize any benefits from the acquisition of Prolifaron

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

- . the existence, terms and status of collaborative arrangements and strategic partnerships, such as our collaboration with Procter & Gamble;
- . the progress, timing and scope of our research and development programs;
- . the progress, timing and scope of our preclinical studies and clinical trials;
- . the time and cost necessary to obtain regulatory approvals;
- . the time and cost necessary to further develop manufacturing processes, arrange for contract manufacturing or build manufacturing facilities and obtain the necessary regulatory approvals for those facilities;
- . the time and cost necessary to develop sales, marketing and distribution capabilities;
- . the cost necessary to sell, market and distribute our products, if any are approved;
- . changes in applicable governmental regulatory policies; and
- . any new collaborative, licensing and other commercial relationships that we may establish.

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

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

We rely heavily on Procter & Gamble 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 Procter & Gamble 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 Procter & Gamble, or 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.



Prior to December 2001, Procter & Gamble was generally funding all clinical development and manufacturing costs for 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 collaboration. Per the MOU, our revised collaboration provides for us and P&G to 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. Procter & Gamble agreed to retain responsibility and costs for future development and commercialization outside the U.S. Additionally, as part of the MOU, we will receive milestone payments for achieving specified development steps, regulatory filings and approvals, but will not receive previously agreed sales milestones and will generally forego further research and development support payments from P&G.

P&G has the right to terminate the collaboration at any time. Termination of our agreement with Procter & Gamble would cause significant delays in the development of pexelizumab and result in additional development costs. If we were to continue development of pexelizumab, we would need to fund the development and commercialization of pexelizumab on our own or identify a new development partner. We cannot guarantee that Procter & Gamble will devote the resources necessary to successfully develop and commercialize pexelizumab in a timely manner, if at all. Furthermore, Procter & Gamble may devote the necessary resources, but we may still not successfully develop and commercialize pexelizumab. We might also have to repeat testing already completed with Procter & Gamble.

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, fluctuations in the trading prices or business prospects of our competitors and collaborators, including, but not limited to Procter & Gamble, 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 outstanding 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, 2001, the sales price of our common stock has ranged from a low of \$9.58 per share to a high of \$26.69 per share and since August 1, 1999, the sales price of our common stock has ranged from a low of \$10.00 per share to a high of \$119.88 per share. While we cannot predict our future performance, if



our stock continues to fluctuate in a wide range, an investment in our stock or our outstanding notes 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 obtain a license to continue the sale or development of our drugs and/or pay damages. If we cannot obtain a license, we may be prevented from the sale or development of our drugs.

Parts of our 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, recombinant human single chain antibodies, and genetically engineered animals. 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, and other products are tissues from genetically engineered animals.

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. 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 of these actions are successful, we could be required to pay damages or to obtain a license to sell or develop our drugs. A required license may not be available on acceptable terms, if at all.

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. For example, little is known about the potential long-term health risks of transplanting pig tissue into humans, a goal of our UniGraft product development program. Use of C5 Inhibitors, such as pexelizumab and eculizumab, is associated with an increased risk for infection with Neisseria bacteria. Serious cases of Neisseria infection can result in brain damage, loss of limbs or parts of limbs, kidney failure, or death.



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.

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. 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 for testing, our drug development efforts will be delayed. If any of our outside manufacturers stops manufacturing our products or reduces the amount manufactured, 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 would be materially adversely affected. Submission of products and new development programs for regulatory approval would be delayed. Our competitive position and our prospects for achieving profitability could be materially and adversely affected.

Manufacture of drug products 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 would have a materially 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.

Other than our agreement with Procter & Gamble to develop and commercialize pexelizumab, we have no arrangements to manufacture our products on a commercial basis. Currently, we are relying on Procter & Gamble to retain appropriate commercial manufacturing for pexelizumab through one or more third-party manufacturers. The failure of Procter & Gamble to obtain appropriate commercial manufacturing for pexelizumab on a timely basis, or at all, may prevent or impede the commercialization of pexelizumab. We have not proceeded far enough in negotiations with any other potential partner to be certain of the cost of a commercial manufacturing arrangement for our potential products nor have we explored the cost or time required to establish our own commercial manufacturing facility. We are aware however, that due to the nature of the current market for third-party commercial manufacturing arrangements, many arrangements would require substantial penalty payments by us if we were not to use the manufacturing capacity contracted for. 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, and have only recently begun to develop marketing personnel and capabilities. If we are unable to establish those capabilities, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully sell our 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 Procter & Gamble for sales, marketing and distribution of pexelizumab. Procter & Gamble, 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 from government health administration authorities, private health insurers and other organizations for our future products, our products may be too costly for regular use and our ability to generate revenues would be harmed.

Our products, once commercialized, like similar products in the market place, 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 a low 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 on the price of our products without a corresponding decrease in expenses will have a material adverse effect on our ability to achieve profitability.

Even if we successfully develop our products for transplanting animal cells into humans, this technology may not be accepted by the market due to medical concerns or unanticipated regulation.

Our program for the development of animal cells for transplantation into humans may never result in any therapeutic products. This technology is subject to extensive clinical testing and we are not aware of any such technology that has been approved for sale by the FDA or comparable foreign regulatory authorities. Even if we succeed in developing these products, our products may not be widely accepted by the medical community or third-party payors until more facts are established and ethical consensus is reached regarding the use of animal cells. In addition, concerns relating to the risk of introducing animal viruses to infect the human species through the transplantation process may also create additional regulatory hurdles for FDA approval. If accepted, the degree of acceptance may limit the size of the market for our products. Moreover, due to the controversial nature of transplantation of animal cells into humans generally, market prices for our securities may be subject to increased volatility.

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 Avant Immunotherapeutics, Inc, Millennium Pharmaceuticals, Inc., Tanox, Inc., Abbott Laboratories, Baxter International Inc., Gliatech Inc., Neurogen Corporation, and Biocryst Pharmaceuticals have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. We are also aware that Pfizer, Inc., GlaxoSmithKline plc and Merck & Co., 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 to even 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 specific 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, Leonard Bell, M.D., our Chief Executive Officer and Director, David W. Keiser, our President, Chief Operating Officer and Director, 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 insurance policy for Dr. Bell and we have an employment agreement with Dr. Bell. We are currently negotiating new employment agreements with Mr. Keiser and Dr. Squinto. We cannot assure you that we will be



able to negotiate employment agreements with Mr. Keiser and Dr. Squinto or what the terms of those agreements would be. To our knowledge, none of our key personnel is planning to retire or is nearing retirement age. Further, to our knowledge, there is no tension between any of our key personnel and the Board. If we lose the services of our management and scientific personnel or fail to recruit other scientific and technical personnel, our research and product development programs would be significantly and detrimentally affected.

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

The conviction of our former independent public accountants, Arthur Andersen LLP, on federal obstruction of justice charges may adversely affect Arthur Andersen LLP's ability to satisfy any claims arising from the provision of auditing services to us and may impede our access to the capital markets.

On March 14, 2002, our previous independent public accounting firm, Arthur Andersen LLP, was indicted on federal obstruction of justice charges arising from the federal government's investigation of Enron Corp. On June 15, 2002, a jury returned with a guilty verdict against Arthur Andersen LLP following a trial. As a public company, we are required to file with the U.S. Securities and Exchange Commission, or SEC, periodic financial statements audited or reviewed by an independent public accountant. On May 31, 2002, we dismissed Arthur Andersen LLP as our independent public accountants, and engaged a new independent public accounting firm to audit our financial statements for fiscal 2002. It may be impossible for you to obtain recoveries from Arthur Andersen LLP with respect to its audits of our financial statements as a result of its conviction in the Enron matter. In addition, Arthur Andersen LLP has not performed any procedures in connection with our Annual Report on Form 10-K for the fiscal year ended July 31, 2002 and has not consented to the incorporation by reference of its reports in our Annual Report on Form 10-K for the fiscal year ended July 31, 2002, and therefore, you will not be able to recover against Arthur Andersen LLP for any untrue statements of material fact contained in the financial statements audited by Arthur Andersen LLP or any omissions to state a material fact required to be stated therein.

Should we seek access to the public capital markets, the SEC rules will require us to include or incorporate by reference in any prospectus three years of audited financial statements. The SEC's current rules would require us to present audited financial statements for one or more fiscal years audited by Arthur Andersen LLP and obtain their consent and representations until our audited financial statements for the fiscal year ending July 31, 2004 become available in the first quarter ended October 31, 2004. We expect that we would not be able to obtain the necessary consent and representations from Arthur Andersen LLP who have ceased operations. As a result, we may not be able to satisfy the SEC requirements for a registration statement or for our periodic reports. Even if the SEC decides to accept financial statements previously audited by Arthur Andersen LLP, but without their current consent and representations, those financial statements would not provide us and any underwriters with the same level of protection under current securities laws as would otherwise be the case. In either of these situations, our access to the capital markets would be impaired unless PricewaterhouseCoopers LLP, our current independent public accounting firm, or another independent public accounting firm, is able to audit the financial statements originally audited by Arthur Andersen LLP. Any delay or inability to access the public capital markets caused by these circumstances could have a material adverse effect on our business, profitability and growth prospects.

THE FOLLOWING REPORT IS A COPY OF A REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP AND HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP. THE COMPANY IS UNABLE TO OBTAIN A REISSUED REPORT OR CONSENT TO INCORPORATION BY REFERENCE OF ARTHUR ANDERSEN LLP'S REPORT FROM ARTHUR ANDERSEN LLP BECAUSE ARTHUR ANDERSEN LLP HAS CEASED OPERATIONS.

Report of Independent Public Accountants

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

We have audited the accompanying consolidated balance sheets of Alexion Pharmaceuticals, Inc. (a Delaware corporation) and subsidiaries (collectively, the Company) as of July 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the three years in the period ended July 31, 2001. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Alexion Pharmaceuticals, Inc. and subsidiaries as of July 31, 2001 and 2000, and the consolidated results of their operations and their cash flows for each of the three years in the period ended July 31, 2001, in conformity with accounting principles generally accepted in the United States.

As further discussed in Note 2 to the consolidated financial statements, during the year ended July 31, 2001, the Company changed its method of revenue recognition relating to non-refundable upfront licensing fees in accordance with Staff Accounting Bulletin No. 101.

/s/ Arthur Andersen LLP

Hartford, Connecticut  
August 31, 2001

