

ALEXION PHARMACEUTICALS INC

Form 10-K

February 23, 2009

[Table of Contents](#)

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

Washington, D.C. 20549

**FORM 10-K**

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

**x Annual report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934**  
**For the fiscal year ended December 31, 2008**

or

**“ Transition report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934**  
**For the transition period from to**

Commission file number: 0-27756

**ALEXION PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

**Delaware** **13-3648318**  
(State or Other Jurisdiction of Incorporation or Organization) (I.R.S. Employer Identification No.)  
**352 Knottter Drive, Cheshire Connecticut 06410**  
(Address of Principal Executive Offices) (Zip Code)  
**203-272-2596**  
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: **Common Stock, par value \$0.0001**  
**Rights to Purchase Junior Participating Cumulative**  
**Preferred Stock, par value \$0.0001**  
Name of each exchange on which registered: **The Nasdaq Stock Market LLC**  
Securities registered pursuant to Section 12(g) of the Act: **None**

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

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

Large Accelerated Filer: ☒

Accelerated Filer: ☐

Non-Accelerated Filer: ☐

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based upon the last sale price of the Common Stock reported on The Nasdaq Stock Market LLC on June 30, 2008, was approximately \$2,795,465,875.

The number of shares of Common Stock outstanding as of February 17, 2009 was 81,695,309.

DOCUMENTS INCORPORATED BY REFERENCE

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

Portions of the registrant's Definitive Proxy Statement to be used in connection with its Annual Meeting of Stockholders to be held on May 13, 2009, are incorporated by reference into Part III of this report.

---

**Table of Contents**

**PART I**

Unless the context requires otherwise, references in this report to we, our, us, Company and Alexion refer to Alexion Pharmaceuticals, Inc. and its subsidiaries. Amounts, except per share amounts, are denominated in thousands.

**Note Regarding Forward-Looking Statements**

This annual report on Form 10-K contains forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management's beliefs and certain assumptions made by our management, and may include, but are not limited to, statements regarding the potential benefits and commercial potential of Soliris® (eculizumab), for its approved indications and any future indications, timing and effect of sales of Soliris in various markets worldwide, level of future Soliris sales and collections, costs, expenses and capital requirements, cash outflows, cash from operations, status of reimbursement, price approval and funding processes in various countries worldwide, progress in developing commercial infrastructure and interest about Soliris in the patient, physician and payor communities, the safety and efficacy of Soliris and our product candidates, estimates of the potential markets and estimated commercialization dates for Soliris around the world, sales and marketing plans, any changes in the current or anticipated market demand or medical need for Soliris, status of our ongoing clinical trials, commencement dates for new clinical trials, clinical trial results, evaluation of our clinical trial results by regulatory agencies in other countries, prospects for regulatory approval in other countries, the need for additional research and testing, the uncertainties involved in the drug development process and manufacturing, our future research and development activities, assessment of competitors and potential competitors, estimates of the capacity of manufacturing and other facilities to support Soliris and our product candidates, potential costs resulting from product liability or other third party claims, the sufficiency of our existing capital resources and projected cash needs, assessment of impact of recent accounting pronouncements, and the effect of shifting currency exchange rates. Words such as anticipates, expects, intends, plans, believes, seeks, estimates, variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this report under the section entitled Risk Factors. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in other reports or documents we file from time to time with the Securities and Exchange Commission.

**Item 1. BUSINESS.**

**Overview**

Alexion Pharmaceuticals, Inc., Alexion or the Company, is a biopharmaceutical company engaged in the discovery, development and delivery of biologic therapeutic products aimed at treating patients with severe and life-threatening disease states, including hematologic and neurologic diseases, transplant rejection, cancer and autoimmune disorders. Our marketed product Soliris® (eculizumab) is the first therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH.

## **Table of Contents**

Soliris is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation associated with chronic hematologic and neurological disorders, transplant rejection, and autoimmune disorders. Soliris is a humanized antibody that generally blocks complement activity for one to two weeks after a single dose at the doses currently prescribed. The initial indication for which we received approval for Soliris is PNH. PNH is a rare, debilitating and life-threatening, acquired genetic deficiency blood disorder defined by the destruction of red blood cells, or hemolysis. The chronic hemolysis in patients with PNH may be associated with life-threatening thromboses, recurrent pain, kidney disease, disabling fatigue, impaired quality of life, severe anemia, pulmonary hypertension, shortness of breath and intermittent episodes of dark-colored urine (hemoglobinuria).

Since our incorporation in January 1992 until April 2007, we devoted most of our resources to drug discovery, research, and product and clinical development. In March 2007, the Food and Drug Administration, or FDA, granted marketing approval for Soliris. In the United States, Soliris is indicated for the treatment of all patients with PNH to reduce hemolysis. We began commercial sale of Soliris in the United States during April 2007.

In June 2007, the European Commission, or E.C., approved the use of Soliris for patients with PNH in the European Union, which also serves as the basis for approval in Iceland and Norway. Subsequently, we engaged with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country and have initiated commercialization in those countries where this process was completed.

We have submitted an application for marketing authorization in Australia for Soliris for the treatment of patients with PNH. The application was accepted for priority review. Soliris has received Orphan Drug Designation in Australia, which provides certain regulatory and filing fee advantages, including market exclusivity, except in limited circumstances, for several years after approval. In September 2008, we were granted limited marketing authorization for Soliris for the treatment of patients with PNH in Switzerland. In January 2009, Health Canada approved the use of Soliris for patients with PNH in Canada.

We completed the 12-week AEGIS study of Japanese patients in October 2008. This study was a single registration study to evaluate the safety, efficacy, and pharmacology of Soliris as a treatment for Japanese patients with PNH. The open label study was authorized by Japan's Pharmaceutical and Medical Devices Agency. Summary results were reported in December 2008. As previously announced by the Company in December 2008, the pre-specified primary efficacy endpoint of change in hemolysis was achieved with statistical significance, and the drug appeared to be safe and well tolerated in study patients.

We are also focusing our research efforts on the use of eculizumab as a treatment for patients with other rare and severe complement-mediated conditions, including chronic hemolytic and thrombotic disorders, transplant rejection and chronic and debilitating neurological disorders. The FDA authorized our Investigational New Drug Application, or IND, for studying the safety and efficacy of eculizumab in treating myasthenia gravis, a rare autoimmune syndrome characterized by the failure of neuromuscular transmission, and we commenced clinical development in 2008. We are currently developing clinical programs to investigate the use of eculizumab as a treatment for patients with other complement-mediated disorders, including three severe, life-threatening, and rare hematologic disorders: atypical hemolytic uremic syndrome, or aHUS, a disease in which the lack of naturally occurring complement inhibitors can cause life-threatening kidney damage; catastrophic anti-phospholipid syndrome, a disorder in which uncontrollable blood clotting often leads to multiple organ failure; and cold agglutinin disease, an auto-immune hemolytic anemia. The program for aHUS was initiated in January 2009.

## **Table of Contents**

The FDA also authorized our IND to evaluate the activity of an antibody to the immune regulator CD200 in patients with chronic lymphocytic leukemia, or CLL, an incurable chronic cancer that results from expansion of B-lymphocytes, and other blood tumors such as multiple myeloma. We commenced dosing of initial CLL patients with anti-CD200 in the second quarter of 2008.

We are aware that independent investigators have commenced a study to evaluate eculizumab in organ transplantation. We are also aware that investigator-initiated trials of eculizumab have begun in patients with multifocal motor neuropathy, or MMN, a severe autoimmune neurologic disorder and dense deposit disease, a severe kidney disease.

Also, we completed a phase I/II proof of concept study of IV eculizumab in allergic asthmatic patients in the fourth quarter of 2008.

Since September 2005, we have formed a number of wholly owned subsidiaries to support commercial and regulatory operations throughout the world, including Alexion Europe SAS, our regional executive and sales office in Paris, France, Alexion International S.a.r.l., our regional executive and sales office in Lausanne, Switzerland, and additional sales and marketing subsidiaries in Belgium, France, Germany, Italy, Spain, Switzerland, the United Kingdom, Japan and Australia.

Our principal executive offices are located at 352 Knotter Drive, Cheshire, Connecticut 06410 and our telephone number is (203) 272-2596. Our Web site address is [www.alexionpharm.com](http://www.alexionpharm.com). On our Web site, we make available, free of charge, our annual and transition reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practical after we electronically file such material with or furnish it to the SEC. The information found on our Web site is not part of this or any other report we file with or furnish to the SEC.

## ***Litigation***

In March 2007, PDL BioPharma, Inc., or PDL, filed a civil action against us in the U.S. District Court for the District of Delaware claiming willful infringement of certain PDL patents, or the PDL Patents, due to sales of Soliris. We denied such claims and filed counterclaims. In December 2008, we entered into a patent license agreement and settlement agreement with PDL for the purpose of resolving all claims previously filed by PDL and all counterclaims previously filed by Alexion. Pursuant to the patent license agreement, we acquired a fully paid, nonexclusive, irrevocable, perpetual worldwide license to some claims of the PDL Patents and a covenant not to sue from PDL for other claims of the PDL Patents, in each case for the commercialization of Soliris for all indications. We are obligated to make a total of \$25,000 in payments to PDL, \$12,500 of which was paid in January 2009 and \$12,500 of which is due in June 2009. No royalties or other amounts are owed to PDL with respect to sales of Soliris for any indication. Upon receipt of the \$25,000 license payment, the previously announced claims filed by PDL and counterclaims filed by us will be dismissed. Under the terms of the patent license agreement, PDL separately granted us the right to take a worldwide, royalty-bearing license under the PDL Patents to commercialize additional Alexion humanized antibodies that may be covered by the PDL Patents in the future.

## ***Matters Relating to our Common Stock***

In July 2008, the Company's Board of Directors approved a two-for-one stock split to be effected in the form of a 100 percent stock dividend. The additional shares were distributed on August 22, 2008 to stockholders.

## **Table of Contents**

of record as of the close of trading on August 12, 2008. All share and per share data presented in this Form 10-K have been retroactively restated to reflect this stock split.

In October 2008, certain holders of our 1.375% Convertible Senior Notes due February 2012 exercised conversion rights with respect to an aggregate principal amount of \$52,778 resulting in the issuance of 3,356 shares of Alexion common stock. The shares were issued in November 2008. As of December 31, 2008, the outstanding principal balance of the notes is \$97,222.

### ***Products and Development Programs***

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

potential 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 cause excessive or inappropriate activation, which may result in acute and chronic inflammatory conditions and damage to healthy tissues.

Some of the hematologic, autoimmune, or inflammatory diseases in which the complement cascade is activated include:

PNH;

myasthenia gravis;

multifocal motor neuropathy;

asthma;

autoimmune and other hemolytic anemias;

atypical hemolytic uremic syndrome;

transplantation;

cold agglutinin disease;

membranoproliferative glomerulonephropathy type II (dense deposit disease);

Guillain-Barré syndrome;

rheumatoid arthritis;

age-related macular degeneration;

antiphospholipid antibody syndrome including the catastrophic form;



**Table of Contents**

autoimmune kidney disease;

lupus;

inflammatory skin and muscle disorders; and

specific types of multiple sclerosis.

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. Eculizumab is an antibody known as a C5 complement inhibitor, or a C5 Inhibitor, which is designed to selectively block the production of inflammation-causing proteins of the complement cascade. We believe that selective suppression of this immune response may provide a significant therapeutic advantage relative to existing therapies. In addition to PNH, for which the use of eculizumab has been approved in the United States, Europe and Canada, we believe that C5 Inhibitors may be useful in the treatment of a variety of other serious diseases and conditions resulting from aberrant complement response.

Our drug programs, including investigator sponsored programs, are as follows:

<b>Program</b>	<b>Indication</b>	<b>Stage</b>
Soliris (eculizumab)	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Approved (U.S., E.U. and Canada)
Eculizumab (intravenous)	Atypical HUS	Phase II
	Presensitized Renal Transplant*	Phase II
	Myasthenia Gravis	Phase II
	Multifocal Motor Neuropathy*	Phase II
	Dense Deposit Disease*	Phase II
	Catastrophic Antiphospholipid Syndrome	Preclinical
	Cold Agglutinin Disease	Preclinical
Eculizumab (new formulation)	Asthma	Phase I/II
CD200 Mab	CLL	Phase I/II
	Multiple Myeloma	Preclinical

\* Investigator sponsored program

**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.

## **Table of Contents**

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

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

activation of platelets, white blood cells, and blood-vessel lining endothelial cells that are deficient in complement inhibitors;

activation and destruction of muscle and other tissue cells;

activation of white blood cells;

attraction of white blood cells into inflamed tissues;

production of inflammatory chemicals including tumor necrosis factor-alpha;

activation of blood-clotting systems;

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

activation of kidney cells; and

initiation of cell suicide programs in heart cells.

The following diagram illustrates the complement cascade:

Because of the generally beneficial effects of the components of the complement cascade prior to C5 and the potent inflammatory, destructive and disease-promoting effects of the cleavage products of C5, we have identified C5 as an effective anti-inflammatory drug target. Our C5 Inhibitor, eculizumab, specifically and tightly binds to C5 blocking its cleavage into harmful byproducts, which inhibits subsequent damage from the downstream inflammatory mediators.

In human studies Soliris, a C5 Inhibitor, had the following effects in patients with PNH:

reduction of red blood cell destruction (hemolysis);

reduction in incidence of life-threatening blood clots (thromboses) in a broad patient population, including in patients with a history of aplastic anemia and myelodysplastic syndromes;



**Table of Contents**

improvement of severe anemia;

improvement of disabling fatigue and other quality of life outcomes;

decrease or elimination of blood transfusion requirements;

reduction of inflammation and blood clotting activation;

reduction in chronic kidney disease; and

reduction in incidence of high blood pressure in the lungs (pulmonary hypertension).

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

prevention and amelioration of asthmatic attacks;

enhancement of survival in organ transplantation models;

prevention of kidney damage and preservation of kidney function in a model of complement inhibitor deficiency;

prevention of nerve degeneration and improvement in function in myasthenia gravis models;

prevention of nerve degeneration and improvement in function in multifocal motor neuropathy model;

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

enhancement of survival in a model of lupus; and

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

***Soliris***

Soliris is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation related to chronic hematologic, neurologic and autoimmune disorders and transplant rejection. Soliris is a humanized antibody which, administered at the doses currently prescribed, generally blocks complement activity for one to two weeks after a single dose.

The FDA granted marketing approval for Soliris for patients with PNH in March 2007, the E.C. approved the use of Soliris for patients with PNH in the European Union in June 2007 and Health Canada approved the use of Soliris for patients with PNH in January 2009. Soliris has been granted orphan drug designation for the treatment of PNH which entitles us to exclusivity for seven years in the United States and for ten years

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

in Europe. However, if a competitive product that is the same as Soliris, as defined under the applicable regulations, is shown to be clinically superior to our product in the treatment of PNH, or if a competitive product is different from Soliris, as defined under the applicable regulations, the orphan drug exclusivity we have obtained may not block the approval of such competitive product. We market and sell Soliris with our own sales force. Following approval by the E.C., we engaged with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country and have initiated commercialization where this process was completed. In some European countries, we recorded meaningful sales to individual patients through approved named-patient programs during 2008.

## **Table of Contents**

We have submitted an application for marketing authorization in Australia for Soliris for the treatment of patients with PNH. The application was accepted for priority review. Soliris has received Orphan Drug Designation in Australia, which provides certain regulatory and filing fee advantages, including market exclusivity, except in limited circumstances, for several years after approval. In September 2008, we were granted limited marketing authorization for Soliris for the treatment of patients with PNH in Switzerland. In January, 2009, Health Canada approved the use of Soliris for patients with PNH in Canada.

We completed the 12-week AEGIS study of Japanese patients in October 2008. This study was a single registration study to evaluate the safety, efficacy, and pharmacology of Soliris as a treatment for Japanese patients with PNH. The open label study was authorized by Japan's Pharmaceutical and Medical Devices Agency. Summary results were reported in December 2008. As previously announced by the Company in December 2008, the pre-specified primary efficacy endpoint of change in hemolysis was achieved with statistical significance, and the drug appeared to be safe and well tolerated in study patients.

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

PNH is a rare, debilitating and life-threatening acquired genetic deficiency blood disorder defined by the destruction of red blood cells. Patients with PNH have an acquired genetic deficiency in certain protective proteins on the surface of their blood cells, allowing their own complement system to attack and destroy these blood cells. Patients with PNH suffer from chronic complement activation of some of their blood cells and hemolysis, or destruction of red blood cells caused by the C5 cleavage product C5b-9. This hemolysis is believed to lead to further clinical complications including thromboses, kidney disease, liver dysfunction, disabling fatigue, impaired quality of life, recurrent pain, shortness of breath, pulmonary hypertension, intermittent episodes of dark colored urine (hemoglobinuria), and anemia. The red blood cell destruction may be sufficiently large that recurrent blood transfusions are necessary to support normal red blood cell function. The prevalence, or number of affected patients at any one time, has not been definitively determined but has been estimated at approximately 8,000–10,000 total patients in North America and Western Europe. Approximately one-half of the patients with PNH die from the disease within 10-15 years of diagnosis. Soliris is the only therapy approved for PNH.

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

## **Eculizumab Development Programs: Chronic Hemolytic and Thrombotic Disorders**

### **Atypical Hemolytic Uremic Syndrome (aHUS)**

Atypical hemolytic uremic syndrome, or aHUS, is a rare life-threatening disease characterized by the triad of microangiopathic hemolytic anemia, low platelet count and acute renal failure. It is a disorder of the regulation of the complement alternative pathway; many patients exhibit genetic mutations in complement inhibitor genes. It is a thrombotic microangiopathy that affects small blood vessels leading to chronic intravascular hemolysis, consumption of platelets, and clots in kidney blood vessels, resulting in acute renal failure. The prognosis for patients with aHUS is poor. Approximately 70% of patients with the most common mutation experience chronic renal insufficiency, chronic dialysis, or death by one year after the first clinical episode. Atypical HUS commonly recurs in patients who undergo renal transplantation. In addition, depending on the mutation, the disease can lead to loss of the transplanted kidney in up to approximately 90% of aHUS patients who undergo kidney transplantation.

## **Table of Contents**

Approximately 50% of patients with aHUS have been identified to have genetic mutations in one of the complement control proteins or neutralizing autoantibodies to complement regulatory factors, which can lead to uncontrolled complement activation. Excessive complement activation may contribute to the blood vessel inflammation and clotting by stimulating activation of white blood cells, platelets, and the endothelial lining of blood vessels.

In December 2008, preliminary data on the use of eculizumab in two patients with aHUS outside, of a clinical trial, was presented at the American Society of Hematology Meeting in San Francisco. We are currently initiating four prospective, open-label clinical studies of eculizumab as a treatment for patients with aHUS in North America and multiple European countries.

### **Catastrophic Antiphospholipid Syndrome (CAPS)**

Antiphospholipid syndrome, or APS, is an autoimmune condition characterized by blood vessel clotting in the presence of antibodies that target specific proteins (antiphospholipid, or aPL). Catastrophic antiphospholipid syndrome, or CAPS, is a rare and extreme form of APS characterized by near simultaneous clotting of blood vessels in multiple organs leading to multiorgan failure. Initial mortality in patients experiencing a first episode of CAPS is approximately one-quarter to one-half and treatment with anticoagulants may be ineffective.

In pregnant patients with APS, activated complement proteins are identified in the placenta. In animal models of APS, inhibition of complement rather than anticoagulation is required to block fetal loss. C5 inhibitor treatment in animal models of APS was shown to inhibit blood clotting and tissue damage.

### **Cold Agglutinin Disease (CAD)**

Cold Agglutinin Disease, or CAD, is a rare autoimmune hemolytic anaemia characterized by activation of the complement cascade and sticking together (agglutination) of red blood cells. Patients may be typically first afflicted after reaching the age of sixty.

As blood is cooled during circulation through the distal parts of the arms and legs, specific antibodies bind to the red blood cells resulting in activation of the complement cascade and sticking together (agglutination) of red blood cells leading to hemolysis. Clinical manifestations of CAD include symptoms of chronic hemolysis such as fatigue, dyspnea, weakness, hemoglobinuria, kidney damage, pallor and jaundice as well as cold-induced circulatory symptoms ranging from mild discomfort to severe pain in affected limbs and tissues. In the most severe cases, complications of progressive hemolysis or anemia, or complications of blood transfusions, may result in death. Current therapies, including cold avoidance, corticosteroids, immunosuppressive drugs, intravenous immunoglobulin G (IgG) and chemotherapy agents are largely ineffective in controlling hemolysis in patients with CAD.

In December 2008, preliminary data on the use of eculizumab in a patient with CAD outside of a clinical trial was presented at the American Society of Hematology Meeting in San Francisco.

### **Eculizumab Development Programs: Nephrology**

#### **Antibody-Mediated Rejection (AMR)**

Patients undergoing solid organ transplantation may experience severe antibody-mediated rejection in the early post-transplant period. For example, in a patient undergoing a kidney transplant this may be characterized by the acute onset of renal dysfunction and rapid progression to destruction of the transplanted kidney.

## **Table of Contents**

AMR results when antibodies in the transplant recipient vigorously attacks the blood vessels of the donor kidney. During severe AMR, these donor specific antibodies bind to the blood vessel lining of the donor organ and initiate activation of the complement cascade, resulting in severe blood vessel inflammation and clotting. Administration of a C5 inhibitor in animal models of AMR inhibits complement activation, tissue damage and transplant rejection.

We are aware that independent investigators commenced a study to evaluate eculizumab in presensitized renal transplant patients and we understand that patient enrollment is currently ongoing in this trial.

### **Dense Deposit Disease (DDD)**

Dense deposit disease, or DDD, also called Type II membranoproliferative glomerulonephritis, is a rare form of glomerulonephritis, associated with genetic mutations in complement inhibitor genes leading to sustained complement activation and inflammation. Clinically, it is characterized by the onset of severe proteinuria, often accompanied by nephrotic syndrome which is refractory to immunosuppressant therapy. In most cases, the disease evolves into chronic renal failure, requiring dialysis and renal transplantation.

We are aware that independent investigators have commenced a study to evaluate eculizumab in patients with dense deposit disease.

## **Eculizumab Development Programs: Chronic and Debilitating Neurological Disorders**

### **Myasthenia Gravis (MG)**

Myasthenia gravis, or MG, is a rare autoimmune syndrome characterized by autoantibodies attacking a specific target in the nerve-muscle junctions leading to failure of neuromuscular transmission. Patients with MG initially experience weakness in their ocular, or eye muscles, and the disease typically progresses to head, spinal, limb and respiratory muscles. Symptoms can include drooping eyelid, blurred vision, slurred speech, difficulty chewing or swallowing, weakness in the arms and legs and difficulty breathing.

In an experimental animal model of MG, administration of a C5 Inhibitor was found to prevent experimentally acquired MG and to inhibit disease progression.

In the third quarter of 2007, we filed an IND with the FDA to initiate clinical development and received authorization from the FDA in July 2008. Patient enrollment is currently ongoing in this Phase II clinical trial.

### **Multifocal Motor Neuropathy (MMN)**

Multifocal motor neuropathy, or MMN, is a rare autoimmune disorder in which autoantibodies attack the nerve-muscle junctions. Patients with MMN demonstrate a slow progressive asymmetrical weakness of limbs without sensory loss. Antibodies and complement activation products have been identified at the nerve-muscle junctions in diseases similar to MMN. Complement inhibition has recently been shown to be protective in animal models of MMN.

We are aware that an investigator submitted a request to a drug regulatory agency to initiate studies of eculizumab in patients with MMN. We understand that patients are currently being screened for enrollment in this Phase II clinical trial.



## **Table of Contents**

### **Eculizumab: New Formulation**

#### **Asthma**

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

Administration of a C5 Inhibitor significantly reduced bronchial inflammation and airway constriction in animal studies. The researchers found that animals given an anti-C5 blocking antibody—either systemically or when inhaled through a nebulizer (a common asthma inhalation device)—showed substantial reductions in airway reactivity, even in the face of airway challenges with methacholine, a drug administered to confirm an asthma diagnosis. We completed a phase I/II proof of concept study of IV eculizumab in allergic asthmatic patients in the fourth quarter of 2008.

### **Other Product Candidates**

#### **Anti-CD200 Antibody: Oncology Programs**

We are developing an antibody for the treatment of B-Cell Chronic Lymphocytic Leukemia, or B-CLL, an incurable chronic cancer that results from expansion of B-lymphocytes and other cancers including blood tumors such as multiple myeloma, or MM. Our antibody binds to CD200, a protein that is upregulated on the surface of B-CLL and MM tumor cells. Our antibody targets CLL and MM cells and blocks the interaction of CD200 with the CD200 receptor, with the objective of enhancing the body's immune response to these tumors. Our anti-CD200 antibody has been shown to have potent anti-tumor activity in a model of CLL.

The FDA has authorized our IND to study the activity of an antibody to the immune regulator CD200 in patients with chronic lymphocytic leukemia, or CLL, an incurable chronic cancer that results from expansion of B-lymphocytes. We commenced dosing of initial CLL patients with our anti-CD200 antibody in the second quarter of 2008.

#### **Antibody Discovery Technology Platform**

In September 2000, we acquired Prolifaron, Inc., a privately held biopharmaceutical company and integrated this entity into Alexion as a wholly-owned subsidiary, Alexion Antibody Technologies, Inc. or AAT. The AAT technology includes extensive research expertise and methodologies that we call Combinatorial Human Antibody Library Technologies or CoALT, in the area of creating fully human antibodies from libraries containing billions of human antibody genes. As of December 31, 2006, we terminated operations at AAT and relocated CoALT and other AAT technologies to our expanded research and discovery groups in our Cheshire, Connecticut headquarters.

Our goal, through CoALT and related technologies, is to develop new fully human or humanized therapeutic antibodies addressing multiple disease areas, including autoimmune and inflammatory disorders and cancer. These technologies involve, in part, the generation of diverse libraries of human antibodies derived from patients' blood samples, and the screening of these libraries against a wide array of potential drug targets. We believe that these technologies may be optimally suited to the rapid generation of novel, fully human and humanized, therapeutic antibodies directed at validated clinical targets. To date, we have focused on identifying antibodies that may be therapeutically effective in different cancers, and autoimmune and inflammatory

## **Table of Contents**

disorders. In addition, we believe that these technologies could permit the preclinical validation of new gene targets that are being identified by numerous groups from recent access to the human genome. We also believe that these technologies might identify therapeutic antibodies when the libraries are screened against certain of these new gene targets.

### **Manufacturing**

We currently rely on a single third-party contract manufacturer for commercial quantities of Soliris. We obtain drug product to meet our requirements for clinical studies using both internal and third-party contract manufacturing capabilities. For both clinical and commercial requirements, we have contracted and expect to continue contracting for product finishing, vial filling and packaging through third parties.

In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island for the future commercial production of Soliris and manufacturing development of future products. We have completed production of eculizumab for process validation purposes and are in the process of compiling a supplemental BLA, or sBLA, for commercial production of eculizumab at this facility. We expect to submit the sBLA in 2009. We transferred our pilot manufacturing capabilities from New Haven, Connecticut to Smithfield, Rhode Island during 2007, and we have commenced the use of this facility for the production and purification of certain of our product candidates for clinical studies.

Our most significant agreement with a third party manufacturer is the Large-Scale Product Supply Agreement with Lonza Sales AG, or Lonza, dated December 18, 2002, which has been amended from time to time. This agreement, the Lonza Agreement, relates to the manufacture of eculizumab. We executed the latest amendment to the Lonza Agreement in June 2007 to provide for additional production and minimum quantity purchase commitments of Soliris of \$30,000 to \$35,000 from 2009 through 2013. Such commitments may be cancelled only in limited circumstances. If we terminate the Lonza Agreement without cause, we will be required to pay for batches of product scheduled for manufacture under our arrangement.

We are required to prepay certain amounts to Lonza related to the production of Soliris, which are reflected as prepaid manufacturing costs. Once we take title to the inventory produced by Lonza, the amounts are reclassified into inventory. On an ongoing basis, we evaluate our plans to proceed with production of Soliris by Lonza, which depends upon our commercial requirements as well as the progress of our clinical development programs.

### **Sales and Marketing**

We have established a commercial organization to support sales of Soliris in the United States, in the major markets in Europe and, on a more limited basis, in Japan and the Asia Pacific region. Our sales force is small in both the United States and Europe compared to other drugs with similar gross revenues; however, we believe that a relatively smaller sales force is appropriate to effectively market Soliris given the limited PNH patient population. If we receive regulatory approval in territories other than the United States, Europe and Canada, we may expand our own commercial organizations in such territories and market and sell Soliris through our own sales force in these territories. However, we will evaluate sales efforts on a country-by-country basis, and it is possible that we will promote Soliris in collaboration with marketing partners or rely on relationships with one or more companies with established distribution systems and direct sales forces in certain countries.

**Table of Contents****Customers**

In the United States, our customers are primarily specialty distributors and specialty pharmacies who supply physician office clinics, hospital outpatient clinics, infusion clinics or home health care providers. In some cases, we also sell Soliris to government agencies. Outside the United States, our customers are primarily hospitals, hospital buying groups, pharmacies, other health care providers and distributors.

During 2008, sales to our single largest customer, AmerisourceBergen, accounted for 21% of our Soliris net product sales, and no other customer individually accounted for more than 10% of total net product sales.

During 2007, sales to our three largest customers accounted for the following portions of our Soliris net product sales, and no other customer individually accounted for more than 10% of net sales:

<b>Customer</b>	<b>December 31, 2007</b>
Amerisource Bergen Corporation	40.4%
IDIS Limited	24.7%
McKesson Corporation	11.1%
	76.2%

We generally do not focus our promotional activities on distributors, and they do not set or determine demand for Soliris. Because of the pricing of Soliris, the limited number of patients, the short period from sale of product to patient infusion and the lack of contractual return rights, Soliris customers generally carry limited inventory.

Please also see Management's Discussion and Analysis - Revenues, and Note 17 on Page F-41, for financial information about geographic areas.

**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, as well as patents that we have licensed or may license from other parties, to develop and maintain our competitive position.

We have filed several U.S. patent applications and international counterparts of certain of these applications. In addition, we have in-licensed several additional U.S. and international patents and patent applications. As of December 31, 2008, we own or in-license over 78 U.S. patents and 42 U.S. patent applications. These patents and patent applications relate to technologies or products in the C5 Inhibitor program, high throughput screening, vectors, cancer, recombinant antibodies, and other technologies. We own or in-license 61 foreign patents and 140 pending foreign patent applications. We owe royalties to a third party and other fees to owners of one or more patents in connection with the manufacture and sale of Soliris for PNH, and we may owe royalties and fees to other third parties with respect to any future commercial manufacture and sale of Soliris and our product candidates.

## **Table of Contents**

We record actual and estimated royalties to third parties related to the sale and commercial manufacture of Soliris. These estimates are influenced by our assessment of the likelihood of third parties asserting that their patents are infringed by the manufacture or sale of Soliris and the likely outcome of any such assertion (see Note 11 of the Consolidated Financial Statements included in this Form 10-K). On a periodic basis and based on specific events such as the outcome of litigation, we may reassess these estimates, resulting in adjustments to cost of sales.

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

We are aware of broad patents owned by others relating to the manufacture, use and sale of recombinant humanized antibodies, recombinant human antibodies, and recombinant human single chain antibodies. Soliris and many of our product candidates are either genetically engineered antibodies, including recombinant humanized antibodies, recombinant human antibodies, or recombinant human single chain antibodies. We have received notices from the owners of patents claiming that their patents may be infringed by the development, manufacture or sale of Soliris or some of our drug candidates. We are also aware of other patents owned by third parties that might be claimed by such third parties to be infringed by the development and commercialization of Soliris or some of our drug candidates. In respect to some of these patents, we have obtained licenses, or expect to obtain licenses. However, with regard to such other patents, we have determined in our judgment that:

our products do not infringe the patents;

the patents are not 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.

If any patent holder successfully challenges our judgment that our products do not infringe their patents or that their patents are invalid, we could be required to pay costly damages or to obtain a license to sell or develop our drugs. A required license may be costly or may not be available on acceptable terms, if at all. A costly license, or inability to obtain a necessary license, could materially and adversely affect our ability to commercialize our products, including Soliris.

## **Table of Contents**

It is our policy to require our employees, consultants and parties to collaborative agreements to execute confidentiality agreements upon the commencement of employment or consulting relationships or collaborations with us. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us is to be kept confidential and not to be disclosed to third parties except in specific circumstances. In the case of employees, the agreements also 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.

## **License Agreements**

In March 1996, the Company entered into a license agreement with the Medical Research Council, or MRC, whereby MRC granted to the Company worldwide non-exclusive rights to certain patents related to the humanization and production of monoclonal antibodies. We pay MRC royalties on a quarterly basis with respect to sales of Soliris. The royalty is payable until the last to expire of the patents covered by the license agreement, which is expected to be in 2015. MRC may terminate the license if Alexion files for bankruptcy or becomes insolvent, or if Alexion fails to perform its obligations under the agreement and such failure is not remedied within three months after delivery of notice. Under the agreement, Alexion has agreed to (a) make royalty payments with respect to sales of licensed products, (b) promote the sale of Soliris of good marketable quality, and (c) use reasonable endeavors to meet market demand for licensed products.

In December 2008, we entered into a patent license agreement with PDL in connection with the resolution of all civil claims previously filed by PDL and all counterclaims previously filed by Alexion. Pursuant to the license agreement, we acquired a fully paid, nonexclusive, irrevocable, perpetual worldwide license to some claims of certain PDL patents and a covenant not to sue from PDL for other claims of such PDL patents, in each case for the commercialization of Soliris for all indications.

We are party to other license agreements related to the manufacture and sale of Soliris, however, as with the PDL license agreement, we do not pay royalties under such agreements with respect to sales of Soliris.

## **Government Regulation**

The preclinical studies and clinical testing, manufacture, labeling, storage, record keeping, advertising, promotion, export, and marketing, among other things, of our products and product candidates, including Soliris, 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. Soliris is regulated by the FDA as a biologic. Biologics require the submission of a Biologics License Application, or BLA, and approval by FDA prior to being marketed in the United States. Manufacturers of biologics may also be subject to state regulation. Failure to comply with FDA requirements, both before and after product approval, may subject us and/or our partners, contract manufacturers, and suppliers to administrative or judicial sanctions, including FDA refusal to approve applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, fines and/or criminal prosecution.

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

- (1) preclinical laboratory tests and animal tests;

## **Table of Contents**

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

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

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

Clinical trials are typically conducted in three sequential phases, but the phases may overlap and different trials may be initiated with the same drug candidate within the same phase of development in similar or differing patient populations. Phase I studies may be conducted in a limited number of patients, but are usually conducted in healthy volunteer subjects. The drug is usually tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmacodynamics and pharmacokinetics.

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

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

The results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA as part of a BLA requesting approval to market the product candidate. Under the Prescription Drug User Fee Act, as amended, the fees payable to the FDA for reviewing a BLA, as well as annual fees for commercial manufacturing

## **Table of Contents**

establishments and for approved products, can be substantial. Each BLA submitted to the FDA for approval is typically reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If found complete, the FDA will file the BLA, thus triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable. The FDA's established goals for the review of a BLA is six months for Priority applications and 10 months for Standard applications, whereupon a review decision is to be made. The FDA, however, may not approve a drug within these established goals and its review goals are subject to change from time to time. Further, the outcome of the review, even if generally favorable, may not be an actual approval but an action letter that describes additional work that must be done before the application can be approved. Before approving a BLA, the FDA may inspect the facilities at which the product is manufactured and will not approve the product unless current Good Manufacturing Practices, or cGMP, compliance is satisfactory. The FDA may deny approval of a BLA if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can delay the approval process. FDA approval of any application may include many delays or never be granted. If a product is approved, the approval will impose limitations on the indicated uses for which the product may be marketed, may require that warning statements be included in the product labeling, and may require that additional studies be conducted following approval as a condition of the approval, may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. To market a product for other indicated uses, or to make certain manufacturing or other changes requires FDA review and approval of a BLA Supplement or new BLA. Further post-marketing testing and surveillance to monitor the safety or efficacy of a product is required. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. In addition new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

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

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

## **Table of Contents**

### **Orphan Drug Designation**

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

### **Foreign Regulation**

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

For example, under European Union regulatory systems, we may submit marketing authorizations either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions, and the holder of a national marketing authorization may submit an application to the remaining member states. We submitted our Marketing Authorization Application for Soliris for the treatment of PNH to the European Medicines Agency, or EMEA, using the centralized procedure.

In June 2007, the European Commission, or E.C., approved the use of Soliris for patients with PNH in the European Union, which also serves as the basis for approval in Iceland and Norway. The EMEA reviewed the Soliris MAA under its Accelerated Assessment Procedure and Soliris was the first product approved in the European Union under such process. In September 2008 we were granted limited marketing authorization for Soliris for the treatment of patients with PNH in Switzerland. In January, 2009, Health Canada approved the use of Soliris for patients with PNH in Canada.

### **Reimbursement**

Sales of pharmaceutical products depend in significant part on the coverage and reimbursement policies of government programs, including Medicare and Medicaid in the United States, and other third-party payers. These health insurance programs may restrict coverage of some products by using payor formularies under which only selected drugs are covered, variable co-payments that make drugs that are not preferred by the payor more expensive for patients, and by using utilization management controls, such as requirements for prior authorization or prior failure on another type of treatment. Payors may especially impose these obstacles to coverage for higher-priced drugs, and consequently Soliris may be subject to payor-driven restrictions.



## **Table of Contents**

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. A member state may approve a specific price or level of reimbursement for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Following E.C. approval of Soliris for patients with PNH in June 2007, we engaged with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country and have initiated commercialization in those countries where this process is completed.

In furtherance of our efforts to facilitate access to Soliris, we have created the Soliris OneSource Treatment Support Program in the United States, a treatment support service for patients with PNH and their healthcare providers. Alexion case managers provide education about PNH and Soliris and help facilitate solutions for reimbursement, coverage and access.

## **Competition**

There are currently no approved drugs other than Soliris for the treatment of PNH. However, 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. 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 preclinical testing, human clinical trials, product manufacturing, marketing, sales and distribution and other regulatory approval and commercial procedures. They may also have a greater number of significant patents and greater legal resources to seek remedies for cases of alleged infringement of their patents by us to block, delay, or compromise our own drug development process.

We compete with large pharmaceutical companies that produce and market synthetic compounds and with specialized biotechnology firms in the U.S., Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us; in some instances, these products have already entered clinical trials or are already being marketed. Other companies are engaged in research and development based on complement proteins.

Each of Adienne, Adprotech Ltd., Alligator Biosciences, Arana Therapeutics, Avant Immunotherapeutics, Inc., XOMA, Ltd., Novo Nordisk A/S, Archemix Corporation, Evolutech Ltd., Amgen Inc., Genentech, Inc., Incode, Pharming Group N.V., CSL-Behring, Peptech Ltd., Lev Pharma, Inc., Ophtherion, Inc., Shire

## **Table of Contents**

Pharmaceuticals, Taligen, Potentia Pharmaceuticals, Inc., Ophthotech Corporation and ChemoCentryx, Inc. have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. We are also aware that Abbott Laboratories, Inc., Baxter International, Inc., Millennium Pharmaceuticals, Inc. and Neurogen Corporation, have had programs to develop complement inhibitor therapies. We believe that our potential C5 Inhibitors differ substantially from those of our competitors due to our compounds' demonstrated ability to specifically intervene in the complement cascade, for potentially prolonged periods of time, at what we believe to be the optimal point so that the disease-causing actions of complement proteins generally are inhibited while the normal disease-preventing functions of complement proteins and other aspects of immune function generally remain intact.

Each of AstraZeneca, MorphoSys AG and Dyax Corporation has publicly announced intentions to develop therapeutic human antibodies from libraries of human antibody genes. Additionally, each of Amgen, Inc. and Medarex, Inc. has publicly announced intentions to develop therapeutic human antibodies from mice that have been bred to include some human antibody genes.

## **Employees**

As of December 31, 2008, we had 504 full-time, world-wide employees, of which 249 were engaged in research, product development, manufacturing, and clinical development, 167 in sales and marketing, and 88 in administration, business development and finance. Our U.S. employees are not represented by any collective bargaining unit, and we regard the relationships with all our employees as satisfactory.

## **Table of Contents**

### **Item 1A. RISK FACTORS**

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

#### **Risks Related to Our Lead Product Soliris**

*We depend heavily on the success of our lead product, Soliris, which was approved in the United States and in Europe in March 2007 and June 2007, respectively, and in Canada in January 2009, for the treatment of PNH. If we are unable to increase sales of Soliris in the United States and Europe and commercialize Soliris in additional countries or if we are significantly delayed or limited in doing so, our business will be materially harmed.*

Our ability to generate revenues will depend on commercial success of Soliris in the United States, Europe and throughout the rest of the world and whether physicians, patients and healthcare payers view Soliris as therapeutically effective relative to cost. Since we launched Soliris in the United States in April 2007, almost all of our revenue has been attributed to sales of Soliris, and we expect that Soliris product sales will continue to contribute to a significant percentage or almost all of our total revenue over the next several years.

The commercial success of Soliris and our ability to generate and increase revenues will depend on several factors, including the following:

the number of patients with PNH who are diagnosed with the disease and identified to us;

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

successful continuation of commercial sales in the United States and in European countries where we are already selling Soliris, and successful launch in countries where we have not yet obtained marketing approval or commenced sales;

ability to obtain and maintain sufficient coverage or reimbursement by third-party payers;

acceptance of Soliris in the medical community;

ability to effectively market and distribute Soliris in the United States, Europe and the rest of the world;

receipt and maintenance of marketing approvals from the United States and foreign regulatory authorities; and

establishment and maintenance of commercial manufacturing capabilities ourselves or through third-party manufacturers.

We obtained marketing approval for Soliris in Europe in June 2007 however such approval did not automatically authorize us to commence commercial sales in every country in the European Union. We continue discussions with appropriate authorities in different countries in Europe so that we may, upon conclusion of such discussions, commence commercial sales in those countries. We have submitted applications for marketing



## **Table of Contents**

authorization in countries outside the European Union, including Australia and Canada and have received approval in Canada in January 2009. We cannot guarantee that reimbursement and other discussions and processes will be concluded successfully or on a timely basis and, as a result, sales in certain countries may be delayed or never occur. If we are not successful in commercializing Soliris in the United States and the rest of the world, or are significantly delayed or limited in doing so, we may experience a surplus inventory, our business will be materially harmed and we may need to curtail or cease operations.

*Because the target patient population of Soliris for the treatment of PNH is small and has not been definitively determined, we must be able to successfully identify PNH patients and achieve a significant market share in order to achieve or maintain profitability.*

The prevalence of PNH patients has not been definitively determined but can be estimated at approximately 8,000–10,000 total patients in North America and Western Europe. There can be no guarantee that any of our programs will be effective at identifying PNH patients and the number of PNH patients in the United States and Europe may turn out to be lower than expected or may not be otherwise amenable to treatment with Soliris, all of which would adversely affect our results of operations and our business.

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

We may not be able to sell Soliris on a profitable basis or our profitability may be reduced if we are required to sell our product at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. Soliris is significantly more expensive than traditional drug treatments and almost all patients require some form of third party coverage to afford its cost. Our future revenues and profitability will be adversely affected if we cannot depend on governmental, private third-party payers and other third-party payers, such as Medicare and Medicaid in the United States or country specific governmental organizations, to defray the cost of Soliris to the patient. If these entities refuse to provide coverage and reimbursement with respect to Soliris or determine to provide a lower level of coverage and reimbursement than anticipated, Soliris may be too costly for general use, and physicians may not prescribe it.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us, or such coverage, pricing, and reimbursement may differ in separate regions in the same country. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country and we cannot guarantee that we will have the capabilities or resources to successfully conclude the necessary processes and commercialize Soliris in every or even most countries in which we seek to sell Soliris. Reimbursement sources are different in each country and in each country may include a combination of distinct potential payers, including private insurance and governmental payers. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to successfully and timely conclude reimbursement, price approval or funding processes and begin to market Soliris in foreign countries or if coverage and reimbursement for Soliris in foreign countries is limited. If we discover we are not able to obtain coverage, pricing or reimbursement on terms acceptable to us

---

**Table of Contents**

or at all in any foreign countries, we may not be able to or we may determine not to sell Soliris in such countries and our plans for geographic expansion of sales and our business may be adversely affected as a result.

Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Third-party payers may be especially likely to impose these obstacles to coverage for higher-priced drugs such as Soliris.

In addition to potential restrictions on coverage, the amount of reimbursement for Soliris may also reduce our profitability and worsen our financial condition. In the United States and elsewhere, there have been, and we expect there will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs. See additional discussion below under the headings Healthcare reform measures could adversely affect our business and The current credit and financial market conditions may aggravate certain risks affecting our business.

Even where patients have access to insurance, their insurance co-payment amounts or annual or lifetime caps on reimbursements may represent a barrier to obtaining Soliris. In the United States, Alexion has financially supported the PNH Foundation of the National Organization for Rare Disorders, or NORD, which, among other things, assists patients in acquiring drugs such as Soliris. Organizations such as NORD assist patients who have no insurance coverage for drugs or whose insurance coverage leaves them with prohibitive co-payment amounts or other expensive financial obligations. NORD's ability to provide financial assistance to PNH patients is dependent on funding from external sources, and we cannot guarantee that such funding will be provided at adequate levels, if at all. We have also provided Soliris without charge for related charitable purposes. We are not able to predict the financial impact of the support we may provide for these and other charitable purposes; however, substantial support could have a material adverse effect on our ability to maintain profitability on a quarterly or annual basis in the future.

In furtherance of our efforts to facilitate access to Soliris in the United States, we have created the Soliris OneSource Program, a treatment support service for patients with PNH and their healthcare providers. Alexion Nurse case managers provide education about PNH and Soliris and help facilitate solutions for reimbursement, coverage and access. Although case managers assist patients and healthcare providers in locating and accessing Soliris, we cannot guarantee a sufficient level of coverage, reimbursement or financial assistance.

*We may not be able to gain or maintain market acceptance among the medical community or patients which would prevent us from achieving or maintaining profitability in the future.*

We cannot be certain that Soliris will gain or maintain market acceptance among physicians, patients, healthcare payers, and others. Although we have received regulatory approval for Soliris in the United States, Europe and Canada, such approvals do not guarantee future revenue. We cannot predict whether physicians, other healthcare providers, government agencies or private insurers will determine that our products are safe and therapeutically effective relative to cost. Medical doctors' willingness to prescribe, and patients' willingness to accept, our products depend on many factors, including prevalence and severity of adverse side effects in both clinical trials and commercial use, effectiveness of our marketing strategy and the pricing of our products, publicity concerning our products or competing products, our ability to obtain and maintain third-party coverage or reimbursement, and availability of alternative treatments, including bone marrow transplants. If Soliris fails to

## **Table of Contents**

achieve market acceptance, we may not be able to market and sell it successfully, which would limit our ability to generate revenue and could harm our business.

*If we fail to comply with continuing United States and foreign regulations, we could lose our approvals to market Soliris, and our business would be seriously harmed.*

We cannot guarantee that we will be able to maintain our regulatory approvals for Soliris. If we do not maintain our regulatory approvals for Soliris, the value of our company and our results of operations will be materially harmed. We and our future partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by the FDA, other federal and state agencies, and governmental authorities in other countries. These regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, adverse event reporting requirements, and export of biologics. As a condition of approval for marketing our product, the FDA or governmental authorities in other countries may require us to conduct additional clinical trials. For example, in connection with the approval of Soliris in the United States, we have agreed to perform clinical studies assessing long term safety outcomes in the Soliris Safety Registry, monitoring immunogenicity, monitoring compliance with vaccination requirements, and determining the effects of anticoagulant withdrawal among PNH patients receiving eculizumab. The FDA can propose to withdraw approval if new clinical data or information shows that a product is not safe for use in an approved indication or determines that such studies are inadequate. We are required to report any serious and unexpected adverse experiences and certain quality problems with Soliris to the FDA, the EMEA and certain other health agencies. We, the FDA, the EMEA or another health agency may have to notify healthcare providers of any such developments. The discovery of any previously unknown problems with Soliris, manufacturer or facility may result in restrictions on Soliris, manufacturer or manufacturing facility, including withdrawal of Soliris from the market. Certain changes to an approved product, including the way it is manufactured or promoted, often require prior regulatory approval before the product as modified may be marketed. Our manufacturing and other facilities and those of any third parties manufacturing Soliris, will be subject to inspection prior to grant of marketing approval and subject to continued review and periodic inspections by the regulatory authorities. Any third party we would use to manufacture Soliris for sale must also be licensed by applicable regulatory authorities.

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

administrative and judicial sanctions, including, warning letters;

finest and other civil penalties;

withdrawal of a previously granted approval;

interruption of production;

operating restrictions;

delays in approving or refusal to approve Soliris or a product candidate;

product recall or seizure;

injunctive; and

criminal prosecution.



---

## **Table of Contents**

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

*If the use of Soliris harms people, or is perceived to harm patients even when such harm is unrelated to Soliris, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.*

The testing, manufacturing, marketing and sale of drugs for use in humans exposes us to product liability risks. Side effects and other problems from using Soliris could (1) lessen the frequency with which physicians decide to prescribe Soliris, (2) encourage physicians to stop prescribing Soliris to their patients who previously had been prescribed Soliris, (3) cause serious adverse events and give rise to product liability claims against us, and (4) result in our need to withdraw or recall Soliris from the marketplace. Some of these risks are unknown at this time.

We have tested Soliris in only a small number of patients. As more patients begin to use Soliris, new risks and side effects may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Previously unknown risks and adverse effects of Soliris may also be discovered in connection with unapproved, or off-label, uses of Soliris. We do not promote, or in any way support or encourage the promotion of Soliris for off-label uses in violation of relevant law, but physicians are permitted to use products for off-label purposes and we are aware of such off-label uses of Soliris. In addition, we expect to study Soliris in diseases other than PNH in controlled clinical settings, and expect independent investigators to do as well. In the event of any new risks or adverse effects discovered as new patients are treated for PNH and as Soliris is studied in or used by patients for off-label indications, regulatory authorities may delay or revoke their approvals; we may be required to conduct additional clinical trials, make changes in labeling of Soliris, reformulate Soliris or make changes and obtain new approvals for our and our suppliers' manufacturing facilities. We may also experience a significant drop in the potential sales of Soliris, experience harm to our reputation and the reputation of Soliris in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of Soliris or substantially increase the costs and expenses of commercializing and marketing Soliris.

We may be sued by people who use Soliris, whether as a prescribed therapy, during a clinical trial, during an investigator initiated study, or otherwise. Many patients who use Soliris are already very ill. Any informed consents or waivers obtained from people who enroll in our trials or use Soliris may not protect us from liability or litigation. Our product liability insurance may not cover all potential types of liabilities or may not cover certain liabilities completely. Moreover, we may not be able to maintain our insurance on acceptable terms. In addition, negative publicity relating to the use of Soliris or a product candidate, or to a product liability claim, may make it more difficult, or impossible, for us to market and sell Soliris. 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.

Patients who use Soliris already often have severe and advanced stages of disease and known as well as unknown significant pre-existing and potentially life-threatening health risks, including for example bone marrow failure. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to Soliris. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market Soliris, or require us to suspend or abandon our commercialization

## **Table of Contents**

efforts. Even in a circumstance in which we do not believe that an adverse event is related to Soliris, the investigation into the circumstance may be time consuming or may be inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals Soliris receives or maintains.

Some patients treated with Soliris for PNH or other diseases, including patients who have participated in our clinical trials, have died or suffered potentially life-threatening diseases either during or after ending their Soliris treatments. In particular, use of C5 Inhibitors, such as Soliris, is associated with an increased risk for certain types of infection, including *Neisseria* bacteria. Serious cases of *Neisseria* infection can result in severe illness, including but not limited to brain damage, loss of limbs or parts of limbs, kidney failure, or death. PNH patients in our TRIUMPH and SHEPHERD trials all received vaccination against *Neisseria* bacteria prior to first administration of Soliris and all patients who are prescribed Soliris in the United States and Europe are required by prescribing guidelines to be vaccinated prior to receiving their first dose; however, vaccination does not eliminate all risk of becoming infected with *Neisseria* bacteria. Some patients treated with Soliris, who had been vaccinated, including patients who have participated in our trials of Soliris for the treatment of PNH and other diseases, have become infected with *Neisseria* bacteria, including patients who have suffered serious illness or death. Each such incident is required to be reported to appropriate regulatory agencies in accordance with relevant regulations.

We are also aware of a potential risk for PNH patients who delay a dose of Soliris or discontinue their treatment of Soliris. Treatment with Soliris blocks complement and allows complement-sensitive PNH red blood cells to increase in number. If treatment with Soliris is thereafter delayed or discontinued, a greater number of red blood cells therefore would become susceptible to destruction when the patient's complement system is no longer blocked. The rapid destruction of a larger number of a patient's red blood cells may lead to numerous complications, including death. Several PNH patients in our studies of Soliris have received delayed doses or discontinued their treatment. In none of those circumstances were significant complications shown to be due to rapid destruction of a larger number of PNH red blood cells; however, we have not studied the delay or termination of treatment in enough patients to determine that such complications in the future are unlikely to occur. Additionally, such delays or discontinuations may be associated with significant complications without evidence of such rapid cell destruction. Clinical evaluations of outcomes in the post-marketing setting are required to be reported to appropriate regulatory agencies in accordance with relevant regulations. Determination of significant complications associated with the delay or discontinuation of Soliris could have a material adverse effect on our ability to sell Soliris for PNH.

*Although we obtained regulatory approval of Soliris for PNH in the United States, Canada, and Europe, we may be unable to obtain regulatory approval for Soliris in any other territory.*

Governments in countries outside the United States and Europe also regulate drugs distributed in such countries and facilities in such countries where such drugs are manufactured, and obtaining their approvals can also be lengthy, expensive and highly uncertain. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. In certain jurisdictions, we are required to finalize operational, reimbursement, price approval and funding processes prior to marketing our products. Soliris became commercially available in certain countries in Europe in the fourth quarter of 2007. We received regulatory approval for Soliris for treatment of patients with PNH in Canada in January 2009. We may not receive regulatory approval for Soliris outside the United States, Canada, and Europe for at least the next several years, if ever.

## **Table of Contents**

Regulatory agencies may require additional information or data with respect to our submissions for Soliris for PNH. We may have to conduct additional lengthy clinical testing and other costly and time-consuming procedures to satisfy foreign regulatory agencies. Even with approval of Soliris by the FDA, Health Canada, and the E.C., other regulatory agencies may not agree with our interpretations of our clinical trial data for Soliris and may decide that our results are not adequate to support approval for marketing of Soliris. In those circumstances, we would not be able to obtain regulatory approval in such country on a timely basis, if ever. Even if approval is granted in such country, the approval may require limitations on the indicated uses for which the drug may be marketed. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. We must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. For example, we were required to conduct clinical studies with Soliris in patients with PNH in Japan; however, there is no assurance that the Japanese regulatory agency will find these studies sufficient for registration of Soliris in Japan. Further, our application for marketing approval of Soliris in Australia received priority review and Soliris received Orphan Drug Designation status but this does not mean that Soliris will be approved or that additional clinical studies in Australia are not required.

*We are completely dependent on a single third party to manufacture commercial quantities of Soliris and our commercialization of Soliris may be stopped, delayed or made less profitable if such third party fails to provide us with sufficient quantities of Soliris.*

Only Lonza Sales AG, or Lonza, is currently capable of manufacturing commercial quantities of Soliris. We will not be capable of manufacturing Soliris for commercial sale, on our own, until such time as we have requested and received the required regulatory approvals for our manufacturing facility in Rhode Island, if ever. Therefore, we anticipate that we will depend entirely on one company, Lonza, to manufacture Soliris for commercial sale until that time. We cannot be certain that Lonza will be able to perform uninterrupted supply chain services. The failure of Lonza to manufacture appropriate supplies of Soliris, on a timely basis, or at all, may prevent or interrupt the commercialization of Soliris. If Lonza were unable to perform its services for any period, we may incur substantial loss of sales. If we are forced to find an alternative supplier for Soliris, in addition to loss of sales, we may also incur significant costs in establishing a new arrangement.

*We are dependent upon a small number of customers for a significant portion of our revenue, and the loss of, or significant reduction or cancellation in sales to, any one of these customers could adversely affect our operations and financial condition.*

In the United States, we sell Soliris to distributors who in turn sell to patient health-care providers. We do not promote Soliris to these distributors and they do not set or determine demand for Soliris. For the fiscal year ended December 31, 2008, our single largest customer, Amerisource Bergen, accounted for 21% of our Soliris net product sales, and our three largest customers accounted for approximately 33% of our net product sales. As of December 31, 2008, two individual customers each accounted for 20% of the accounts receivable balance. We expect such customer concentration to continue for the foreseeable future. Our ability to successfully commercialize Soliris will depend, in part, on the extent to which we are able to provide adequate distribution of Soliris to patients. Although a number of specialty distributors and specialty pharmacies, which supply physician office clinics, hospital outpatient clinics, infusion clinics, home health care providers, and governmental organizations, distribute Soliris, they generally carry a very limited inventory and may be reluctant to distribute Soliris in the future if demand for the product does not increase. Further, it is possible that our distributors could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to

## **Table of Contents**

distribute smaller volume products such as Soliris, or cause higher product distribution costs, lower margins or the need to find alternative methods of distributing our product. Although we believe we can find alternative distributors on a relatively short notice, our revenue during that period of time may suffer and we may incur additional costs to replace a distributor. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us or any failure to pay for the products we have shipped to them could materially and adversely affect our results of operations and financial condition.

*If we are unable to establish and maintain effective sales, marketing and distribution capabilities, or to enter into agreements with third parties to do so, we will be unable to successfully commercialize Soliris.*

We are marketing and selling Soliris ourselves in the United States and through our subsidiaries in Europe, but have only limited experience thus far with marketing, sales or distribution of drug products. We have hired sales representatives for the commercialization of Soliris in the United States and have established commercial capability in Europe. If we are unable to establish the capabilities to sell, market and distribute Soliris, either through our own capabilities or by entering into agreements with others, or to maintain such capabilities in countries where we have already commenced commercial sales, we will not be able to successfully sell Soliris. In that event, we will not be able to generate significant revenues. We cannot guarantee that we will be able to establish and maintain our own capabilities or enter into and maintain any marketing or distribution agreements with third-party providers on acceptable terms, if at all. Even if we hire the qualified sales and marketing personnel we need in the United States and in Europe to support our objectives, or enter into marketing and distribution agreements with third parties on acceptable terms, we may not do so in an efficient manner or on a timely basis. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell Soliris. Establishing and maintaining sales, marketing and distribution capabilities are expensive and time-consuming. Our expenses associated with building up and maintaining the sales force and distribution capabilities around the world may be disproportional compared to the revenues we may be able to generate on sales of Soliris. We cannot guarantee that we will be successful in commercializing Soliris.

*If we market Soliris in a manner that violates health care fraud and abuse laws, we may be subject to civil or criminal penalties.*

In addition to FDA and related regulatory requirements, we are subject to health care fraud and abuse laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, patients, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing, or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation

## **Table of Contents**

that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program.

Although physicians are permitted to, based on their medical judgment, prescribe products for indications other than those cleared or approved by the FDA, manufacturers are prohibited from promoting their products for such off-label uses. We market Soliris for PNH and provide promotional materials and training programs to physicians regarding the use of Soliris for PNH. Although we believe our marketing, promotional materials and training programs for physicians do not constitute off-label promotion of Soliris, the FDA may disagree. If the FDA determines that our promotional materials, training or other activities constitute off-label promotion of Soliris, it could request that we modify our training or promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is later determined we are not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our position and have to divert significant management resources from other matters.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors and because government scrutiny in this area is high, it is possible that some of our business activities could come under that scrutiny.

In recent years, several states and localities, including California, the District of Columbia, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

### **Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candidates, Including Eculizumab for Indications Other than PNH**

*None of our product candidates except for Soliris has received regulatory approvals. Soliris has not been approved for any indication other than for the treatment of patients with PNH. If we are unable to obtain regulatory approvals to market one or more of our product candidates, or Soliris for other indications, our business may be adversely affected.*

All of our product candidates except Soliris are in early stages of development, and we do not expect our other product candidates to be commercially available for several years, if at all. Similarly, Soliris has not been

## **Table of Contents**

approved for any indication other than for the treatment of patients with PNH, and we do not expect approval for use of Soliris in other indications for several years, if at all. Our product candidates are subject to strict regulation by regulatory authorities in the United States and in other countries. We cannot market any product candidate until we have completed all necessary preclinical studies and clinical trials and have obtained the necessary regulatory approvals. We do not know whether regulatory agencies will grant approval for any of our product candidates. Even if we complete preclinical studies and clinical trials successfully, we may not be able to obtain regulatory approvals or we may not receive approvals to make claims about our products that we believe to be necessary to effectively market our products. Data obtained from preclinical studies and clinical trials are subject to varying interpretations that could delay, limit or prevent regulatory approval, and failure to comply with regulatory requirements or inadequate manufacturing processes are examples of other problems that could prevent approval. In addition, we may encounter delays or rejections due to additional government regulation from future legislation, administrative action or changes in the FDA policy. Even if the FDA approves a product, the approval will be limited to those indications covered in the approval.

Outside the United States, our ability to market any of our potential products is dependent upon receiving marketing approvals from the appropriate regulatory authorities. These foreign regulatory approval processes include all of the risks associated with the FDA approval process described above. If we are unable to receive regulatory approvals, we will be unable to commercialize our product candidates, and our business may be adversely affected.

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

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

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

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

## **Table of Contents**

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

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

long treatment time required to demonstrate effectiveness;

lack of sufficient supplies of the product candidate;

disruption of operations at the clinical trial sites;

adverse medical events or side effects in treated patients;

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

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

lack of effectiveness or safety of the product candidate being tested;

lack of sufficient funds;

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

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

*The regulatory approval process is costly and lengthy and we may not be able to successfully obtain all required regulatory approvals.*

The preclinical development, clinical trials, manufacturing, marketing and labeling of pharmaceuticals are all subject to extensive regulation by numerous governmental authorities and agencies in the United States and other countries. We must obtain regulatory approval for each of our product candidates before marketing or selling any of them. It is not possible to predict how long the approval processes of the FDA or any other applicable federal or foreign regulatory authority or agency for any of our product candidates will take or whether any such approvals ultimately will be granted. The FDA and foreign regulatory agencies have substantial discretion in the drug approval process, and positive results in preclinical testing or early phases of clinical studies offer no assurance of success in later phases of the approval process. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. Generally, preclinical and clinical testing of product candidates can take many years and require the expenditure of substantial resources, and the data obtained from these tests and trials can be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. If we encounter significant delays in the regulatory process that result in excessive costs, this may prevent us from continuing to develop our product candidates. Any delay in obtaining, or failure to obtain, approvals could adversely affect the marketing of our products and our ability to generate product revenue. The risks associated with the approval process include:

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

failure of our product candidates to meet a regulatory agency's requirements for safety, efficacy and quality;

limitation on the indicated uses for which a product may be marketed;

unforeseen safety issues or side effects; and

governmental or regulatory delays and changes in regulatory requirements and guidelines.



## **Table of Contents**

*Even if our drug candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients and health care payers.*

Physicians may elect not to recommend our drugs even if they receive marketing approval for a variety of reasons, including the timing of the market introduction of competitive drugs; lower demonstrated clinical safety and efficacy compared to other drugs; lack of cost-effectiveness; lack of availability of reimbursement from third-party payers; convenience and ease of administration; prevalence and severity of adverse side effects; other potential advantages of alternative treatment methods; and ineffective marketing and distribution support. Sales of pharmaceutical products depend in significant part on the coverage and reimbursement policies of government programs, including Medicare and Medicaid in the United States, and other third-party payers. These health insurance programs may restrict coverage of some products by using payor formularies under which only selected drugs are covered, variable co-payments that make drugs that are not preferred by the payor more expensive for patients, and by using utilization management controls, such as requirements for prior authorization or failure on another type of treatment. Payors may especially impose these obstacles to coverage for higher-priced drugs, and consequently Soliris may be subject to payor-driven restrictions. In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. A member state may approve a specific price or level of reimbursement for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

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

Clinical quantities of eculizumab are manufactured by us in our Rhode Island facility and by Lonza. Clinical quantities of CD200 are manufactured solely by us in Rhode Island. Manufacture of our drug products is highly technical and only a small number of companies have the ability and capacity to manufacture our drug products for our development and commercialization needs. We cannot be certain that any third party will be able or willing to honor the terms of its agreement, including any obligations to manufacture the drug products in accordance with regulatory requirements and to our quality specifications and volume requirements. Due to the highly technical requirements of manufacturing our drug products, our third-party collaborators and we may be unable to manufacture our drug products despite their and our efforts.

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

We currently have no experience or capacity for manufacturing drug products in volumes that would be necessary to support commercial sales and we can provide no assurance that we will be able to do so

## **Table of Contents**

successfully. We depend on a single manufacturer for commercial supply of Soliris and a few outside vendors for other manufacturing services, such as packaging, vialing and labeling. We acquired a commercial-scale manufacturing plant in Smithfield, Rhode Island in July 2006. However, that plant is not currently approved by the FDA or other regulatory agencies to manufacture Soliris. We expect that it will be at least 2010 before product from the plant is approved for commercial sale in the United States. We have no experience in developing commercial-scale manufacturing similar to anticipated production in Smithfield, Rhode Island. We can provide no assurance that we will be able to develop the Smithfield, Rhode Island site into a plant capable of manufacturing our drug products under conditions required by the FDA or foreign regulatory agencies on a timely basis, if at all. Our plant in Smithfield, Rhode Island will be subject to FDA inspection and approval before we can begin sales of Soliris or other drug products manufactured in this facility, and we will continue to be subject to ongoing FDA inspections thereafter. Our Smithfield, Rhode Island plant will also be subject to European regulatory inspection and approval before we can sell Soliris or any other drug product in Europe that is manufactured in this facility and we will continue to be subject to ongoing European regulatory inspection thereafter.

We, and our outside manufacturers, may experience higher manufacturing failure rates than in the past, if and when, we attempt to substantially increase production volume. If we experience interruptions in the manufacture of our products, our drug development and commercialization efforts will be delayed. If any of our outside manufacturers stops manufacturing our products or reduces the amount manufactured, or is otherwise unable to manufacture our required amounts at our required quality, we will need to find other alternatives, which is likely to be expensive and time consuming. Even if we are able to find alternatives they may ultimately be insufficient for our needs. As a result, our ability to conduct testing and drug trials and our plans for commercialization would be materially adversely affected. Submission of products and new development programs for regulatory approval, as well as our plans for commercialization, would be delayed or suspended. Our competitive position and our prospects for achieving or maintaining profitability would be materially and adversely affected.

Due to the nature of the current market for third-party commercial manufacturing, many arrangements require substantial penalty payments by the customer for failure to use the manufacturing capacity for which it contracted. Penalty payments under these agreements typically decrease over the life of the agreement, and may be substantial initially and de minimis or non-existent in the final period. The payment of a substantial penalty would harm our financial condition.

### **Risks Related to Intellectual Property**

*If we cannot protect the confidentiality and proprietary nature of our trade secrets, and other intellectual property, 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, we may also rely heavily on collaboration with suppliers, outside scientists and other drug companies. Collaboration presents a strong risk of exposing our trade secrets. If our trade secrets were exposed, it would help our competitors and adversely affect our business prospects.

In order to protect our drugs and technology more effectively, we need to obtain and maintain patents covering the drugs and technologies we develop. We may obtain patents or the right to practice patents through ownership or license. Soliris and our drug candidates are expensive and time-consuming to test and develop.

## **Table of Contents**

Without patent protection, competitors may copy our methods, or the chemical structure or other aspects of our drugs. Even if we obtain and maintain patents, the patents may not be broad enough to protect our drugs from copycat products.

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

Parts of our technology, techniques and proprietary compounds and potential drug candidates, including those which are or may be in-licensed, may be found to infringe patents owned by or granted to others. We previously reported that three civil actions were filed against us relating to the commercialization of Soliris and the intellectual property rights of third parties. Each of these cases was resolved in 2008, however, additional third parties may claim that the manufacture, use or sale of Soliris or other drugs under development infringes patents owned or granted to such third parties. We are aware of broad patents owned by others relating to the manufacture, use and sale of recombinant humanized antibodies, recombinant human antibodies, and recombinant human single chain antibodies. Soliris and many of our product candidates are either genetically engineered antibodies, including recombinant humanized antibodies, recombinant human antibodies, or recombinant human single chain antibodies. In addition to the actions described above, we have received notices from the owners of some of these patents claiming that their patents may be infringed by the development, manufacture or sale of Soliris or some of our drug candidates. We are also aware of other patents owned by third parties that might be claimed by such third parties to be infringed by the development and commercialization of Soliris and some of our drug candidates. In respect to some of these patents, we have obtained licenses, or expect to obtain licenses. However, with regard to such other patents, we have determined in our judgment that:

Soliris and our product candidates do not infringe the patents;

the patents are not valid; or

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

Any holder of these patents or other patents covering similar technology could sue us for damages and seek to prevent us from manufacturing, selling or developing our drugs. Legal disputes can be costly and time consuming to defend. If we cannot successfully defend against any future actions or conflicts, if they arise, we may incur substantial legal costs and may be liable for damages, be required to obtain costly licenses or need to stop manufacturing, using or selling Soliris, which would adversely affect our business. A required license may be costly or may not be available on acceptable terms, if at all. A costly license, or inability to obtain a necessary license, could have a material adverse effect on our business.

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

## **Table of Contents**

### **Risks Related to Our Operations**

*We have had a history of losses and may not be able to maintain profitability on a quarterly or annual basis in the future.*

Until the quarter ended June 30, 2008, we had never been profitable since we started our company in January 1992. We may not be able to generate sufficient revenues to achieve profitability in any subsequent quarters or on an annual basis. Even if we do achieve profitability in any subsequent quarters, we may not be able to sustain or increase profitability on a quarterly or annual basis. You should not consider our revenue growth in recent periods as indicative of our future performance. Our revenue in future periods could decline. Because we have only limited experience thus far with marketing, sales and distribution of Soliris, we have limited insight into the trends that may emerge and affect us. We may make errors in predicting and reacting to relevant business trends, which could harm our business. As of December 31, 2008, we had an accumulated deficit of approximately \$696,000. Since we began our business, we have focused on research and development of product candidates. We launched Soliris for sale in the United States during April 2007 and began commercial sales in Europe during the fourth quarter of 2007. We cannot guarantee that we will be successful in marketing and selling Soliris in the United States and Europe, on a continued basis, and we do not know when we will have Soliris available for sale in other countries and regions, if ever. All of our other product candidates are still in the early stages of research and development. We will have substantial expenses as we continue our research and development efforts, continue to conduct clinical trials, and continue to develop manufacturing, sales, marketing and distribution capabilities in the United States and abroad. Our future profitability depends on our ability to successfully market Soliris in the United States and Europe, on receiving regulatory, pricing, coverage, and reimbursement approvals of Soliris in other countries and regions, our ability to successfully market Soliris in other countries and regions, and our ability to successfully manufacture and commercialize our drug candidates. The extent and the timing of our future losses and our profitability are highly uncertain.

*If our competitors get to the marketplace before we do, or with better or cheaper drugs, Soliris and our product candidates may not be profitable to continue to pursue.*

Both the FDA and the European Medicines Evaluation Agency, or EMEA, have granted orphan drug designation for Soliris in the treatment of PNH, which entitles us to exclusivity for seven years in the United States and for ten years in Europe. However, if a competitive product that is the same as Soliris, as defined under the applicable regulations, is shown to be clinically superior to Soliris in the treatment of PNH, or if a competitive product is different from Soliris, as defined under the applicable regulations, the orphan drug exclusivity we have obtained may not block the approval of such competitive product. Several biotechnology and pharmaceutical companies throughout the world have programs to develop complement inhibitor therapies or have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. Other companies have publicly announced intentions to develop therapeutic human antibodies from libraries of human antibody genes or therapeutic human antibodies from mice that have been bred to include some human antibody genes. A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us. These and other companies, many of which have significantly greater resources than us, may develop, manufacture, and market better or cheaper drugs than Soliris or our product candidates. They may establish themselves in the marketplace before Alexion for Soliris for other indications or for any of our other product candidates. 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

## **Table of Contents**

arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may not be able to find equivalent opportunities elsewhere.

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

We believe that revenues and collections from sales of Soliris along with our existing cash, cash equivalents and marketable securities will provide sufficient capital to fund our operations and product development for at least twelve months. We may need to raise additional capital before or after that time to complete or continue the development or commercialization of our products and product candidates. We are currently selling or preparing for the commercialization of Soliris in several countries in Europe and in Canada, evaluating and preparing regulatory submissions for Soliris in other countries, and conducting, preparing or evaluating several clinical trials. Funding needs may shift between projects and potentially accelerate and increase as we continue launch and commercialization activities throughout the world and as we initiate or continue clinical trials for our product candidates.

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

the cost necessary to sell, market and distribute Soliris;

the rate of new patient sales and drug utilization by treated patients;

the time and cost necessary to obtain and maintain regulatory approvals for Soliris and for eculizumab for other indications in multiple countries;

the ability to obtain and maintain reimbursement approvals and funding for Soliris and the time necessary to obtain such approvals and funding;

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

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

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

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

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

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

We may not receive funding when we need it or funding may only be available on unfavorable terms. Financial markets in the U.S., Europe and the rest of the world have been experiencing significant volatility in security prices, substantially diminished liquidity and credit availability,

rating downgrades of certain investments and declining valuations of others. There can be no assurance that we will be able to access credit or equity markets in order to finance our operations in the United States or Europe, grow our operations in any

## **Table of Contents**

territory, or expand development programs for of our product candidates, or that there will not be a further deterioration in financial markets and confidence in economies. 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 or relinquish commercialization rights. This could result in sharing revenues that we might otherwise retain for ourselves. Any of these actions would harm our business.

*If we fail to recruit and retain personnel, we may not be able to implement our business strategy.*

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

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

*We are significantly leveraged.*

On December 31, 2008 we had outstanding \$97,222 principal amount of 1.375% convertible senior notes which will mature on February 1, 2012. Our subsidiary Alexion Manufacturing borrowed \$44,000 to finance the purchase and construction of our Smithfield, Rhode Island manufacturing facility which may not be prepaid in whole or in part prior to July 11, 2009. The loan is guaranteed by us and bears a fixed annual rate of 9.12%. The loan principal is required to be repaid in equal monthly installments of \$489, starting March 2010 and until August 2017, at which time all outstanding balances are due. During the first quarter of 2008, we entered into a revolving credit facility with Bank of America and may borrow up to \$25,000, with up to a \$5,000 sublimit for letters of credit that can be used for working capital requirements and other general corporate purposes. The loan is collateralized by substantially all of our assets, including the pledge of the equity interests of certain direct subsidiaries, but excluding intellectual property, assets of foreign subsidiaries and assets related to our manufacturing facility in Smithfield, Rhode Island. We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.75% to 2.25% depending on our liquidity (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect and (B) the Federal Funds Rate then in effect plus 0.50%, plus 0% to 0.25% depending on our liquidity (as calculated in accordance with the agreement). Interest is payable quarterly for Base Rate loans and, in the case of LIBOR-based loans, at the end of the applicable interest period, with the principal due on February 28, 2011, the maturity date. In addition, we paid \$7,500 and are required to pay an additional principal amount of \$2,500 in connection with the acquisition of certain patents from the Oklahoma Medical Research Foundation, or OMRF. In connection with the settlement of our patent litigation with PDL, we agreed to make a \$25,000 payment to PDL, \$12,500 of which has been paid in January 2009 and \$12,500 of which is due in June 2009.

## **Table of Contents**

Our 1.375% convertible senior notes, the mortgage loan, the revolving credit facility and the OMRF and PDL obligation, remain outstanding or available, and the degree to which we are leveraged could, among other things:

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

make it difficult for us to obtain financing for acquisitions or in-licensing opportunities or other purposes on favorable terms, if at all;

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

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

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

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

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

*We may expand our business through acquisitions or in-licensing opportunities that could disrupt our business and harm our financial condition.*

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions or in-licensing of business or products to do so. Acquisitions of new businesses or products and in-licensing of new products 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;



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

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 compete with pharmaceutical companies that have significantly greater resources than us for many of the same acquisition and in-licensing opportunities. Such pharmaceutical companies that are less leveraged and

## **Table of Contents**

have better access to capital resources may preclude us from completing any acquisition or in-licensing. Even if we are able to complete an acquisition or in-licensing, we cannot assure you that any acquisition or in-licensing of new products will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or an acquired or in-licensed product. In addition, our future success would depend in part on our ability to manage the rapid growth associated with any such acquisitions or in-licensing. 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. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all. Furthermore, the development or expansion of our business, any acquired business or any acquired or in-licensed products may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our capital stock, which could dilute current stockholders' ownership interest in our company, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest in our company upon conversion.

*Our ability to use net operating loss carry forwards to reduce future tax payments may be limited if there is a change in ownership of Alexion, or if taxable income does not reach sufficient levels.*

As of December 31, 2008, we have approximately \$745,000 of U.S. Federal net operating loss carryforwards ( NOLs ) available to reduce taxable income in future years. A portion of these NOLs are currently subject to an annual limitation under section 382 of the Internal Revenue Code of 1986, as amended.

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

In addition, the ability to use net operating loss carryforwards will be dependent on our ability to generate taxable income. The net operating loss carryforwards may expire before we generate sufficient taxable income. NOLs totaling \$3,800 expired in the year ended December 31, 2007. No NOLs expired during the year-ended December 31, 2008.

*We may have exposure to additional tax liabilities which could have a material impact on our results of operations and financial position.*

As a company with international operations, we are subject to income taxes, as well as non-income based taxes, in both the United States and various foreign jurisdictions. Significant judgment is required in determining

## **Table of Contents**

our worldwide tax liabilities. Although we believe our estimates are reasonable, the ultimate outcome with respect to the taxes we owe may differ from the amounts recorded in our financial statements. In addition, if the Internal Revenue Service, or other taxing authority, disagrees with the positions taken by our company, we could have additional tax liability and this could have a material impact on our results of operations and financial position.

*Our international sales and operations are subject to the economic, political, legal and business conditions in the countries in which we do business, and our failure to operate successfully or adapt to changes in these conditions could cause our international sales and operations to be limited or disrupted.*

Over the past few years, we have significantly expanded our international operations and expect to continue to do so in the future. Our operations in foreign countries subject us to the following additional risks:

fluctuations in currency exchange rates;

economic problems or political instability that disrupts foreign healthcare payment systems;

difficulties or inability to obtain financing in international markets;

unexpected changes in tariffs, trade barriers and regulatory requirements;

difficulties enforcing contractual and intellectual property rights;

changes in laws, regulations or enforcement practices with respect to our business, including without limitation laws relating to reimbursement, competition, pricing and sales and marketing of our products;

trade restrictions and restrictions on direct investments by foreign entities;

compliance with tax, employment and labor laws;

costs and difficulties in staffing, managing and monitoring international operations; and

longer payment cycles.

We conduct a substantial portion of our business in currencies other than the U.S. dollar, primarily Euros. While we attempt to hedge certain currency risks, currency fluctuations between the U.S. dollar and the currencies in which we do business have caused foreign currency transaction gains and losses in the past and will likely do so in the future. Likewise, past currency fluctuations have at times resulted in foreign currency transaction gains, and there can be no assurance that these gains can be reproduced.

*The current credit and financial market conditions may aggravate certain risks affecting our business.*

Sales of Soliris are dependent, in large part, on reimbursement from government health administration organizations and private and governmental third-party payers. As a result of the current credit and financial market conditions, these organizations may be unable to satisfy their reimbursement obligations, may delay payment or may seek to reduce reimbursement for Soliris in the future, which could have a material

adverse effect on our business and results of operations.

Additionally, we rely upon third-parties for certain parts of our business, including Lonza, our sole manufacturer of Soliris, licensees, wholesale distributors of Soliris, contract clinical trial providers, contract manufacturers and other third-party suppliers. Because of the recent volatility in the financial markets, there may

## **Table of Contents**

be a disruption or delay in the performance or satisfaction of commitments to us by these third parties which could have a material adverse effect on our business and results of operations.

*Healthcare reform measures could adversely affect our business.*

The United States government and governments in foreign countries have shown significant interest in pursuing healthcare reform in order to reduce costs of healthcare. Any government-adopted reform measures could adversely impact the pricing of Soliris or the amount of reimbursement available for Soliris from governmental agencies or other third-party payors. The pricing and reimbursement environment for Soliris may become more challenging due to, among other reasons, policies of a new presidential administration or new healthcare legislation passed by Congress. While we cannot predict what, if any, legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could delay or prevent our entry into new markets, affect our sales in the markets where we are already selling Soliris and materially harm our business, financial condition and results of operations.

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

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

The trading price of our common stock has been volatile and may continue to be volatile in the future. Factors such as announcements of fluctuations in our or our competitors' operating results or clinical or scientific results, fluctuations in the trading prices or business prospects of our competitors and collaborators, changes in our prospects, particularly with respect to sales of Soliris, and market conditions for biopharmaceutical stocks in general could have a significant impact on the future trading prices of our common stock and our convertible senior notes. In particular, the trading price of the common stock of many biopharmaceutical 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, sales of Soliris, the announcement of the results of our clinical trials or product development and the results of our efforts to obtain regulatory approval for our products. In particular, between January 1, 2007 and December 31, 2008, the closing sales price of our common stock fluctuated from a low of \$17.89 per share to a high of \$47.51 per share, as reported after giving effect to the forward two-for-one stock split effected on August 22, 2008. While we cannot predict our future performance, if our stock price continues to fluctuate in a wide range, an investment in our common stock may result in considerable uncertainty for an investor.

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

Because we are a Delaware corporation, the anti-takeover provisions of Delaware law could make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to stockholders. We are subject to the provisions of Section 203 of the Delaware General Laws, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

**Table of Contents**

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

Pursuant to our stockholder rights plan, each share of common stock has an associated preferred stock purchase right. The rights will not trade separately from the common stock until, and are exercisable only upon, the acquisition or the potential acquisition through tender offer by a person or group of 20% or more of the outstanding common stock. The rights are designed to make it more likely that all of our stockholders receive fair and equal treatment in the event of any proposed takeover of us and to guard against the use of partial tender offers or other coercive tactics to gain control of us. These provisions could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices. These provisions could also limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and could adversely affect the price of our common stock.

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

None.

**Item 2. PROPERTIES.**

We conduct our operations at owned and leased facilities described below.

Location	Operations Conducted	Approximate Square Feet	Lease Expiration Date
Cheshire, Connecticut	Executive, Sales and Research Offices	125,424	2017
Smithfield, Rhode Island	Commercial & Research Manufacturing	56,500	N/A
Paris, France	Regional Executive & Sales Office	4,921	2009
Lausanne, Switzerland	Regional Executive & Sales Office	1,378	2013

We believe that our administrative office space is adequate to meet our needs for the foreseeable future. We also believe that our research and development facilities and our manufacturing facility, together with third party manufacturing facilities, will be adequate for our on-going activities. In addition to the locations above, we also lease offices in certain countries to facilitate our operations as a global organization.

**Table of Contents**

**Item 3. *LEGAL PROCEEDINGS.***

Alexion previously reported that on March 16, 2007, PDL BioPharma, Inc., or PDL, filed a civil action against Alexion in the U.S. District Court for the District of Delaware claiming willful infringement by Alexion of certain PDL patents, or the PDL Patents, due to sales of Soliris. Alexion denied such claims and filed counterclaims. In the fourth quarter of 2008, Alexion and PDL entered into a patent license agreement and settlement agreement for the purpose of resolving all claims previously filed by PDL and all counterclaims previously filed by Alexion. Pursuant to the license agreement, Alexion acquired a fully paid, nonexclusive, irrevocable, perpetual worldwide license to some claims of the PDL Patents and a covenant not to sue from PDL for other claims of the PDL Patents, in each case for the commercialization of Soliris for all indications. Alexion is obligated to make a total of \$25,000 in payments to PDL, \$12,500 of which was paid in the first quarter of 2009 and \$12,500 of which is due in June 2009. No royalties or other amounts are owed to PDL with respect to sales of Soliris for any indication. Upon receipt of the \$25,000 license payment, the previously announced claims filed by PDL and counterclaims filed by Alexion will be dismissed. Under the terms of the License Agreement PDL separately granted Alexion the right to take a worldwide, royalty-bearing license under the PDL Patents to commercialize additional Alexion humanized antibodies that may be covered by the PDL Patents in the future.

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

There were no matters submitted to a vote of security holders during the fourth quarter of 2008.

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

The executive officers and key employees of the Company and their respective ages and positions with the Company as of February 17, 2009 are as follows:

<b>Name</b>	<b>Age</b>	<b>Position with Alexion</b>
*Leonard Bell, M.D.	50	Chief Executive Officer, Secretary, Treasurer, Director
*Stephen P. Squinto, Ph.D.	52	Executive Vice President and Head of Research and Development
*Patrice Coissac	60	Corporate Senior Vice President and President of Alexion Europe SAS
*Thomas I.H. Dubin, J.D.	46	Senior Vice President and General Counsel
*David L. Hallal	42	Senior Vice President, Commercial Operations, Americas
Russell P. Rother, Ph.D.	48	Senior Vice President and Chief Scientific Officer
*Vikas Sinha, M.B.A., C.A.	45	Senior Vice President and Chief Financial Officer
Camille L. Bedrosian, M.D.	55	Senior Vice President and Chief Medical Officer
Claude Nicaise, M.D.	56	Senior Vice President Strategic Development and Global Regulatory Affairs
M. Stacy Hooks, Ph.D.	41	Senior Vice President, Manufacturing and Technical Services
Glenn Melrose	53	Vice President, Human Resources
Daniel N. Caron	45	Vice President, Site 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, and Chief Executive Officer, Secretary and Treasurer since April 2002. From 1991 to 1992, Dr. Bell was an Assistant Professor of Medicine and Pathology and co-Director of the program in Vascular Biology at the Yale University School of Medicine. From 1990 to 1992, Dr. Bell was an attending physician at the Yale-New Haven Hospital and an Assistant Professor in the Department of Internal Medicine at the Yale University School of Medicine. Dr. Bell was a recipient of the Physician Scientist Award from the National Institutes of Health and Grant-in-Aid from the American Heart Association as well as various honors and awards from academic and professional organizations. His work has resulted in more than 20 scientific publications and 9 patent applications. Dr. Bell was also a director of The Medicines Company from May 2000 until April 2005. 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 the Yale University School of Medicine.

**Stephen P. Squinto, Ph.D.** is a founder of Alexion and has been Executive Vice President and Head of Research and Development since June 2007. He held the position of Executive Vice President and Head of Research between August 2000 and June 2007. He also 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 and an Adjunct Professor of Neuroscience at the Tulane University.



## **Table of Contents**

Medical School. 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 molecular and cellular biology. Dr. Squinto served as a Director of the Biotechnology Research and Development Corporation, a biotechnology consortium, from 1997 to 2003. Dr. Squinto received his B.A. in Chemistry and Ph.D. in Biochemistry and Biophysics from Loyola University of Chicago.

**Patrice Coissac**, joined Alexion as Corporate Senior Vice President, General Manager and President of Alexion Europe SAS in November 2005. Mr. Coissac has a broad international background in the pharmaceutical industry. In 2004-2005, he founded and ran his own consulting firm to serve biopharmaceutical companies in their strategic development. From 1999 to mid 2003, when Pharmacia was acquired by Pfizer, Mr. Coissac served as President of Pharmacia SAS France and was responsible for the integration of Monsanto (Searle) with Pharmacia & Upjohn in France. Prior to joining Pharmacia, Mr. Coissac held several managerial positions at leading pharmaceutical companies including Head of Operations for Novartis Belgium and President of Boehringer Mannheim Therapeutics France. Mr. Coissac also served as Marketing Senior Vice President for global pharmaceutical operations at Corange International and previously held several global marketing positions in Sandoz Pharmaceuticals in Tokyo, Japan where he was posted during several years, in Switzerland in Sandoz World Headquarters and in France at the beginning of his career.

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

**David L. Hallal** has been Senior Vice President, Commercial Operations, Americas since November 2008. He was Senior Vice President, US Commercial Operations from November 2007 until November 2008. Prior to that, Mr. Hallal was Vice President, US Commercial Operations from June 2006 until November 2007. Mr. Hallal is responsible for all Commercial Functions in the U.S., Canada, and Latin America, including marketing, sales, and reimbursement/access. Prior to Alexion, from April 2004 to June 2006, Mr. Hallal was Vice President of Sales at OSI Eyetech where he led the U.S. launch of the first-in-class anti-VEGF therapy, Macugen for age-related macular degeneration. From August 2002 to February 2004, Mr. Hallal was Senior Director of Sales for Biogen Idec's Immunology Sales Team, where he built a sales organization dedicated to the launch of the first-in-class biologic Amevive for psoriasis. For more than ten years starting in 1992, Mr. Hallal held various leadership positions at Amgen, focusing on Epogen®, Neupogen®, Neulasta® and Aranesp® in the hematology and oncology marketplace. More specifically from April 1999 to August 2002, he served as the Southeast Oncology Sales Director and Oncology Health Systems Sales Director. From 1998 to 1999, Mr. Hallal served as Amgen's Director of Oncology National Accounts. From 1992 to 1998, Mr. Hallal served in roles of escalating responsibility for the promotion of Epogen and Neupogen, including National Account Manager where he was responsible for forging relationships with managed care organizations in the U.S. He holds a B.A. from the University of New Hampshire.

## **Table of Contents**

**Russell P. Rother, Ph.D.** has been Chief Scientific Officer since January 2008, Senior Vice President, Research from 2005 to 2008, Vice President, Discovery Research from 2001 to 2005, Senior Director of Discovery Research from 1999 to 2001, Director of Gene Technologies from 1996 to 1999, Senior Staff Scientist from 1994 to 1996 and Staff Scientist from 1992 to 1994. As one of the original scientists at Alexion, Dr. Rother played a critical role in the engineering and development of Alexion's current antibody therapeutics and continues to lead discovery efforts in the identification of new indications and targets. Dr. Rother was a leader in the initiation of the paroxysmal nocturnal hemoglobinuria (PNH) program and played a major role in its development and approval. 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 50 scientific papers and patents in the fields of hematology, complement biology, transplantation, autoimmunity, and gene therapy. Dr. Rother received a B.S. in Biology from Southwestern Oklahoma State University and a Ph.D. in Microbiology and Immunology from the University of Oklahoma Health Sciences Center in conjunction with the Oklahoma Medical Research Foundation.

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

**Camille L. Bedrosian, M.D.** has served as our Senior Vice President and Chief Medical Officer since May 2008. From 2002 to 2008, Dr. Bedrosian served as Chief Medical Officer for ARIAD Pharmaceuticals, Inc., a biotechnology company developing small molecules for oncology patients, in Cambridge, MA. From 1997 to 2002, Dr. Bedrosian served in the Clinical Research and Development Department of Genetics Institute, Inc., which became part of Wyeth, and assumed roles of increasing responsibility including Senior Director, Oncology/Hematology and Therapeutic Area Director for Hemophilia. From 1986 to 1997, she was a Fellow, an Associate, and then Assistant Professor of Medicine in the Division of Hematology and Oncology at Duke University Medical Center and the Duke Comprehensive Cancer Center. Dr. Bedrosian received her B.A. degree from Harvard University/Radcliffe College in Chemistry, her M.S. in Biophysics from M.I.T., and her M.D. from Harvard Medical School.

**Claude Nicaise, M.D.** joined Alexion as Senior Vice President of Strategic development and Global Regulatory Affairs in July 2008. Since 1983, and until joining Alexion, Dr. Nicaise served in various positions of increasing responsibility at Bristol-Myers Squibb, including the following senior management positions: Vice-President of Global Development, Vice-President Worldwide Regulatory Science and Strategy, and Oncology,

## **Table of Contents**

Infectious Disease and NeuroScience. Dr. Nicaise received his medical degree from the Universite libre de Bruxelles in Belgium.

**M. Stacy Hooks, Ph.D.** has been Senior Vice President of Technical Operations since July 2008, Vice President of Manufacturing and Technical Services from July 2006 to July 2008, Executive Director, Manufacturing and Technical Services from August 2004 to July 2006, Senior Director, Manufacturing and Technical Services from January 2004 to August 2004, and Director of Quality Control from December 2002 to January 2004. Dr. Hooks is responsible for managing the development, manufacturing, process validation, quality and testing of products. From 2001 to 2002, Dr. Hooks was a Director of Quality Assurance at Pharmacia, Inc. From 2000 to 2001, Dr. Hooks was the Director of Quality at QIAGEN, Inc., a multinational life sciences company. From 1996 to 2000 Dr. Hooks was employed at MedImmune, Inc., a biopharmaceutical firm, in increasing roles of responsibility, most recently as the Associate Director of Quality Control. Prior to MedImmune Dr. Hooks was employed at Biogen-IDEC. Dr. Hooks received his B.S. in Chemistry from Murray State University and a Ph.D. in Chemistry from Emory University.

**Glenn Melrose** joined Alexion as Vice President, Human Resources in July 2007 after serving in the same position at NPS Pharmaceuticals, Inc. from June 2005. He joined Amersham in 1998 where he held various positions of increasing responsibility in sales and marketing, before rising to the position of Vice President, Human Resources, North America, ultimately leading the worldwide Human Resources function for Amersham Biosciences in 2003 and 2004. Mr. Melrose received a B.S. in Biology from Washington and Lee University and an M.S. in Experimental Biology from the University of Maryland. He began his career as a scientist at the University of Maryland Cancer Center and Becton Dickinson before joining Amersham Diagnostics in 1988.

**Daniel N. Caron** has been Vice President, Site Operations and Engineering since July 2008. After joining the Company in 1992, Mr. Caron was Operations Manager from 1992 to 1993, Senior Operations Manager from 1993 to 1996, Director of Operations from 1996 to 1998, and Senior Director, Operations and Engineering from 1998 to 2004 and Executive Director, Operations and Engineering from 2004 to 2008. Mr. Caron has been responsible for managing the engineering, build-out, and operations of the Company's research, manufacturing, and administrative facilities. Prior to 1992, Mr. Caron was a research scientist at Imclone Systems, Inc., a biopharmaceutical firm. Mr. Caron received his B.A. in Biology, from Adelphi University and M.S. in Biomedical Engineering from Polytechnic University of New York.

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

Our common stock is quoted on The Nasdaq Stock Market, LLC under the symbol ALXN. The following table sets forth the range of high and low sales prices for our common stock on The Nasdaq Stock Market, LLC for the periods indicated since January 1, 2007.

	High	Low
<b>Fiscal 2007</b>		
First Quarter		
(January 1, 2007 to March 31, 2007)	\$ 21.89	\$ 17.89
Second Quarter		
(April 1, 2007 to June 30, 2007)	\$ 25.07	\$ 20.93
Third Quarter		
(July 1, 2007 to September 30, 2007)	\$ 33.35	\$ 22.97
Fourth Quarter		
(October 1, 2007 to December 31, 2007)	\$ 39.90	\$ 33.42
<b>Fiscal 2008</b>		
First Quarter		
(January 1, 2008 to March 31, 2008)	\$ 38.56	\$ 25.49
Second Quarter		
(April 1, 2008 to June 30, 2008)	\$ 36.46	\$ 30.51
Third Quarter		
(July 1, 2008 to September 30, 2008)	\$ 47.51	\$ 36.66
Fourth Quarter		
(October 1, 2008 to December 31, 2008)	\$ 42.04	\$ 31.00

As of February 17, 2009, we had 408 stockholders of record of our common stock and an estimated 8,000 beneficial owners. The closing sale price of our common stock on February 17, 2009 was \$39.42 per share.

In July 2008, the Company's Board of Directors approved a two-for-one stock split to be effected in the form of a 100 percent stock dividend. The additional shares were distributed on August 22, 2008 to stockholders of record as of the close of trading on August 12, 2008. All per share data presented in the accompanying table has been retroactively restated to reflect this stock split.

**DIVIDEND POLICY**

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

**Table of Contents****EQUITY COMPENSATION PLAN INFORMATION (shares in thousands)**

<b>Plan Category</b>	<b>Number of shares of common stock to be issued upon exercise of outstanding options (2)</b>	<b>Weighted-average exercise price of outstanding options</b>	<b>Weighted-average term to expiration of options outstanding</b>	<b>Number of shares of common stock remaining available for future issuance under equity compensation plans</b>
Equity compensation plans approved by stockholders (1)	7,042	21.42	6.65	5,810
Equity compensation plans not approved by stockholders				

- (1) Reflects number of shares of common stock to be issued upon exercise of outstanding options under all of our equity compensation plans, including our 2004 Incentive Plan. No shares of common stock are available for future issuance under any of our equity compensation plans, except the 2004 Incentive Plan.
- (2) Does not include 1,035 restricted shares outstanding that were issued under the 2004 Incentive Plan.
- (3) The outstanding options and restricted shares are not transferable for consideration and do not have dividend equivalent rights attached.

**Table of Contents**

**THE COMPANY'S STOCK PERFORMANCE**

The following graph compares cumulative total return of the Company's Common Stock with the cumulative total return of (i) the NASDAQ Stock Market-United States, and (ii) the NASDAQ Biotechnology Index. The graph assumes (a) \$100 was invested on July 31, 2003 in each of the Company's Common Stock, the stocks comprising the NASDAQ Stock Market-United States and the stocks comprising the NASDAQ Biotechnology Index, and (b) the reinvestment of dividends. The comparisons shown in the graph are based on historical data and the stock price performance shown in the graph is not necessarily indicative of, or intended to forecast, future performance of our stock.

**COMPARISON OF 65 MONTH CUMULATIVE TOTAL RETURN\***

Among Alexion Pharmaceuticals, Inc., The NASDAQ Composite Index

And The NASDAQ Biotechnology Index

\*\$100 invested on 7/31/03 in stock & index-including reinvestment of dividends.

Fiscal year ending December 31.

**CUMULATIVE TOTAL RETURN**

	7/03	7/04	7/05	12/05	12/06	12/07	12/08
Alexion Pharmaceuticals, Inc.	100.00	94.71	154.91	120.46	240.27	446.34	430.58
NASDAQ Composite	100.00	110.43	127.55	130.36	146.10	159.51	92.93
NASDAQ Biotechnology	100.00	96.61	118.79	126.84	126.37	128.50	118.65

**Table of Contents****Item 6. SELECTED CONSOLIDATED FINANCIAL DATA.**

The following selected financial data is derived from, and should be read in conjunction with, the financial statements, including the notes thereto, and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Form 10-K.

(amounts in thousands, except per share amounts)

		Year Ended December 31,		Five Month Period Ended December 31,		Year Ended July 31,	
	2008	2007	2006	2005	2004	2005	2004
Revenues:							
Net product sales	\$ 259,004	\$ 66,381	\$	\$	\$	\$	\$
Contract research revenue	95	5,660	1,558	664	245	1,064	4,609
Total revenues	259,099	72,041	1,558	664	245	1,064	4,609
Cost of sales	28,366	6,696					
Operating expenses:							
Research and development	62,581	68,961	83,225	48,238	31,914	91,388	59,840
Selling, general and administrative	133,543	96,142	55,418	12,763	6,160	18,951	15,219
Total operating expenses	196,124	165,103	138,643	61,001	38,074	110,339	75,059
Operating income (loss)	34,609	(99,758)	(137,085)	(60,337)	(37,829)	(109,275)	(70,450)
Other income and expense	121	6,723	5,198	1,931	2,407	(240)	(4,336)
Income (loss) before income tax benefit	34,730	(93,035)	(131,887)	(58,406)	(35,422)	(109,515)	(74,786)
Income tax provision (benefit)	1,581	(745)	(373)	(450)	(61)	(765)	(691)
Net income (loss)	\$ 33,149	\$ (92,290)	\$ (131,514)	\$ (57,956)	\$ (35,361)	\$ (108,750)	\$ (74,095)
Earnings (loss) per common share							
Basic	\$ 0.43	\$ (1.27)	\$ (2.07)	\$ (0.95)	\$ (0.64)	\$ (1.95)	\$ (1.71)
Diluted	\$ 0.39	\$ (1.27)	\$ (2.07)	\$ (0.95)	\$ (0.64)	\$ (1.95)	\$ (1.71)
Shares used in computing earnings (loss) per common share							
Basic	77,680	72,622	63,402	61,046	55,370	55,704	43,244
Diluted	89,967	72,622	63,402	61,046	55,370	55,704	43,244

**Consolidated Balance Sheet Data:**

	2008	As of December 31, 2007 2006		2005	2004	As of July 31, 2005 2004	
Cash, cash equivalents, restricted cash, and marketable securities	\$ 139,711	\$ 106,712	\$ 250,148	\$ 212,456	\$ 232,498	\$ 195,404	\$ 266,501
Trade accounts receivable	74,476	46,278					
Inventories	49,821	32,907	2,314				
Total current assets	277,101	205,354	236,776	217,551	235,883	201,162	276,333
Property, plant and equipment	139,885	104,280	39,135				
Total assets	477,551	334,357	333,537	262,711	281,221	248,122	319,575
Note payable							3,920
Mortgage loan	44,000	44,000	26,000				
Convertible notes	97,222	150,000	150,000	150,000	120,000	150,000	120,000
Total stockholders' equity	247,001	101,556	124,677	81,890	138,505	67,671	172,522

**Table of Contents**

In July 2008, the Company's Board of Directors approved a two-for-one stock split to be effected in the form of a 100 percent stock dividend. The additional shares were distributed on August 22, 2008 to stockholders of record as of the close of trading on August 12, 2008. All share and per share data presented in the accompanying selected consolidated financial data have been retroactively restated to reflect this stock split.



## **Table of Contents**

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

In addition to historical information, this report contains forward-looking statements that involve risks and uncertainties, which may cause our actual results to differ materially from plans and results discussed in forward-looking statements. We encourage you to review the risks and uncertainties, discussed in the section entitled item 1A Risk Factors, and the Note Regarding Forward-Looking Statements, included at the beginning of this Form 10-K. The risks and uncertainties can cause actual results to differ significantly from those forecasted in forward-looking statements or implied in historical results and trends.

The following discussion should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Form 10-K.

#### **Overview**

We are a biopharmaceutical company engaged in the discovery, development and delivery of biologic therapeutic products aimed at treating patients with severe and life-threatening disease states, including hematologic and neurologic diseases, transplant rejection, cancer and autoimmune disorders. Our marketed product Soliris® (eculizumab) is the first therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH.

Soliris is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation associated with chronic hematologic and neurological disorders, transplant rejection, and autoimmune disorders. Soliris is a humanized antibody that generally blocks complement activity for one to two weeks after a single dose at the doses currently prescribed. The initial indication for which we received approval for Soliris is PNH. PNH is a rare, debilitating and life-threatening, acquired genetic deficiency blood disorder defined by the destruction of red blood cells, or hemolysis. The chronic hemolysis in patients with PNH may be associated with life-threatening thromboses, recurrent pain, kidney disease, disabling fatigue, impaired quality of life, severe anemia, pulmonary hypertension, shortness of breath and intermittent episodes of dark-colored urine (hemoglobinuria).

Since our incorporation in January 1992 until April 2007, we devoted most of our resources to drug discovery, research, and product and clinical development. In March 2007, the Food and Drug Administration, or FDA, granted marketing approval for Soliris. In the United States, Soliris is indicated for the treatment of all patients with PNH to reduce hemolysis. We began commercial sale of Soliris in the United States during April 2007.

In June 2007, the European Commission, or E.C., approved the use of Soliris for patients with PNH in the European Union, which also serves as the basis for approval in Iceland and Norway. Subsequently, we engaged with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country and have initiated commercialization in those countries where this process was completed.

In June 2007, the European Commission, or E.C., approved the use of Soliris for patients with PNH in the European Union, which also serves as the basis for approval in Iceland and Norway. Subsequently, we engaged with appropriate authorities on the operational, reimbursement, price approval and funding processes that are

## **Table of Contents**

separately required in each country and have initiated commercialization in those countries where this process is completed. In several countries outside the United States, we continued meaningful sales to individual patients through approved named-patient programs during 2008.

We have submitted an application for marketing authorization in Australia for Soliris for the treatment of patients with PNH. The application was accepted for priority review. Soliris has received Orphan Drug Designation in Australia, which provides certain regulatory and filing fee advantages, including market exclusivity for several years after approval subject to certain exceptions. We have also submitted applications for marketing authorization for Soliris in Canada and Switzerland for the treatment of patients with PNH. We were granted limited marketing authorization in Switzerland in September 2008 and approval in Canada in January 2009.

We completed the 12-week AEGIS study of Japanese patients in October 2008. This study was a single registration study to evaluate the safety, efficacy, and pharmacology of Soliris as a treatment for Japanese patients with PNH. The open label study was authorized by Japan's Pharmaceutical and Medical Devices Agency. Summary results were reported in December 2008. The pre-specified primary efficacy endpoint of change in hemolysis was achieved with statistical significance and the drug appeared to be safe and well tolerated in study patients.

We are also focusing our research efforts on the use of eculizumab as a treatment for patients with other rare and severe complement-mediated conditions, including chronic hemolytic and thrombotic disorders, transplant rejection and chronic and debilitating neurological disorders. The FDA authorized our Investigational New Drug Application, or IND, for studying the safety and efficacy of eculizumab in treating myasthenia gravis, a rare autoimmune syndrome characterized by the failure of neuromuscular transmission, and we commenced clinical development in 2008. We are currently developing clinical programs to investigate the use of eculizumab as a treatment for patients with other complement-mediated disorders, including three severe, life-threatening, and rare hematologic disorders: atypical hemolytic uremic syndrome, or aHUS, a disease in which the lack of naturally occurring complement inhibitors can cause life-threatening kidney damage; catastrophic anti-phospholipid syndrome, a disorder in which uncontrollable blood clotting often leads to multiple organ failure; and cold agglutinin disease, an auto-immune hemolytic anemia. The program for aHUS was initiated in January, 2009. Also, we completed a phase I/II proof of concept study of IV eculizumab in allergic asthmatic patients in the fourth quarter of 2008.

We are aware that investigator-initiated trials of eculizumab have begun in patients with multifocal motor neuropathy (MMN), a severe autoimmune neurologic disorder, and dense deposit disease, a severe kidney disease. We are also aware that independent investigators have commenced a study to evaluate eculizumab in organ transplantation.

The FDA has also authorized our IND to evaluate the activity of an antibody to the immune regulator CD200 in patients with chronic lymphocytic leukemia, or CLL, an incurable chronic cancer that results from expansion of B-lymphocytes, and other blood tumors such as multiple myeloma. We commenced dosing of initial CLL patients with anti-CD200 in the second quarter of 2008.

In July 2008, the Company's Board of Directors approved a two-for-one stock split to be effected in the form of a 100 percent stock dividend. The additional shares were distributed on August 22, 2008 to stockholders of record as of the close of trading on August 12, 2008. All share and per share data presented in this Form 10-K have been retroactively restated to reflect this stock split.

## **Table of Contents**

In October 2008, certain holders of our 1.375% Convertible Senior Notes due 2012, or 1.375% Notes, exercised conversion rights with respect to an aggregate principal amount of \$52,778 of the 1.375% Notes resulting in the issuance of 3,356 shares of common stock. The shares were issued in November 2008. On December 31, 2008, the outstanding principal balance of the 1.375% Notes was \$97,222.

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

The significant accounting policies and basis of preparation of our consolidated financial statements are described in Note 1, Business Overview and Summary of Significant Accounting Policies. Under accounting principles generally accepted in the United States, we are required to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingent assets and liabilities in our financial statements. Actual results could differ from those estimates.

We believe the judgments, estimates and assumptions associated with the following critical accounting policies have the greatest potential impact on our consolidated financial statements, so we consider these to be our critical accounting policies:

Revenue recognition

Royalties

Inventories

Research and development expenses

Stock-based compensation

Long-lived assets

Income taxes

### **Revenue Recognition**

#### *Net Product Sales*

Our principal source of revenue is product sales. We have applied the following principles in recognizing revenue:

To date, our product sales have consisted solely of Soliris. We recognize revenue from product sales when persuasive evidence of an arrangement exists, risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured and we have no further performance obligations. Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in the Company's statements of operations, and do not impact net product sales.

In the United States, our customers are primarily specialty distributors and specialty pharmacies who supply physician office clinics, hospital outpatient clinics, infusion clinics or home health care providers. In some cases, we also sell Soliris to government agencies. Outside the United States, our customers are primarily hospitals, hospital buying groups, pharmacies, other health care providers and distributors.



## Table of Contents

In addition to commercial sales, we have recorded revenue on sales for individual patients through named-patient programs outside the United States. The relevant authorities or institutions in those countries have agreed to reimburse for product sold on a named-patient basis where Soliris has not received final approval for commercial sales.

We record estimated rebates payable under governmental programs, including Medicaid and programs in Europe, as a reduction of revenue at the time product sales are recorded. Our calculations related to these rebate accruals require estimates, including estimates of customer mix, to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period and record any necessary adjustments to our reserves. Generally, the length of time between product sale and the processing and reporting of the rebates is three to nine months.

Upon reconciliation of government reporting to our sales records, we revise our estimates of rebates payable, which may have an impact on revenue in the period in which the adjustment was made. Due to the limited number of rebate programs, the small number of patients treated with Soliris, the short period of time from sale of product to patient infusion and the lack of contractual rights of return, we are able to estimate rebates payable to third parties such that future adjustments are expected to be insignificant.

We have provided balances and activity in the rebates payable account for the year ended December 31, 2006, 2007 and 2008 as follows:

	<b>Rebates Payable</b>
<b>Balance at December 31, 2006</b>	<b>\$</b>
Allowances for sales	(1,024)
Payments/credits made for sales	18
 <b>Balance at December 31, 2007</b>	 <b>(1,006)</b>
Allowances for sales	(4,308)
Payments/credits made for sales	1,967
 <b>Balance at December 31, 2008</b>	 <b>\$ (3,347)</b>

Because of the pricing of Soliris, the limited number of patients, the short period from sale of product to patient infusion and lack of contractual return rights, Soliris customers generally carry limited inventory. We monitor inventory within our distribution channel to determine whether deferral of sales are required related to inventory in our sales channels. To date, actual refunds and returns have been negligible.

We also record distribution and other fees paid to our customers as a reduction of revenue. These costs are known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

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

## **Royalties**

Our cost of sales includes royalties to third parties related to the sale and commercial manufacture of Soliris. We estimate our royalty obligations based on existing contractual obligations and our assessment of estimated

## **Table of Contents**

royalties owed to other third parties. These estimates may be influenced by the outcome of unasserted claims and litigation, the results of which are uncertain (see Note 11 of our consolidated financial statements). On a periodic basis and based on events such as the outcome of litigation, we may reassess these estimates, resulting in adjustments to cost of sales.

### **Inventories**

Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of inventory using the average cost method.

For products that are in initial clinical development, we capitalize inventory costs prior to regulatory approval, but subsequent to the filing of the Biologics License Application, or BLA, when we determine that the inventory has probable future economic benefit. Inventory is not capitalized prior to completion of a Phase III clinical trial. We also capitalize the cost of inventory manufactured at our manufacturing plant in property, plant and equipment prior to validation of the facility by the FDA. Once we receive approval by the FDA, the cost of the inventory will be reclassified from property, plant and equipment to inventory.

We analyze our inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of our product is subject to strict quality control, certain batches or units of product may, after a period of time, no longer meet quality specifications or may expire, at which point we would adjust our inventory values. Soliris currently has a maximum estimated life of 48 months and, based on our sales forecasts, we expect to fully realize the carrying value of the Soliris inventory.

The determination of whether or not inventory costs will be realizable requires estimates by our management. A critical input in this determination is future expected inventory requirements, based on internal sales forecasts. We then compare these requirements to the expiry dates of inventory on hand. To the extent that inventory is expected to expire prior to being sold, we will write down the value of inventory. If actual results differ from those estimates, additional inventory write-offs may be required.

To date, we have not recorded any material adjustments to our inventory related to excess, expired or obsolete inventory. In the future, reduced demand, quality issues or excess supply may result in write-downs, which would be recorded as adjustments to cost of sales.

### **Research and Development Expenses**

We accrue costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations (CROs), clinical study sites, laboratories, consultants, or other clinical trial vendors that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through close communication with the CROs and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter for each individual trial. The estimates are reviewed and discussed with the CRO or vendor as

## **Table of Contents**

necessary, and are included in research and development expenses for the related period. For clinical study sites, which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrolment in each quarter. The estimates may differ from the actual amount subsequently invoiced, which may result in adjustment to research and development expense several months after the related services were performed.

### **Stock-Based Compensation**

We have one stock-based compensation plan known as the 2004 Incentive Plan. Under this plan, restricted stock, stock options and other stock-related awards may be granted to our directors, officers, employees and consultants or advisors of the Company or any subsidiary.

Our estimates of employee stock option values rely on estimates of factors we input into the Black-Scholes model. The key factors involve an estimate of future uncertain events. Significant assumptions include the use of historical volatility to determine the expected stock price volatility. We also estimate expected term until exercise, forfeiture or cancellation, as well as the reduction in the expense from expected forfeitures. We currently use historical exercise and cancellation patterns as our best estimate of future estimated life. Actual volatility and lives of options may be significantly different from our estimates. If factors change and we employ different assumptions in the application of FAS 123(R), the compensation expense that we record in future periods may differ significantly from our prior recorded amounts.

### **Long-Lived Assets**

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

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

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

- a significant decrease in market value of assets.

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

Other than the integration plan initiated with our subsidiary, Alexion Antibody Technologies, Inc., we have not experienced a significant triggering event and, therefore, have not recorded any impairment charges related to our long lived assets. To the extent we were to experience a triggering event, particularly as it relates to our largest long-lived asset, the Smithfield, Rhode Island manufacturing facility, the resulting analysis may require an impairment charge to our statement of operations.

## **Table of Contents**

### **Income Taxes**

Despite achieving profitability in 2008, we continue to maintain a valuation allowance on our net operating losses (NOLs) and other deferred tax assets in certain jurisdictions because we have an extended history of annual losses in these jurisdictions. Federal NOL carryforwards total approximately \$745,000. During 2008, we reversed valuation allowances related to several foreign entities, based on an assessment of current and future profitability.

On a quarterly basis, we reassess the valuation allowance for deferred income tax assets. We would consider reversing a significant portion of the valuation reserve upon assessment of certain factors, including: (i) a demonstration of sustained profitability; and (ii) the support of internal financial forecasts demonstrating the utilization of the NOLs prior to their expiration. If we determine that the reversal of the valuation reserves in these jurisdictions is appropriate, a significant one-time benefit will be recognized against our income tax provision in the period of the reversal.

In addition, the portion of our NOLs and income tax credits related to deductions for employee stock options will be credited to additional paid-in capital if and when realized. At such time, we will also commence recognizing an income tax provision at our effective tax rate. However, our ability to utilize our NOLs and credits to offset taxable income will continue to provide us with cash savings until the NOLs and credits are fully utilized or expire. The NOLs and credits remain subject to examination by Federal and state authorities due to their carried forward position.

We adopted the provisions of FIN 48 and FSP FIN 48-1, Definition of Settlement in FASB Interpretation No. 48, or FSP FIN 48-1, effective January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109 and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. We account for interest and penalties related to uncertain tax positions as part of our provision for income taxes. These unrecognized tax benefits relate primarily to issues common among multinational corporations in our industry. We apply a variety of methodologies in making these estimates which include studies performed by independent economists, advice from industry and subject experts, evaluation of public actions taken by the Internal Revenue Service and other taxing authorities, as well as our own experience. We provide estimates for unrecognized tax benefits. Adjustments may be made to these estimates as a result of events such as resolution of tax audits or lapsing of statutory audit periods. We will also refine these estimates over time as our operations mature and as we gain more experience operating as a taxpayer on a worldwide basis. If our estimates are not representative of actual outcomes, our tax provision, and related effective tax rate, recorded in our statement of operations could be materially impacted.



## Table of Contents

### Results of Operations

The following table sets forth consolidated statements of operations data for the periods indicated. This information has been derived from the consolidated financial statements included elsewhere in this Form 10-K.

	Year Ended December 31,		
	2008	2007	2006
<b>Revenues:</b>			
Net product sales	\$ 259,004	\$ 66,381	\$
Contract research revenue	95	5,660	1,458
Other revenue			100
<b>Total revenues</b>	<b>259,099</b>	<b>72,041</b>	<b>1,558</b>
Cost of sales	28,366	6,696	
<b>Research and development expenses:</b>	<b>62,581</b>	<b>68,961</b>	<b>83,225</b>
Selling, general and administrative	133,543	96,142	55,418
<b>Total operating expenses</b>	<b>196,124</b>	<b>165,103</b>	<b>138,643</b>
Operating income (loss)	34,609	(99,758)	(137,085)
<b>Other income (expense):</b>			
Investment income	2,810	8,080	8,076
Interest expense	(2,407)	(2,489)	(2,837)
Foreign currency gain (loss)	(282)	1,132	(41)
Income tax provision (benefit)	1,581	(745)	(373)
Net income (loss)	\$ 33,149	\$ (92,290)	\$ (131,514)
<b>Earnings (loss) per common share:</b>			
Basic	\$ 0.43	\$ (1.27)	\$ (2.07)
Diluted	\$ 0.39	\$ (1.27)	\$ (2.07)

## **Table of Contents**

### ***Comparison of the Year Ended December 31, 2008 to the Year Ended***

#### ***December 31, 2007***

#### **Revenues**

During the year ended December 31, 2008, we recorded sales of Soliris related to commercial sales in the United States of \$113,204 and commercial and named-patient sales outside the United States of \$145,800. Included in revenue from outside the United States, we have recorded a gain of \$4,141 related to our foreign currency cash flow hedging program. During the year ended December 31, 2007, we recorded sales of Soliris related to commercial sales in the United States of \$46,196 and commercial and named-patient sales in the European Union of \$20,185.

In March 2007, the FDA granted approval for Soliris for the treatment of PNH. In June 2007, the E.C. also approved Soliris for the treatment of PNH. Our product sales have been solely attributable to sales of Soliris and have been generated from three sources: commercial sales in the United States (beginning in the second quarter of 2007), named-patient sales prior to full-scale commercialization in certain countries outside the United States (beginning in the first quarter of 2007) and commercial sales in countries outside the United States (beginning in the fourth quarter of 2007). The increases in revenue for fiscal year 2008 versus 2007 were due to an increased number of patients treated with Soliris as a result of our product launch in the United States and in various countries in Europe.

As additional physicians request Soliris for their patients with PNH and obtain governmental reimbursement, we expect that the number of patients receiving Soliris treatments will increase, resulting in an increase in product sales in existing countries. We also expect product sales in the rest of the world to increase as we progress with appropriate authorities on the regulatory, price approval and reimbursement process in additional territories.

We recorded contract research revenues of \$95 and \$5,660 for the years ended December 31, 2008 and 2007, respectively. Of the \$5,660 in contract research revenues recorded in 2007, \$5,343 relates to the termination of our collaborative agreement with Proctor & Gamble, effective March 30, 2007.

#### **Cost of Sales**

Cost of sales was \$28,366 and \$6,696 for the years ended December 31, 2008 and 2007, respectively. Cost of sales includes actual and estimated royalty expenses associated with sales of Soliris, as well as other manufacturing costs. Changes in the estimates of royalties owed to certain third parties could have a material impact on our cost of sales in future periods.

Product sold during the year ended December 31, 2007 included inventory that was previously expensed prior to submission of our BLA and therefore is not included in the cost of sales during this period. During the fourth quarter of 2007, we exhausted the supply of previously expensed inventory. Beginning in 2008, our cost of sales reflected the full manufacturing cost of the inventory.

In the fourth quarter of 2008, we entered into a patent license agreement and settlement agreement with PDL BioPharma in which we are obligated to pay a total of \$25,000 for a fully paid, perpetual license. As a result of the settlement and evaluation of other potential royalties, we recorded a reduction in cost of goods sold of approximately \$1,800 related to an adjustment of estimated accrued royalties for sales of Soliris prior to the fourth quarter. We further expect that this settlement will have a favorable impact of our future cost of goods sold.

**Table of Contents**

On a periodic basis and based on events such as the outcome of litigation, we may reassess the estimates of royalties owed to certain third parties. Changes in these estimates could have a material impact on our cost of sales in future periods.

**Research and Development Expenses**

Our research and development expense includes personnel, facility and external costs associated with the research and development of our product candidates, as well as product development costs.

We group our research and development expenses into two major categories: external direct expenses and all other R&D expenses.

External direct expenses are comprised of costs paid to outside parties for clinical development, product development and discovery research. Clinical costs are comprised of costs to conduct and manage clinical trials related to Soliris and other product candidates. Product development costs, which historically relate primarily to Soliris, are those incurred in performing duties related to pre- and post-approval manufacturing development and regulatory functions. Discovery research costs are incurred in conducting laboratory studies and performing preclinical research for other uses of Soliris and other product candidates. Clinical costs have been accumulated and allocated to each of our programs, while product development and discovery research costs have not been allocated.

All other R&D expenses consist of costs to compensate personnel, to maintain our facility, equipment and overhead and similar costs of our research and development efforts. These costs relate to efforts on our clinical and preclinical products as well as our discovery research efforts. These costs have not been allocated directly to each program.

The following table provides information regarding research and development expenses:

	Year Ended December 31, 2008	Year Ended December 31, 2007	\$ Variance	% Variance
Clinical development	\$ 16,803	\$ 17,294	\$ (491)	-2.8%
Product development	10,519	11,944	(1,425)	-11.9%
Discovery research	1,201	2,801	(1,600)	-57.1%
<b>Total external direct expenses</b>	<b>28,523</b>	<b>32,039</b>	<b>(3,516)</b>	<b>-11.0%</b>
Payroll and benefits	26,380	29,634	(3,254)	-11.0%
Operating and occupancy	4,192	4,615	(423)	-9.2%
Depreciation and amortization	3,486	2,673	813	30.4%
<b>Total other R&amp;D expenses</b>	<b>34,058</b>	<b>36,922</b>	<b>(2,864)</b>	<b>-7.8%</b>
<b>Research and development expense</b>	<b>\$ 62,581</b>	<b>\$ 68,961</b>	<b>\$ (6,380)</b>	<b>-9.3%</b>

**Table of Contents**

The following table summarizes external direct expenses related to our clinical development programs. Please refer to Item 1, Business, for a description of each of these programs:

	Year Ended December 31, 2008	Year Ended December 31, 2007	Year Ended December 31, 2006	Accumulated Expenditures since January 1, 2006
<b>External direct expenses</b>				
Soliris: PNH program	\$ 13,564	\$ 14,084	\$ 16,901	\$ 44,549
Soliris: non-PNH programs	1,167	521		1,688
CD200 program	458			458
Pexelizumab		1,847	11,866	13,713
Other	1,614	842	3,495	5,951
	<b>\$ 16,803</b>	<b>\$ 17,294</b>	<b>\$ 32,262</b>	<b>\$ 66,359</b>

Previous to January 1, 2006, we have spent approximately \$475,838 on all research & development programs. Substantially all of our research and development expenses prior to the year ended December 31, 2006 were related to two products, eculizumab and pexelizumab. We obtained approval for eculizumab for the treatment of PNH in 2007 in the United States and European Union, and ceased development of pexelizumab in 2006.

The successful development of our drug candidates is uncertain and subject to a number of risks. A large portion of our annual expenses relates to commercialization of Soliris and general and administrative costs. We may not have or be able to raise the necessary capital to support both the commercialization of Soliris as well as each of our development programs through and until commercialization. Further, we cannot guarantee that results of clinical trials will be favorable or sufficient to support regulatory approvals for our other programs. We could decide to abandon development or be required to spend considerable resources not otherwise contemplated. For additional discussion regarding the risks and uncertainties regarding our development programs, please refer to the Risk Factors in this Form 10-K, including the risk factors set forth on page 30 ( If we fail to obtain the capital necessary to fund our operations, we will be unable to continue the commercialization of Soliris or continue to complete our product development ), page 25 ( None of our product candidates except for Soliris has received regulatory approvals ), page 25 ( Completion of pre-clinical studies or clinical trials does not guarantee advancement to the next phase of development ) and page 26 ( There are many reasons why drug testing could be delayed or terminated ).

During the year ended December 31, 2008, we incurred research and development expenses of \$62,581, a decrease of \$6,380, or 9.3% versus the \$68,961 incurred during the year ended December 31, 2007. The decrease was primarily due to the following:

Decrease of \$3,254 in research and development payroll and benefit expense related primarily to a reduction in stock-based compensation due to employee forfeitures and additional capitalization to inventory and property, plant and equipment.

Increase of \$813 in depreciation and amortization related primarily to the amortization of costs associated with our new pilot plant located at our manufacturing facility in Smithfield, RI, which was placed in service in the fourth quarter 2007.

## **Table of Contents**

Decrease of \$1,600 in discovery research was primarily due to a reduction in external research and consulting fees.

Decrease of \$1,425 in product development expenses due to increased manufacturing and plant readiness activities including a decrease of approximately \$925 relating to additional capitalization of costs associated with the validation of our manufacturing facility in Smithfield, Rhode Island.

We expect our research and development expenses to increase in 2009 due to clinical trials, manufacturing costs and research related to eculizumab and anti-CD200 development programs. For additional information on these programs, please refer to Product and Development Programs in Item I of this Form 10-K.

## **Selling, General and Administrative Expenses**

During the year ended December 31, 2008, we incurred selling, general and administrative expenses of \$133,543, an increase of \$37,401 or 38.9% versus the \$96,142 incurred during the year ended December 31, 2007. The increase was primarily due to the following:

During the year ended December 31, 2008, salaries, benefits and other labor expenses increased to \$66,856, an increase of \$17,335, or 35%, versus \$49,521 incurred during the year ended December 31, 2007. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of \$17,211 related to our global commercial operations teams. Other increases related to payroll and benefits within our executive, finance, information technology, human resources and legal groups to support our growth as a commercial entity.

Increase in non-labor commercial operations of \$14,746 for the year ended December 31, 2008 was primarily due to the expansion of our foreign operations, which we expanded significantly in the latter half of 2007.

Increase in non-labor general and administration of \$5,977 primarily related to increases in legal costs associated with ongoing litigation and increases in infrastructure costs to support our growth as a commercial entity.

Decrease in non-labor information technology of \$1,293 primarily related to the costs associated with the build out of our European operations in 2007.

We expect our selling, general and administrative expenses to increase in 2009, reflecting the additional growth of our organizational structure in the U.S. and the rest of the world.

## **Other Income (Expense)**

During the year ended December 31, 2008, we recognized \$282 of foreign currency loss, a decrease of \$1,414, or 124.9%, versus a gain of \$1,132 incurred during the year ended December 31, 2007. The decreased impact of foreign currency fluctuations was due to our hedging programs implemented in 2008.

During the year ended December 31, 2008, investment income decreased \$5,270, or 65.2% to \$2,810 due primarily to reduced interest rates earned in money market funds.

During the year ended December 31, 2008, interest expense of \$2,407 was consistent with the amounts recognized during the year ended December 31, 2007.

## **Table of Contents**

### **Income Taxes**

During the year ended December 31, 2008, we recorded an income tax provision of \$1,581, compared to an income tax benefit of \$745 for the year ended December 31, 2007. The tax expense during 2008 is principally attributable to entities in certain foreign jurisdictions who achieved profitability during the year, offset by the reversal of valuation allowances in these foreign jurisdictions and the exchange of research tax credits for cash. The income tax benefit for 2007 is attributable to the exchange of research tax credits for cash.

The Company maintains a valuation allowance against certain U.S. and foreign deferred tax assets as realizability of those assets is uncertain. During 2009, we will continue to monitor our deferred tax assets in order to assess whether adjustments related to our valuation allowance may be required.

### ***Comparison of the Year Ended December 31, 2007 to the Year Ended***

#### ***December 31, 2006***

### **Revenues**

During the year ended December 31, 2007, we recorded sales of Soliris related to commercial sales in the United States of \$46,196 and commercial and named-patient sales in the European Union of \$20,185. Because our commercial and pre-approval sales programs did not begin until 2007, there were no sales of Soliris for the year ended December 31, 2006.

We recorded contract research revenues of \$5,660 and \$1,458 for the years ended December 31, 2007 and 2006, respectively. Contract research revenues reflect the amortization of deferred revenue resulting from cash received from P&G under our collaboration for the development and commercialization of pexelizumab and U.S. government funded research grant revenue for our asthma program.

For the year ended December 31, 2007, the increase in contract research revenue, as compared to the year ended December 31, 2006, was due to the termination of our collaborative agreement with P&G. Effective March 30, 2007, we and P&G agreed to terminate our 1999 collaboration agreement for the development and commercialization of pexelizumab. As the agreement has been terminated, the remaining portion of the \$10,000 non-refundable upfront license fee, or \$5,343, was recognized as revenue during the three months ended March 31, 2007. Due to the termination of the P&G agreement, we expect that future contract research revenue will be dependent upon future awards or grants.

For the year ended December 31, 2007, the decrease in U.S. government grants, as compared to the same period in the prior year, was primarily due to the conclusion of the anthrax program in 2006.

### **Cost of Sales**

Cost of sales was \$6,696 for the year ended December 31, 2007. There was no cost of sales incurred for periods prior to December 31, 2006. Cost of sales includes actual and estimated royalty expenses associated with sales of Soliris, as well as other manufacturing costs. Changes in the estimates of royalties owed to certain third parties could have a material impact on our cost of sales in future periods.

Product sold during the year ended December 31, 2007 included inventory that was previously expensed prior to submission of our BLA, and therefore is not included in the cost of sales during this period. During the fourth quarter of 2007, we exhausted the supply of previously expensed inventory.

**Table of Contents****Research and Development Expenses**

The following table provides information regarding research and development expenses:

	Year Ended December 31, 2007	Year Ended December 31, 2006	\$ Variance	% Variance
Clinical development	\$ 17,294	\$ 32,262	\$ (14,968)	-46%
Product development	11,944	8,035	3,909	49%
Discovery research	2,801	4,973	(2,172)	-44%
<b>Total external direct expenses</b>	<b>32,039</b>	<b>45,270</b>	<b>(13,231)</b>	<b>-29%</b>
Payroll and benefits	29,634	30,061	(427)	-1%
Operating and occupancy	4,615	5,520	(905)	-16%
Depreciation and amortization	2,673	2,374	299	13%
<b>Total other R&amp;D expenses</b>	<b>36,922</b>	<b>37,955</b>	<b>(1,033)</b>	<b>-3%</b>
<b>Research and development expense</b>	<b>\$ 68,961</b>	<b>\$ 83,225</b>	<b>\$ (14,264)</b>	<b>-17%</b>

During the year ended December 31, 2007, we incurred research and development expenses of \$68,961, a decrease of \$14,264, or 17.1% versus the \$83,225 incurred during the year ended December 31, 2006. The decrease was primarily due to, and offset, by the following:

Decrease of \$14,968 in clinical development expense due largely to decreases in spending for pexelizumab program of \$10,022, the reduction or completion of eculizumab programs, including TRIUMPH, SHEPHERD and EXTENSION clinical trials and incurrence of 2006 costs in association with filing the BLA of \$7,516. These decreases were offset by increases of \$7,850 related to new programs in 2007, including EXPLORE and EMBRACE clinical trials and the PNH registry.

Increase of \$3,909 in product development expenses due to an increase of \$5,518 related to expenditures for drug development, quality assurance, scientific communications and regulatory affairs due to the regulatory approvals in both the United States (March 2007) and the European Union (June 2007). The increase was offset by a decrease in manufacturing costs of \$1,622 related to the capitalization of inventory costs beginning with filing of the BLA in September 2006. Prior to September 2006, we expensed all manufacturing costs, resulting in lower 2007 expenses compared to 2006.

Decrease of \$2,172 in discovery research was primarily due to the closure of AAT operations.

**Selling, General and Administrative Expenses**

During the year ended December 31, 2007, we incurred selling, general and administrative expenses of \$96,142, an increase of \$41,263 or 75.2% versus the \$55,418 incurred during the year ended December 31, 2006. The increase was primarily due to the following:

During the year ended December 31, 2007, salaries, benefits and other labor expenses increased to \$49,521, an increase of \$21,863, or 79.0%, versus \$27,658 incurred during the year ended December 31, 2006. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of \$18,250 related to our global commercial operations teams. Other increases related to payroll and benefits within our executive, finance, information technology, human resources and legal groups to support our growth as a commercial entity.





## **Table of Contents**

Increase in non-labor commercial operations of \$14,087 for the year ended December 31, 2007. For the year ended December 31, 2007, this increase was comprised primarily of increases in advertising and promotion of Soliris related to the April 2007 commercial launch in the United States and market research related to approval of Soliris in the European Union, as well as promotion of Soliris for commercial launches in certain European countries.

Increase in non-labor general and administration and information technology of \$3,862 for the year ended December 31, 2007 related to increases in infrastructure costs to support our growth as a commercial entity.

### **Other Income (Expense)**

During the year ended December 31, 2007, we recognized \$1,132 of foreign currency gain. There was no foreign currency gain (loss) recorded in 2006. As a result of our European operations, we have exposure, primarily from accounts receivable and intercompany receivables and payables denominated in foreign currencies, to adverse movements in foreign currency exchange rates, primarily related to the Euro.

During the year ended December 31, 2007, investment income and interest expense were consistent with the results recognized during the year ended December 31, 2006.

### **Income Taxes**

During the year ended December 31, 2007, we recorded an income tax benefit of \$745, compared to \$373 for the year ended December 31, 2006. The increase in the tax benefit was attributable to an increase in the estimated cash exchange of a state incremental research and development tax credit.

### **Liquidity and Capital Resources *(amounts in thousands, except per share data)***

As of December 31, 2008, our consolidated cash, cash equivalents, restricted cash and marketable securities totaled \$139,711. The \$32,999 increase from December 31, 2007 is largely attributable to the significantly increased sales and the resulting collection of accounts receivable and proceeds from employee option exercises, offset by payments for our patent purchase from OMRF and investments in inventory and our Smithfield, Rhode Island facility. Until required for use in the business, we invest our cash reserves in money market funds and high quality commercial, corporate and U.S. Government notes in accordance with our investment policy. We do not have any investments in auction rate securities.

As of December 31, 2008, \$619 of cash was restricted to be used for the construction and other costs related to our Rhode Island manufacturing facility. An additional \$1,100 is restricted as part of a leasehold deposit for office space.

Financial instruments that potentially expose the Company to concentrations of credit risk are limited to cash equivalents, accounts receivable and our foreign exchange derivative contracts. Substantially all cash equivalents are held in a single AAA rated institutional money market fund that participates in the U.S. Department of Treasury's Temporary Guarantee Program for money market funds. At December 31, 2008, two individual customers accounted for 20.3% and 20.0% of the accounts receivable balance. For the period ended December 31, 2008, one customer accounted for 21.0% of our product sales.

## **Table of Contents**

At December 31, 2008, we have foreign currency forward contracts with notional amounts totaling \$128,876. These outstanding foreign currency forward contracts had a fair value of \$5,409, which is included in other current assets. The counterparty to these forward contracts is a large multinational commercial bank, and we believe the risk of nonperformance is not material. However, we can not be assured that the financial institution will not be further impacted by the negative economic environment.

At December 31, 2008, our working capital was \$192,683, compared to \$167,645 at December 31, 2007. At December 31, 2008, our current ratio was 3.28, compared to 5.45 at December 31, 2007. The decrease in current ratio relates primarily to the \$25,000 license payable owed to PDL BioPharma.

We anticipate that cash generated from operations and our existing available cash, as well as 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 twelve months.

### ***Cash Flows from Operating Activities***

Net cash provided by operating activities was \$53,199 for the year ended December 31, 2008 versus \$139,614 used in operating activities for the year ended December 31, 2007. The change is primarily due to the net income achieved in 2008 versus the net loss as compared to the same period in 2007. The components of cash provided by operating activities for the period ended December 31, 2008 are as follows:

Our reported net income, plus non-cash items, including depreciation and amortization, unrealized currency gain, unrealized hedge gains, unrealized pension losses and stock compensation, of \$64,959.

Net cash outflow due to changes in operating assets of \$46,011, primarily attributable to increases in inventories and accounts receivable, offset by increases in accounts payable and accrued expenses of \$32,912. The growth in our sales of Soliris has required substantial investments in working capital items such as inventories and accounts receivable.

In 2009, we expect changes in cash from operations to be highly dependent on sales levels, and the related cash collections, from Soliris. In addition, we expect that cash outflows related to the changes in operating assets will continue to increase related to sales and resulting accounts receivable increases.

### ***Cash Flows from Investing Activities***

Net cash used in investing activities was \$38,650 for the year ended December 31, 2008 versus \$3,077 provided by investing activities for the year ended December 31, 2007. For the year ended December 31, 2008, the net cash used for investing activities consisted of the following:

Cash inflow from the net sale of marketable securities of \$9,368, which was used to fund our operations

Additions to property, plant and equipment of \$39,733, of which \$25,180 was attributable to the construction of our Rhode Island manufacturing facility, with the remaining attributable to spending on information technology and facility capital costs

Outflow of \$7,500 for the purchase of patents from OMRP and \$1,124 for the purchase of a license in association with the acquisition of Legend K.K.

## **Table of Contents**

In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island for the future commercial production of Soliris, for manufacturing development and for manufacturing of future products. Since this date, we have incurred costs related to the construction of the plant to support full-scale commercial manufacturing. We have also capitalized costs related to validation activities, including engineering runs, necessary to obtain approval of the facility from government regulators for the production of a commercially approved drug. To date, these costs primarily include direct labor, materials, overhead and pre-validation inventory related to the facility. We will begin depreciating the fixed assets related to the facility when the assets are substantially complete and ready for their intended use, which will occur upon the regulatory approval of the plant for production of commercial quantities of eculizumab.

Through December 31, 2008, we have capitalized \$116,364 related to the facility, which includes all costs associated with construction, renovation and upgrades, engineering runs and capitalized interest. Through December 31, 2008, costs incurred in seeking regulatory approval, including engineering runs, was \$42,416, and capitalized interest was \$9,045. We expect to continue to incur costs related to the validation process through the end of the 2009. At such point that we receive regulatory approval, we will cease capitalizing costs into property, plant and equipment

### ***Cash Flows from Financing Activities***

Net cash provided by financing activities was \$28,308 and \$64,844 for the year ended December 31, 2008 and 2007, respectively, consisting primarily of proceeds from the issuance of common stock related to the exercise of stock options of \$28,893 and \$47,005, respectively, and proceeds from the mortgage loan agreement with iStar of \$18,000 in 2007.

### ***Contractual Obligations***

Our contractual obligations include our \$97,222, 1.375% Convertible Senior Notes due February 2012, or 1.375% Notes, our \$44,000 mortgage loan due August 2017 with a fixed annual interest rate of 9.12%, a \$25,000 license payable owed to PDL BioPharma and our annual payments of approximately \$4,500 for operating and capital leases, principally for facilities and equipment. We also have contractual obligations related to our third party manufacturer and to certain other third parties described below, as well as open letters of credit totaling \$4,165.

## Table of Contents

The following table summarizes our contractual obligations at December 31, 2008 and the effect such obligations and commercial commitments are expected to have on our liquidity and cash flow in future fiscal years. These do not include milestones and assume non-termination of agreements. These obligations, commitments and supporting arrangements represent payments based on current operating forecasts, which are subject to change:

	Total	Less than 1 Year	2-3 Years	4-5 Years	More than 5 Years
<b>Contractual obligations:</b>					
Convertible notes payable	\$ 97,222	\$	\$	\$ 97,222	\$
Mortgage loan	44,000		10,756	11,734	21,510
Interest expense	24,971	5,428	9,980	5,812	3,751
Capital and operating leases	26,771	5,055	7,961	5,702	8,053
Total contractual obligations	\$ 192,964	\$ 10,483	\$ 28,697	\$ 120,470	\$ 33,314
<b>Commercial commitments:</b>					
Clinical and manufacturing development	\$ 30,000	\$ 3,750	\$ 15,000	\$ 11,250	\$
Licenses	28,890	27,900	395	400	195
Total commercial commitments	\$ 58,890	\$ 31,650	\$ 15,395	\$ 11,650	\$ 195

The contractual obligations table above does not include contingent royalties and other contingent contractual payments we may owe to third parties in the future because such payments are contingent on future sales of our products and the existence and scope of third party intellectual property rights and other factors described under the Risk Factors . The table above also does not include a liability for unrecognized tax benefits related to various federal, state and foreign income tax matters of \$9,569 at December 31, 2008. The timing of the settlement of these amounts was not reasonably estimable at December 31, 2008. We do not expect a settlement within the next twelve months.

### Convertible Notes

We hold \$97,222 principal amount of 1.375% Convertible Senior Notes due February 1, 2012, or the 1.375% Notes. We pay interest on these notes on a semi-annual basis on February 1 and August 1 of each year, beginning August 1, 2005. However, no principal payments are due until February 2012, except under certain circumstances such as liquidation, merger or business combination. The convertible notes payable do not contain covenants related to our financial performance.

In October 2008, certain holders of our 1.375% Notes exercised conversion rights with respect to an aggregate principal amount of \$52,778 of the 1.375% Notes resulting in the issuance of 3,356 shares of common stock. The shares were issued in November 2008.

The 1.375% Notes are convertible into our common stock at an initial conversion rate of 63.5828 shares of common stock (equivalent to a conversion price of approximately \$15.73 per share) per \$1 principal amount of the 1.375% Notes, subject to adjustment, at any time prior to the close of business on the final maturity date of the notes. We do not have the right to redeem any of the 1.375% Notes prior to maturity. The conversion rate and conversion price have been adjusted for the stock split effected on August 22, 2008.

## **Table of Contents**

As of December 31, 2008, the market value of our \$97,222, 1.375% Convertible Notes due February 1, 2012, based on quoted market prices, was estimated at \$211,106 versus \$375,000 at December 31, 2007. The decrease of \$163,894 from December 31, 2007 is largely attributable to the conversion of \$52,778 of principal value of the Notes in October 2008.

### *Mortgage Loan*

We have a mortgage loan of \$44,000 to finance the purchase and construction of our manufacturing facility in Smithfield, Rhode Island. The mortgage loan bears interest at a fixed annual rate of 9.12%. The loan principal is required to be repaid in equal monthly installments of \$489, starting March 2010 and until August 2017, at which time all outstanding balances are due. The loan is collateralized by the assets of our Smithfield, RI manufacturing facility. The loan may not be prepaid in whole or in part prior to July 2009. After that date, the loan can be prepaid in whole, but not in part, and must include a prepayment premium as described in the loan agreement.

As a condition of the loan, we are required to maintain restricted cash accounts. These accounts must maintain certain operating escrow balances. At December 31, 2008, the balance of restricted cash was \$619.

The mortgage loan does not contain covenants related to our financial performance.

### *Revolving Credit Facility*

In February 2008, we entered into a Credit Agreement with Bank of America, N.A. to provide for an available \$25,000 revolving credit facility that can be used for working capital requirements and other general corporate purposes. The loan is collateralized by substantially all of Alexion Pharmaceuticals, Inc.'s assets, including the pledge of the equity interests of certain direct subsidiaries, but excluding intellectual property, assets of foreign subsidiaries and assets related to our manufacturing facility in Smithfield, RI. The borrowing base is limited to the lesser of \$25,000 or 80% of eligible domestic receivables. At December 31, 2008, we had no outstanding balance under the revolving credit facility.

We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.75% to 2.25% depending on Alexion's liquidity (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect and (B) the Federal Funds Rate then in effect plus 0.50%, plus an additional 0% to 0.25% depending on Alexion's liquidity. Interest is payable quarterly for Base Rate loans and, in the case of LIBOR-based loans, at the end of the applicable interest period, with the principal due on February 28, 2011, the maturity date.

The revolving credit facility requires that we comply with quarterly financial covenants related to liquidity and profitability ratios, as well as minimum revenue requirements. Further, the agreement includes negative covenants, subject to exceptions, restricting or limiting our ability and the ability of our subsidiaries to, among other things, incur additional indebtedness, grant liens, engage in certain investment, acquisition and disposition transactions, and enter into transactions with affiliates. The agreement also contains customary representations and warranties, affirmative covenants and events of default, including payment defaults, breach of representations and warranties, covenant defaults and cross defaults. If an event of default occurs, the interest rate would increase and the administrative agent would be entitled to take various actions, including the acceleration of amounts due under the loan.

## **Table of Contents**

### ***Capital Leases***

We currently lease office equipment under capital lease agreements expiring in 2010. The assets and liabilities under capital lease agreements are recorded at the lower of the present value of the minimum lease payments or the fair value of the asset. The assets are amortized over the lower of their related lease terms or their estimated useful lives. The average interest rates on the above capital leases is 9.47% and is imputed based on the lower of our incremental borrowing rate at the inception of each lease.

### ***Operating Leases***

Our operating leases are principally for facilities and equipment. We lease 125,424 square feet of space at our headquarters and research and development facility in Cheshire, Connecticut. The lease is set to expire in May 2017.

We lease additional research space in San Diego, California. In connection with the closure of Alexion Antibody Technologies in 2006, we accrued the fair value of future payments under the lease (see Note 6 of the Consolidated Financial Statements included in this Form 10-K). In September 2007, the Company signed a sub-lease for the AAT facility, which provides for sub-lease payments through the term of the lease, or 2012. We believe our research and development facilities and pilot manufacturing facility, together with third party manufacturing facilities, provides adequate space for our current requirements.

### ***Commercial Commitments***

Our commercial commitments consist of research and development, license, operational, clinical development, and manufacturing cost commitments, along with anticipated supporting arrangements, subject to certain limitations and cancellation clauses. The timing and level of our commercial scale manufacturing costs, which may or may not be realized, are contingent upon the progress of our clinical development programs and our commercialization plans. Our commercial commitments are represented principally by our supply agreement with Lonza Sales AG.

### ***Lonza Agreement***

We have a supply agreement with Lonza Sales AG relating to the manufacture of Soliris, which requires payments to Lonza at the inception of the contract and as product is manufactured. On an ongoing basis, we evaluate our plans to proceed with production of Soliris by Lonza, which depends upon our commercial requirements, the progress of our clinical development programs and the status of our Smithfield, Rhode Island manufacturing facility.

We have agreed to purchase certain minimum quantities of product from Lonza under our existing arrangements. If we terminate the Lonza Agreement without cause, we will be required to pay for batches of product scheduled for manufacture under our arrangement.

### ***License and Patent Rights***

In February 2008, we agreed to acquire certain patents related to complement-inhibition technology from Oklahoma Medical Research Foundation, or OMRF, for \$10,000. In addition to the initial payment of \$3,000 paid in February 2008 and the \$4,500 paid in December 2008, a final payment of \$2,500 is due during or prior to

## **Table of Contents**

July 2009. No further amounts, including royalties, will be owed to OMRF in respect of sales of Soliris or other use of the OMRF patents.

In December 2008, we entered into a definitive license agreement with PDL BioPharma, Inc. with respect to certain patents relating to the humanization of antibodies for \$25,000. The initial payment of \$12,500 was paid in January 2009, with a final payment of \$12,500 due by June 30, 2009. No additional payments will be owed by Alexion to PDL under such patents in respect of Soliris sales for any indication.

### *Additional Commercial Commitments*

Additional payments, related to our commercial commitments, such as licenses, aggregating up to approximately \$1,795, would be required if we elect to continue development under our current preclinical development programs and if specified development milestones are reached (including achievement of commercialization). These amounts are not included in the above table.

### *Income Taxes*

At December 31, 2008, we have pre-tax federal, state, and foreign net operating loss carryforwards of \$745,102, \$713,040, and \$20,310, respectively. These NOLs expire between 2009 and 2027. We also have federal and state research and development income tax credit carryforwards of approximately \$18,826 and \$8,834 respectively. These income tax credits expire between 2009 and 2027. Due to the amount of our NOLs and credit carryforwards, we do not anticipate paying substantial U.S. federal income taxes in the foreseeable future. We do expect to pay cash taxes in a number of foreign jurisdictions, as well as certain states, where our net operating losses were fully utilized during 2008. We were subject to the alternative minimum tax during 2008 and expect that we will continue to be subject to cash payments for the alternative minimum tax in the near term.

The Tax Reform Act of 1986 contains certain provisions that can limit a taxpayer'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 percent over a three-year period. We have determined that these limiting provisions were triggered during a prior year. However, we believe that such limitation is not expected to result in the expiration or loss of any of our federal NOLs.

### *Recently Issued Accounting Standards*

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133 (SFAS 161). This statement is intended to improve transparency in financial reporting by requiring enhanced disclosures of an entity's derivative instruments and hedging activities and their effects on the entity's financial position, financial performance, and cash flows. SFAS 161 applies to all derivative instruments within the scope of SFAS 133, Accounting for Derivative Instruments and Hedging Activities (SFAS 133) as well as related hedged items, bifurcated derivatives, and nonderivative instruments that are designated and qualify as hedging instruments. Entities with instruments subject to SFAS 161 must provide more robust qualitative disclosures and expanded quantitative disclosures. SFAS 161 is effective prospectively for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application permitted. We are currently evaluating the disclosure implications of this statement, and we expect to include expanded disclosures of our derivative instruments as a result of the adoption of SFAS 161.

## **Table of Contents**

In April 2008, the FASB issued FSP No. FAS 142-3, Determination of the Useful Life of Intangible Assets. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets (SFAS 142). The objective of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141(R), and other U.S. Generally Accepted Accounting Principles (GAAP). This FSP applies to all intangible assets, whether acquired in a business combination or otherwise and shall be effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years and applied prospectively to intangible assets acquired after the effective date. Early adoption is prohibited. We have evaluated the new statement and have determined that it will not have a significant impact on the determination or reporting of our financial results.

In April 2008, the FASB issued FSP No. FAS 142-3, Determination of the Useful Life of Intangible Assets. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets (SFAS 142). The objective of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141(R), and other U.S. Generally Accepted Accounting Principles (GAAP). This FSP applies to all intangible assets, whether acquired in a business combination or otherwise and shall be effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years and applied prospectively to intangible assets acquired after the effective date. Early adoption is prohibited. We have evaluated the new statement and have determined that it will not have a significant impact on the determination or reporting of our financial results.

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

(amounts in thousands, except per share data)

#### **Interest Rate Risk**

As of December 31, 2008, we held all of our cash equivalents and investments in money market funds with original maturity dates of three months or less.

Our outstanding long-term liabilities as of December 31, 2008 included our \$97,222, 1.375% Convertible Senior Notes due February 1, 2012. As the notes bear interest at a fixed rate, our results of operations would not be impacted by interest rate changes.

In July 2006, we borrowed \$26,000 to finance the purchase and construction of our Smithfield, Rhode Island manufacturing facility. In July 2007, we amended the mortgage loan agreement with iStar Financial Inc. to increase the loan amount by \$18,000, resulting in an aggregate principal balance of \$44,000. From the effective date of the amendment, the mortgage loan bears interest at a fixed annual rate of 9.12%. Accordingly, any changes in the interest rate will not impact our financial statements.

During the first quarter of 2008, we entered into a revolving credit facility with Bank of America and may borrow up to \$25,000. We may elect that the loans under the agreement bear interest at a rate per annum equal to



## **Table of Contents**

(i) LIBOR plus 1.75% to 2.25% depending on Alexion's liquidity (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect and (B) the Federal Funds Rate then in effect plus 0.50%, plus 0% to 0.25% depending on Alexion's liquidity (as calculated in accordance with the agreement). We do not expect changes in interest rates related to our revolving credit facility to have a material effect on our financial statements.

In conjunction with the purchase of patents from OMRF, we agreed to pay an aggregate principal amount of \$7,000, representing the balance of the \$10,000 purchase price for the OMRF patent rights. Interest shall accrue on any unpaid amount at the rate of 50% of the sum of the prime rate (as published in the Money Rates section of the Wall Street Journal (New York edition) plus 1%, per annum. We do not expect changes in interest rates related to this payable to have a material effect on our financial statements.

## **Foreign Exchange Market Risk**

As a result of our foreign operations, we face exposure to movements in foreign currency exchange rates, primarily the Euro and British Pound. The current exposures arise primarily from cash, accounts receivable, intercompany receivables and payables and product sales denominated in foreign currencies. Both positive and negative impacts to our international product sales from movements in foreign currency exchange rates are partially mitigated by the natural, opposite impact that foreign currency exchange rates have on our international operating expenses.

In the first quarter of 2008, we began a program to limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet. In the third quarter of 2008, we commenced a program to hedge a portion of our forecasted product sales to mitigate fluctuations in foreign exchange rates. Both programs utilize forward foreign exchange contracts intended to reduce, not eliminate, the impact of fluctuations in foreign currency rates.

As of December 31, 2008, we had foreign currency forward contracts with notional amounts totaling \$128,876. As of December 31, 2008, our outstanding foreign currency forward contracts had a fair value of \$5,409, which is included in other current assets/liabilities.

We do not use derivative financial instruments for speculative trading purposes. The counterparty to these forward contracts is a multinational commercial bank. The Company believes the risk of counterparty nonperformance is not material.

Since our foreign currency hedges are designed to offset gains and losses on our monetary assets and liabilities, we do not expect that a hypothetical 10% adverse change fluctuation in exchange rates would result in a material change in the fair value of our foreign currency sensitive assets, which include our monetary assets and liabilities and our forward contracts. The analysis above does not consider the impact that hypothetical changes in foreign currency exchange rates would have on future transactions such as anticipated sales.

## **Table of Contents**

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

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

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

None.

### **Item 9A. CONTROLS AND PROCEDURES**

#### **Disclosure Controls and Procedures.**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act,) as of December 31, 2008. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2008, our disclosure controls and procedures were effective to provide reasonable assurance that information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure, and ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

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

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

Management utilized the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, to conduct an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2008. Based on the assessment, management has concluded that, as of December 31, 2008, our internal control over financial reporting is effective.

The effectiveness of our internal control over financial reporting as of December 31, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

**Table of Contents**

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

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

We have expanded and improved our internal control structure to meet the requirements of a worldwide commercial entity, including the addition of appropriate processes related to revenue recognition, inventory and operations in additional international jurisdictions. Other than these changes, there has been no change in our internal control over financial reporting that occurred during the year ended December 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9A (T). *CONTROLS AND PROCEDURES.***

Not applicable

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

None.

**Table of Contents**

**PART III**

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

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

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

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

**CODE OF ETHICS**

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

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

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

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

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

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

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

**Table of Contents**

**PART IV**

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

The information required by this Item will be set forth in our definitive Proxy Statement under the caption Independent Registered Public Accounting Firm, to be filed within 120 days after the end of the year ended December 31, 2008 covered by this Annual Report on Form 10-K, and is incorporated herein by reference to our Proxy Statement.

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

**(1) Financial Statements**

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

**(2) Financial Statement Schedules**

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

**(3) Exhibits:**

- 3.1 Certificate of Incorporation, as amended. (1)
- 3.2 Bylaws, as amended. (2)
- 4.1 Specimen Common Stock Certificate. (3)
- 4.2 Rights Agreement between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer & Trust Company, Rights Agent, dated as of February 14, 1997. (4)
- 4.3 Amendment No. 1 to Rights Agreement, dated as of September 18, 2000, between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer and Trust Company. (5)
- 4.4 Amendment No. 2 to Rights Agreement, dated as of December 12, 2001, between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer and Trust Company, which includes as Exhibit B the form of Right Certificate. (6)
- 4.5 Amendment No. 3 to Rights Agreement, dated as of November 16, 2004, between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer and Trust Company. (7)
- 4.6 Amendment No. 4 to Rights Agreement, dated February 23, 2007, between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer and Trust Company. (8)
- 4.7 Indenture between Alexion Pharmaceuticals, Inc. and U.S. Bank National Association relating to Alexion Pharmaceuticals, Inc.'s 1.375% Convertible Senior Notes due 2012. (9)
- 4.8 Registration Rights Agreement between Alexion Pharmaceuticals, Inc., Morgan Stanley & Co. Incorporated, Bear, Stearns & Co. Inc., SG Cowen & Co., LLC and J.P. Morgan Securities Inc. (9)

**Table of Contents**

10.1	Employment Agreement, dated as of February 14, 2006, between the Company and Dr. Leonard Bell. (10)
10.2	Employment Agreement, dated as of February 14, 2006, between the Company and David W. Keiser. (10)
10.3	Employment Agreement, dated as of February 14, 2006, between the Company and Dr. Stephen P. Squinto. (10)
10.4	Employment Agreement, dated as of February 14, 2006, between the Company and Vikas Sinha. (10)
10.5	Employment Agreement, dated November 7, 2005, between the Company and Patrice Coissac. (11)
10.6	Amendment to Employment Agreement, dated July 25, 2007, between the Company and Patrice Coissac. (12)
10.7	Amendment to Employment Agreement, dated January 14, 2008, between the Company and Patrice Coissac. (12)
10.8	Form of Employment Agreement (Senior Vice Presidents). (10)
10.9	Severance Letter Agreement, dated as of November 7, 2005, by and between Alexion Europe SAS and Patrice Coissac. (11)
10.10	Agreement of Lease, dated May 9, 2000, between the Company and WE Knotter L.L.C. (13)
10.11	Company's 1992 Stock Option Plan, as amended. (14)
10.12	Company's 2000 Stock Option Plan, as amended. (2)
10.13	Company's 1992 Outside Directors Stock Option Plan, as amended. (14)
10.14	Company's Amended and Restated 2004 Incentive Plan.
10.15	License Agreement dated March 27, 1996 between the Company and Medical Research Council. (16)+
10.16	Research and Development Facility lease, dated February 1, 2002, between the Company and PMSI SRF L.L.C. (17)
10.17	Large-Scale Product Supply Agreement, dated December 18, 2002, between Alexion International Sarl and Lonza Sales AG, as amended. (15)+
10.18	Amendment No. 13 to the Large-Scale Product Supply Agreement dated December 18, 2002, between Alexion International Sarl and Lonza Sales AG, dated June 8, 2007.*
10.19	Form of Stock Option Agreement for Directors. (18)
10.20	Form of Stock Option Agreement for Executive Officers (Form A). (19)
10.21	Form of Stock Option Agreement for Executive Officers (Form B). (19)
10.22	Form of Restricted Stock Award Agreement for Executive Officers (Form A). (20)
10.23	Form of a Stock Option Agreement for named executive officer(s) of Alexion Europe SAS. (12)
10.24	Form of a Restricted Stock Agreement for named executive officer(s) of Alexion Europe SAS. (12)
10.25	Form of Stock Option Agreement (Incentive Stock Options).

## **Table of Contents**

10.26	Form of Stock Option Agreement (Nonqualified Stock Options).
10.27	Form of Restricted Stock Award Agreement.
10.28	Form of Stock Option Agreement for Participants in France.
10.29	Form of Restricted Stock Unit Agreement for Participants in France.
10.30	Purchase and Sale Agreement by and between The Dow Chemical Company and Alexion Manufacturing LLC, dated as of April 13, 2006, as amended. (21)
10.31	Loan and Security Agreement between Alexion Manufacturing LLC and iStar Financial Inc., dated as of July 11, 2006. (21)
10.32	Completion, Payment, and Performance Guarantee by Alexion Pharmaceuticals, Inc. in favor of iStar Financial Inc., dated as of July 11, 2006. (21)
10.33	Construction Mortgage Deed, Assignment of Leases and Rents, Security Agreement and Fixture Filing, dated as of July 11, 2006 by Alexion Manufacturing LLC in favor of iStar Financial Inc. (21)
10.34	Environmental Indemnity Agreement by and among Alexion Manufacturing LLC, Alexion Pharmaceuticals, Inc. in favor of iStar Financial Inc., dated as of July 11, 2006. (21)
10.35	First Amendment to Loan Agreement and Other Loan Documents, between Alexion Manufacturing LLC and iStar Financial Inc., dated July 18, 2007. (22)
10.36	Amended and Restated Promissory Note, dated July 18, 2007 issued by Alexion Manufacturing LLC. (22)
10.37	First Amendment to Construction Mortgage Deed, Assignment of Leases and Rents, Security Agreement and Fixture Filing, by Alexion Manufacturing LLC in favor of iStar Financial Inc., dated July 18, 2007. (22)
10.38	Settlement and Assignment Agreement, dated as of February 8, 2008, between the Company and Oklahoma Medical Research Foundation. (23)
10.39	Credit Agreement, dated February 13, 2008, between the Company and Bank of America, N.A. (24)+
10.40	Security Agreement, dated February 13, 2008, between the Company, Bank of America, N.A., and the other loan parties named therein. (24)
10.41	Note, dated February 13, 2008, issued by the Company to Bank of America, N.A. (24)
10.42	Patent License Agreement, dated December 31, 2008, between the Company and PDL BioPharma, Inc.*
10.43	Settlement Agreement, dated December 31, 2008, between the Company and PDL BioPharma, Inc.*
12.1	Statement Regarding Computation of Ratio of Earnings to Fixed Charges. (1)
21.1	Subsidiaries of Alexion Pharmaceuticals, Inc.
23.1	Consent of PricewaterhouseCoopers LLP.
31.1	Certificate of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002.

## **Table of Contents**

- 31.2 Certificate of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
- 32.1 Certificate of Chief Executive Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.
- 32.2 Certificate of Chief Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.
- (1) Incorporated by reference to our Registration Statement on Form S-3 (Reg. No. 333-128085), filed on September 2, 2005.
- (2) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2004.
- (3) Incorporated by reference to our Registration Statement on Form S-1 (Reg. No. 333-00202).
- (4) Incorporated by reference to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on February 21, 1997.
- (5) Incorporated by reference to Amendment No. 1 to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on October 6, 2000.
- (6) Incorporated by reference to Amendment No. 2 to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on February 12, 2002.
- (7) Incorporated by reference to Amendment No. 3 to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on November 17, 2004.
- (8) Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2006, filed on February 23, 2007.
- (9) Incorporated by reference to our report on Form 8-K, filed on January 25, 2005.
- (10) Incorporated by reference to our Report on Form 8-K filed on February 16, 2006.
- (11) Incorporated by reference to our report on Form 8-K, filed on November 14, 2005.
- (12) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.
- (13) Incorporated by reference to our Registration Statement on Form S-3 (Reg. No. 333-36738) filed on May 10, 2000.
- (14) Incorporated by reference to our Registration Statement on Form S-8 (Reg. No. 333-71879) filed on February 5, 1999.
- (15) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2003.
- (16) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended July 31, 1996.
- (17) Incorporated by reference to our quarterly report on Form 10-Q for the quarter ended January 31, 2002.
- (18) Incorporated by reference to our report on Form 8-K, filed on December 16, 2004.
- (19) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2005.
- (20) Incorporated by reference to our report on Form 8-K, filed on March 14, 2005.
- (21) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2006.
- (22) Incorporated by reference to our report on Form 8-K, filed on July 23, 2007.
- (23) Incorporated by reference to our report on Form 8-K, filed on February 14, 2008.
- (24) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008.
- + Confidential treatment was granted for portions of such exhibit.
- \* Certain portions of this exhibit have been omitted pursuant to a request for an order granting confidential treatment by the Securities and Exchange Commission. The omitted non-public information has been filed with the Securities and Exchange Commission.



**Table of Contents**

**Item 15(b) Exhibits**

See (a) (3) above.

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

See (a) (2) above.

**Table of Contents**

**SIGNATURES**

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

ALEXION PHARMACEUTICALS, INC.

By: /s/ LEONARD BELL

**Leonard Bell, M.D.**

*Chief Executive Officer,  
Secretary and Treasurer*

**Dated: February 23, 2009**

By: /s/ VIKAS SINHA

**Vikas Sinha, M.B.A., C.A.**

*Senior Vice President and Chief Financial Officer*

**Dated February 23, 2009**

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

/s/ LEONARD BELL		February 23, 2009
<b>Leonard Bell, M.D.</b>	Chief Executive Officer, Secretary, Treasurer and Director (principal executive officer)	
/s/ VIKAS SINHA		February 23, 2009
<b>Vikas Sinha, M.B.A., C.A.</b>	Senior Vice President and Chief Financial Officer (principal financial officer)	
/s/ SCOTT PHILLIPS		February 23, 2009
<b>Scott Phillips</b>	Corporate Controller and Chief Accounting Officer (principal accounting officer)	
/s/ MAX LINK		February 23, 2009
<b>Max Link, Ph.D.</b>	Chairman of the Board of Directors	
/s/ DAVID W. KEISER		February 23, 2009
<b>David W. Keiser</b>	Director	
/s/ LARRY L. MATHIS		February 23, 2009
<b>Larry L. Mathis</b>	Director	

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

/s/ JOSEPH A. MADRI

Director

February 23, 2009

**Joseph A. Madri, Ph.D., M.D.**

**Table of Contents**

/s/ R. DOUGLAS NORBY	Director	February 23, 2009
<b>R. Douglas Norby</b>		
/s/ ALVIN S. PARVEN	Director	February 23, 2009
<b>Alvin S. Parven</b>		
/s/ RUEDI E. WAEGER	Director	February 23, 2009
<b>Ruedi E. Waeger, Ph.D.</b>		

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Contents**

**For the Years Ended December 31, 2008, 2007 and 2006**

	<b>Page(s)</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Financial Statements</u>	
<u>Consolidated Balance Sheets</u>	F-4
<u>Consolidated Statements of Operations</u>	F-5
<u>Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Loss</u>	F-6
<u>Consolidated Statements of Cash Flows</u>	F-8
<u>Notes to Consolidated Financial Statements</u>	F-9 to F-43

F-1

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders

of Alexion Pharmaceuticals, Inc.:

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Alexion Pharmaceuticals, Inc. and its subsidiaries at December 31, 2008 and December 31, 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it accounts for uncertain tax positions in 2007.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail,

**Table of Contents**

accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

Hartford, Connecticut

February 23, 2009

F-3

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

(amounts in thousands, except per share amounts)

	December 31, 2008	2007
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 138,012	\$ 95,321
Marketable securities		10,433
Trade accounts receivable	74,476	46,278
Inventories	49,821	32,907
Prepaid manufacturing costs	1,864	13,775
Deferred tax assets	972	
Prepaid expenses and other current assets	11,956	5,703
 Total current assets	 277,101	 204,417
Property, plant and equipment, net	139,885	104,280
Intangible assets, net	32,325	937
Goodwill, net	19,954	19,954
Restricted cash	1,699	958
Deferred tax assets	3,397	
Other assets	3,190	3,811
 Total assets	 \$ 477,551	 \$ 334,357
<b>Liabilities and Stockholders' Equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 8,655	\$ 9,072
Accrued expenses	46,200	28,324
Deferred revenue	1,128	41
License payable	25,000	
Deferred tax liabilities	639	
Current debt obligations	2,500	
Current portion of capital lease obligations	296	272
 Total current liabilities	 84,418	 37,709
Capital lease obligations, less current portion	203	499
Mortgage loan	44,000	44,000
Convertible notes	97,222	150,000
Deferred tax liabilities	906	
Other liabilities	3,801	593
 Total liabilities	 230,550	 232,801
 <b>COMMITMENTS AND CONTINGENCIES (Notes 2 and 11)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock, \$.0001 par value; 5,000 shares authorized, no shares issued or outstanding		
Common stock, \$.0001 par value; 145,000 shares authorized; 81,532 and 75,746 shares issued at December 31, 2008 and 2007, respectively	5	4
Additional paid-in capital	941,439	833,534
Treasury stock, at cost, 57 shares	(1,260)	(1,260)
Accumulated other comprehensive income (loss)	2,947	(1,443)
Accumulated deficit	(696,130)	(729,279)
 Total stockholders' equity	 247,001	 101,556



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

Total liabilities and stockholders' equity	\$ 477,551	\$ 334,357
--	------------	------------

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

F-4

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

(amounts in thousands, except per share amounts)

	Year Ended December 31,		
	2008	2007	2006
Revenues:			
Net product sales	\$ 259,004	\$ 66,381	\$
Contract research revenues	95	5,660	1,558
Total revenues	259,099	72,041	1,558
Cost of sales	28,366	6,696	
Operating expenses:			
Research and development	62,581	68,961	83,225
Selling, general and administrative	133,543	96,142	55,418
Total operating expenses	196,124	165,103	138,643
Operating income (loss)	34,609	(99,758)	(137,085)
Other income and expense:			
Investment income	2,810	8,080	8,076
Interest expense	(2,407)	(2,489)	(2,837)
Foreign currency gain (loss)	(282)	1,132	(41)
Income (loss) before income taxes	34,730	(93,035)	(131,887)
Income tax provision (benefit)	1,581	(745)	(373)
Net income (loss)	\$ 33,149	\$ (92,290)	\$ (131,514)
Earnings (loss) per common share			
Basic	\$ 0.43	\$ (1.27)	\$ (2.07)
Diluted	\$ 0.39	\$ (1.27)	\$ (2.07)
Shares used in computing earnings (loss) per share			
Basic	77,680	72,622	63,402
Diluted	89,967	72,622	63,402

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

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

(amounts in thousands)

	Common Stock		Additional Paid-In Capital	Treasury Stock at Cost		Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity	Comprehensive Income (Loss)
	Shares Issued	Amount		Shares	Amount				
Balances, December 31, 2005	61,960	\$ 3	\$ 589,250	50	\$ (981)	\$ (315)	\$ (506,067)	\$ 81,890	
Foreign currency translation						(120)		(120)	\$ (120)
Net change in unrealized gains on marketable securities						258		258	258
Issuance of common stock, net of issuance costs of \$8,121	6,900	1	140,282					140,283	
Issuance of common stock from exercise of options	1,850		13,544					13,544	
Issuance of restricted common stock	426								
Exchange of common shares for treasury				7	(279)			(279)	
Share-based compensation expense			20,615					20,615	
Net loss							(131,514)	(131,514)	(131,514)
Balances, December 31, 2006	71,136	4	763,691	57	(1,260)	(177)	(637,581)	124,677	\$ (131,376)
Adoption of FASB Interpretation No. 48							592	592	
Opening balance at January 1, 2007, as adjusted	71,136	4	763,691	57	(1,260)	(177)	(636,989)	125,269	
Foreign currency translation						(1,316)		(1,316)	\$ (1,316)
Net change in unrealized gains on marketable securities						50		50	50
Issuance of common stock from exercise of options	4,192	0	47,005					47,005	
Issuance of restricted common stock	418								
Recognition of equity impact on R&D tax credit			813					813	
Share-based compensation expense			22,025					22,025	
Net loss							(92,290)	(92,290)	(92,290)
Balances, December 31, 2007	75,746	4	833,534	57	(1,260)	(1,443)	(729,279)	101,556	\$ (93,556)

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

(amounts in thousands)

	Common Stock		Additional Paid-In Capital	Treasury Stock at Cost		Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity	Comprehensive Income (Loss)
	Shares Issued	Amount		Shares	Amount				
Foreign currency translation						(74)		(74)	\$ (74)
Unrealized loss on pension obligation						(471)		(471)	(471)
Unrealized gain on hedging activities						4,935		4,935	4,935
Costs associated with 2 for 1 stock split			(99)					(99)	
Conversion of convertible notes to common stock	3,356	1	52,185					52,185	
Issuance of common stock from exercise of options	2,120	0	28,893					28,893	
Issuance of restricted common stock	310								
Recognition of equity impact on R&D tax credit			404					404	
Share-based compensation expense			26,523					26,523	
Net income							33,149	33,149	33,149
Balances, December 31, 2008	81,532	\$ 5	\$ 941,439	57	\$ (1,260)	\$ 2,947	\$ (696,130)	\$ 247,001	\$ 37,539

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

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

(amounts in thousands)

	Year Ended December 31,		
	2008	2007	2006
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ 33,149	\$ (92,290)	\$ (131,514)
Adjustments to reconcile net income (loss) to net cash used by operating activities:			
Non-cash exit costs		(375)	539
Loss on disposal of property, plant & equipment	44	542	141
Depreciation and amortization	7,608	4,927	3,706
Share-based compensation expense	23,682	22,025	20,615
Unrealized currency loss	3		
Unrealized hedge loss	473		
Changes in operating assets and liabilities:			
Accounts receivable	(31,262)	(49,545)	
Inventories	(15,700)	(30,593)	(2,314)
Prepaid expenses and other assets	951	(440)	(2,993)
Accounts payable and accrued expenses	32,912	11,478	2,673
Deferred revenue	1,339	(5,343)	(767)
Net cash provided by (used in) operating activities	53,199	(139,614)	(109,914)
<b>Cash flows from investing activities:</b>			
Purchase of marketable securities	(206,778)	(48,719)	(734,567)
Proceeds from maturity or sale of marketable securities	216,146	87,985	853,924
Purchase of property, plant and equipment	(39,733)	(68,825)	(31,856)
Purchase of technology rights	(8,624)		
Decrease (increase) in restricted cash	339	32,636	(33,594)
Net cash (used in) provided by investing activities	(38,650)	3,077	53,907
<b>Cash flows from financing activities:</b>			
Debt issuance costs	(312)		
Payments on capital leases	(273)	(161)	(224)
Proceeds from mortgage loan		18,000	26,000
Exchange of treasury shares			(279)
Net proceeds from issuance of common stock	28,893	47,005	153,827
Net cash provided by financing activities	28,308	64,844	179,324
Effect of exchange rate changes on cash	(166)	188	(120)
Net change in cash and cash equivalents	42,691	(71,505)	123,197
Cash and cash equivalents at beginning of period	95,321	166,826	43,629
Cash and cash equivalents at end of period	\$ 138,012	\$ 95,321	\$ 166,826
<b>Supplemental disclosures</b>			
Cash paid for interest (net of amounts capitalized)	\$ 7,322	\$ 6,146	\$ 2,081
Cash paid for income taxes	\$	\$ 24	\$

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

See Notes 6 and 11 for investing and financing non-cash disclosures

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

F-8

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**For the Years Ended December 31, 2008, 2007 and 2006**

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

**1. Business Overview and Summary of Significant Accounting Policies**

**Business**

Alexion Pharmaceuticals, Inc. ( Alexion or the Company ) is a biopharmaceutical company engaged in the discovery, development and delivery of biologic therapeutic products aimed at treating patients with severe and life-threatening disease states, including hematologic and neurologic diseases, transplant rejection, cancer and autoimmune disorders. Our marketed product Soliris® (eculizumab) is the first therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH. We were incorporated in 1992 and began commercial sale of Soliris in the United States and Europe in 2007.

**Stock Split**

In July 2008, the Company's Board of Directors approved a two-for-one stock split to be effected in the form of a 100 percent stock dividend. The additional shares were distributed on August 22, 2008 to stockholders of record as of the close of trading on August 12, 2008. All share and per share data presented in the accompanying consolidated financial statements and throughout these notes have been retroactively restated to reflect this stock split.

**Basis of Presentation and Principles of Consolidation**

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

**Dividend Policy**

We have never paid a cash dividend on shares of our stock. We currently intend to retain our earnings to finance future operations and do not anticipate paying any cash dividends on our stock in the foreseeable future.

**Use of Estimates**

Under accounting principles generally accepted in the United States of America, we are required to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingent assets and liabilities in our financial statements. Actual results could differ from those estimates.

**Foreign Currency Translation**

The financial statements of our subsidiaries with functional currencies other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

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

**For the Years Ended December 31, 2008, 2007 and 2006**

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

stockholders' equity and weighted average exchange rates for operating results. Translation gains and losses are included in accumulated other comprehensive income in stockholders' equity. Foreign currency transaction gains and losses are included in the results of operations in other income (expense).

**Segment Reporting**

SFAS No. 131, "Disclosure about Segments of an Enterprise and Related Information", establishes annual and interim reporting standards for an enterprise's operating segments and related disclosures about its products, services, geographic areas and major customers. We operate in a single segment; the discovery, development and commercialization of biopharmaceutical products (see Note 17 for geographic information).

**Cash and Cash Equivalents**

Cash and cash equivalents are stated at cost plus accrued interest, which approximates fair value, and include short-term highly liquid investments with original maturities of three months or less.

**Restricted Cash**

Under the terms of our mortgage loan (Note 9), we maintain a restricted cash balance for the payment of taxes, insurance and other required amounts, equal to the amount required under our mortgage loan agreement. At December 31, 2008 and 2007, the restricted cash balance for the mortgage loan was \$619 and \$958, respectively. At December 31, 2008, we also recorded \$1,100 of restricted cash related to a facility operating lease.

**Fair Value of Financial Instruments**

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term maturities. Our marketable securities, all of which are available-for-sale, are carried at fair value based on quoted market prices. Our convertible notes and other debt obligations are carried at historical cost (see Notes 9 and 15 for fair value information).

**Marketable Securities**

We invest our excess cash balances in marketable securities of highly rated financial institutions and investment-grade debt instruments. We limit the amount of investment exposure as to institution, maturity and investment type. We classify our marketable securities as available-for-sale and, accordingly, record such securities at fair value. Unrealized gains or losses, deemed temporary, are included in accumulated other comprehensive loss as a separate component of stockholders' equity. If any adjustment to fair value reflects a



**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

decline in the value of the security, we consider all available evidence to evaluate the extent to which the decline is other than temporary and mark the security to market through a charge to our statement of operations.

**Accounts Receivable**

Our standard credit terms vary based on the country of sale and range from 30 to 90 days. Our days sales outstanding ranges from 80 to 100 days. We sell Soliris to a limited number of customers, and we evaluate the creditworthiness of each such customer on a regular basis. In certain European countries, sales by us are subject to payment terms that are statutorily determined. This is primarily the case in countries where the payer is government-owned or government-funded, which we consider to be creditworthy. It has been our experience that length of time from sale to receipt of payment in such countries typically exceeds our credit terms. We make judgments as to our ability to collect outstanding receivables and will provide allowances for the portion of receivables if and when collection becomes doubtful.

For the year ended December 31, 2008, two individual customers each accounted for 20% and 20% of the accounts receivable balance. For the year ended December 31, 2007, three individual customers each accounted for 39%, 26% and 12% of the accounts receivable balance. For the year ended December 31, 2008, a single individual customer accounted for 21% of net product sales. For the year ended December 31, 2007, three individual customers each accounted for 40%, 25% and 11% of net product sales. No other customer accounted for more than 10% of net product sales.

**Inventories**

Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of inventory using the average cost method.

The components of inventories as of December 31 are as follows:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Raw Materials	\$ 3,805	\$ 4,985
Work-In-Process	27,017	17,677
Finished Goods	18,999	10,245
	<b>\$ 49,821</b>	<b>\$ 32,907</b>

*Capitalization of Inventory Costs*

We capitalize inventory produced for commercial sale, including the capitalization of inventory, for products that are in initial clinical development, costs prior to regulatory approval but subsequent to the filing of a Biologics License Application, or BLA, when the Company has determined that the inventory has probable

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

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

**For the Years Ended December 31, 2008, 2007 and 2006**

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

future economic benefit. Inventory is not capitalized prior to completion of a phase III clinical trial. We also capitalize the cost of inventory manufactured at our manufacturing plant in property, plant and equipment prior to validation of the facility by the FDA. Once we receive approval by the FDA, the cost of the inventory will be reclassified from property, plant and equipment to inventory.

The cost of some product sold during the year ended December 31, 2007 was expensed to R&D prior to submission of our BLA, and therefore is not included in the cost of sales during this period. The previously expensed inventory was fully depleted during the fourth quarter of 2007.

*Inventory Write-Offs*

We analyze our inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of our product is subject to strict quality control, certain batches or units of product may, after a period of time, no longer meet quality specifications or may expire, at which point we would adjust our inventory values. Soliris currently has a maximum estimated life of 48 months and, based on our sales forecasts, we expect the carrying value of the Soliris inventory and prepaid manufacturing costs to be fully realized.

To date, our work-in-process and finished goods inventory has been purchased under a third party contract arrangement with Lonza Sales AG. We will continue to sell inventory which was purchased under this arrangement until our manufacturing facility in Smithfield, Rhode Island obtains regulatory approval, at which time we expect that inventory purchases under our contract arrangement with Lonza may be reduced.

**Derivative Instruments**

We follow the provisions of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and related interpretations (SFAS 133). SFAS No. 133 establishes accounting and reporting standards for derivative instruments and hedging activities and requires the Company to recognize these as either assets or liabilities on the balance sheet and measure them at fair value. The accounting for gains and losses resulting from changes in fair value is dependent on the use of the derivative and whether it is designated and qualifies for hedge accounting.

All hedging activities are documented at the inception of the hedge and must meet the definition of highly effective in offsetting changes to future cash flows within the meaning of SFAS No. 133 to be a qualifying hedge. The effectiveness of the qualifying hedge contract is assessed quarterly to ensure compliance with SFAS 133. We record the fair value of the qualifying hedges in other current assets and other current liabilities. Gains or losses resulting from changes in the fair value of qualifying hedges are recorded in other comprehensive income until the forecasted transaction occurs. When the forecasted transaction occurs, this amount is reclassified into revenue. Any non-qualifying portion of the gains or losses resulting from changes in fair value, if any, is reported in other income or other expense.

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

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

**For the Years Ended December 31, 2008, 2007 and 2006**

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

**Prepaid Manufacturing Costs**

Cash advances paid by us to secure future manufacturing production at third-party contract manufacturers, as well as advances paid prior to receipt of the inventory, are recorded as prepaid manufacturing costs. These costs are recognized over the period of manufacturing production on a unit-of-production method. The cash advances are subject to forfeiture if we terminate the scheduled production. We expect the carrying value of the prepaid manufacturing costs to be fully realized.

**Property, Plant and Equipment**

Property, plant and equipment are stated at cost and are depreciated on a straight-line basis over the estimated useful lives of the assets. We estimate economic lives as follows:

Building and improvements   five to thirty two years

Laboratory and other equipment   five to fifteen years

Furniture and office equipment   three to five years

Leasehold improvements and assets under capital lease arrangements are amortized over the lesser of the estimated useful life or the term of the respective lease. Maintenance costs are expensed as incurred.

Construction-in-progress reflects amounts incurred for property, plant, or equipment construction or improvements that have not been placed in service. For products we expect to commercialize, we capitalize to construction-in-progress certain incremental costs associated with the validation effort required for licensing of manufacturing equipment by government regulators for the production of a commercially approved drug. To date, these costs primarily include direct labor, materials, overhead and pre-validation inventory related to our Smithfield, Rhode Island manufacturing facility, which have been incurred in preparing the equipment for its intended use. We will begin depreciating the property, plant and equipment related to the facility when the assets are substantially complete and ready for their intended use, which will occur upon regulatory approval of the plant for production of commercial quantities of eculizumab.

**Long-Lived Assets**

We evaluate our long-lived assets, which are primarily comprised of intangible assets and property, plant and equipment, for impairment whenever events or changes in circumstances indicate the carrying value of an asset or group of assets is not recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to future undiscounted net cash flows expected to be generated by the assets group. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. The Company did not recognize any impairment loss for long-lived assets during the years ended December 31, 2008 and 2007. See Note 8 for information related to exit activities in the year ended December 31, 2006.



**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

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

**For the Years Ended December 31, 2008, 2007 and 2006**

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

**Goodwill**

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

**Revenue Recognition**

Principal sources of revenue are product sales and contract research revenues from research and development support payments. We have applied the following principles in recognizing revenue:

*Net Product Sales*

We recognize revenue from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured and we have no further performance obligations. Revenue is recorded upon receipt of the product by the patients' health-care provider, which is typically a hospital, physician's office, pharmacy or health care facility. Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in the Company's statements of operations and do not impact net product sales.

In the United States, our customers are primarily specialty distributors and specialty pharmacies who supply physician office clinics, hospital outpatient clinics, infusion clinics or home health care providers. In some cases, we also sell Soliris to government agencies. Outside the United States, our customers are primarily hospitals, hospital buying groups, pharmacies, other health care providers and distributors.

Through December 31, 2008, we have recorded revenue on sales for individual patients through named-patient programs in certain European countries. The relevant authorities in those countries have agreed to reimburse for product sold on a named-patient basis where Soliris has not received formal approval for commercial sales.

Because of the pricing of Soliris, the limited number of patients, the short period from sale of product to patient infusion and the lack of contractual return rights, Soliris customers generally carry limited inventory. We monitor inventory within our distribution channel to determine whether deferral of sales is required based on inventory in our sales channel. To date, actual refunds and returns have been negligible.

We record estimated rebates payable under governmental programs, including Medicaid and programs in Europe, as a reduction of revenue at the time product sales are recorded. Our calculations related to these rebate accruals require estimates, including estimates of customer mix, to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period and record any

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

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

**For the Years Ended December 31, 2008, 2007 and 2006**

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

necessary adjustments. Generally, the length of time between product sale and the processing and reporting of the rebates is three to nine months. Upon reconciliation of government reporting to our sales records, we revise our estimates of rebates payable, which may have an impact on revenue in the period in which the adjustment was made.

We also record distribution and other fees paid to our customers as a reduction of revenue. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

We also record the effective portion of our cash flow hedges to revenue in the period in which the derivative contract is settled.

*Contract Research Revenue*

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

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

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

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

Effective March 30, 2007, we and Procter & Gamble Pharmaceuticals, or P&G, agreed to terminate our 1999 collaboration agreement for the development and commercialization of pexelizumab. As the agreement has been terminated, and no further obligations remain, the remaining portion of the \$10,000 non-refundable up-front license fee, or \$5,343, was recognized as revenue during 2007.

**Royalties**

Our cost of sales for the year ended December 31, 2008 and 2007 includes royalties to third parties related to the sale and commercial manufacture of Soliris. We estimate our royalty obligations based on existing

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

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

**For the Years Ended December 31, 2008, 2007 and 2006**

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

contractual obligations and our assessment of estimated royalties owed to other third parties. These estimates may be influenced by the outcome of litigation and other claims, the results of which are uncertain (see Note 11). On a periodic basis and based on specific events such as the outcome of litigation, we may reassess these estimates, resulting in adjustments to cost of sales.

**Research and Development Expenses**

Research and development expenses are comprised of costs incurred in performing research and development activities including salaries and benefits, pre-clinical, clinical trial and related clinical manufacturing costs, manufacturing development and scale-up costs, contract services and other outside contractor costs, research license fees, depreciation and amortization of lab facilities, and lab supplies. These costs are expensed as incurred. We accrue costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the vendors that perform the services.

Through March 30, 2007, we had a research agreement in which we shared costs with our collaborator, P&G. We recorded these costs as research and development expenses as incurred. A portion of these costs were reimbursed by our collaborator and were recorded as a reduction of research and development expense.

**Stock-Based Compensation**

We have one stock-based compensation plan known as the 2004 Incentive Plan. Under this plan, restricted stock, stock options and other stock-related awards may be granted to our directors, officers, employees and consultants or advisors of the Company or any subsidiary. To date, stock-based compensation issued under the plan consists of incentive and non-qualified stock options and restricted stock. Stock options are granted to employees at exercise prices equal to the fair market value of our stock at the dates of grant. Generally, stock options and restricted stock granted to employees fully vest four years from the grant date. Stock options have a contractual term of 10 years. We recognize stock-based compensation expense, based on the fair value of stock awards, on a straight-line basis over the requisite service period of the individual grants, which typically equals the vesting period.

**Net Income (Loss) Per Common Share**

Basic earnings per share (EPS) is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding. For purposes of calculating diluted EPS, net income (loss) is adjusted for the after-tax amount of interest and deferred financing costs associated with the convertible debt, and the denominator reflects the potential dilution, using the treasury stock method, that could occur if options, convertible debt, or other contracts to issue common stock were exercised or converted into common stock.

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

The following table summarizes the calculation of basic and diluted EPS for years ended December 31, 2008, 2007 and 2006:

	<b>2008</b>	<b>December 31 2007</b>	<b>2006</b>
Net income (loss) used for basic calculation	\$ 33,149	\$ (92,290)	\$ (131,514)
Effect of dilutive securities:			
Interest expense and deferred financing cost amortization, net of tax, related to our 1.375% convertible senior notes	1,943		
Net income (loss) used for diluted calculation	\$ 35,092	\$ (92,290)	\$ (131,514)
Shares used in computing net income (loss) per common share basic	77,680	72,622	63,402
Effect of dilutive securities:			
Shares issuable upon the assumed conversion of our 1.375% convertible senior notes	8,970		
Stock awards	3,317		
Dilutive potential common shares	12,287		
Shares used in computing net income (loss) per common share diluted	89,967	72,622	63,402
Earnings (loss) per share:			
Basic	\$ 0.43	\$ (1.27)	\$ (2.07)
Diluted	\$ 0.39	\$ (1.27)	\$ (2.07)

The following table represents the potentially dilutive shares excluded from the calculation of EPS for the years ended December 31, 2008, 2007 and 2006 because their effect is anti-dilutive:

	<b>December 31 2008</b>	<b>2007</b>	<b>2006</b>
Potentially dilutive securities:			
Shares issuable upon conversion of our convertible notes		9,537	9,537
Stock awards	1,459	9,298	11,394
Dilutive potential common shares	1,459	18,836	20,931

**Income Taxes**

The provision for income taxes includes federal, state, local and foreign taxes. Income taxes are accounted for using the asset and liability method in accordance with SFAS No. 109, Accounting for Income Taxes (FAS 109). Deferred tax assets and liabilities are recognized for the estimated future tax consequences of temporary differences between the financial statement carrying amounts and their respective tax basis at the statutory tax rates that will be in effect when the differences are expected to be recovered or settled. A valuation allowance for



F-17

## **Table of Contents**

### **Alexion Pharmaceuticals, Inc.**

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

#### **For the Years Ended December 31, 2008, 2007 and 2006**

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

the net deferred tax assets is recorded to the extent we cannot determine that the ultimate realization of net deferred tax assets is more likely than not.

In the ordinary course of business, there is inherent uncertainty in quantifying our income tax positions. We assess our income tax positions and record tax benefits for all years subject to examination based upon management's evaluation of the facts, circumstances and information available at the reporting dates. For those tax positions where it is more-likely-than-not that a tax benefit will be sustained, we have recorded the largest amount of tax benefit with a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority that has full knowledge of all relevant information. For those income tax positions where it is not more-likely-than-not that a tax benefit will be sustained, no tax benefit has been recognized in the financial statements. If applicable, associated interest and penalties is also recognized.

We adopted the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 48, Accounting for Uncertainty in Income Taxes, (FIN 48) on January 1, 2007. As a result of this adoption, we recognized a benefit of \$592 to the January 1, 2007 accumulated deficit balance.

#### **Comprehensive Income (Loss)**

SFAS No. 130, Reporting Comprehensive Income, requires us to display comprehensive income (loss) and its components as part of our financial statements. Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes changes in equity that are excluded from net income (loss), such as translation adjustments, unrealized holding gains and losses on available-for-sale marketable securities and unrealized hedging gains and losses. All of these changes in equity are reflected net of tax, as appropriate.

#### **Recently Issued Accounting Standards**

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133 (SFAS 161). This statement is intended to improve transparency in financial reporting by requiring enhanced disclosures of an entity's derivative instruments and hedging activities and their effects on the entity's financial position, financial performance, and cash flows. SFAS 161 applies to all derivative instruments within the scope of SFAS 133, Accounting for Derivative Instruments and Hedging Activities (SFAS 133) as well as related hedged items, bifurcated derivatives, and nonderivative instruments that are designated and qualify as hedging instruments. Entities with instruments subject to SFAS 161 must provide more robust qualitative disclosures and expanded quantitative disclosures. SFAS 161 is effective prospectively for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application permitted. We are currently evaluating the disclosure implications of this statement, and we expect to include expanded disclosures of our derivative instruments as a result of the adoption of SFAS 161.

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

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

**For the Years Ended December 31, 2008, 2007 and 2006**

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

In April 2008, the FASB issued FSP No. FAS 142-3, Determination of the Useful Life of Intangible Assets. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets (SFAS 142). The objective of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141(R), and other U.S. Generally Accepted Accounting Principles (GAAP). This FSP applies to all intangible assets, whether acquired in a business combination or otherwise and shall be effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years and applied prospectively to intangible assets acquired after the effective date. Early adoption is prohibited. We have evaluated the new statement and have determined that it will not have a significant impact on the determination or reporting of our financial results.

**Reclassifications and adjustments**

Certain prior year amounts have been reclassified to conform to the current presentation.

**2. Collaboration and License Agreements**  
**Procter & Gamble Pharmaceuticals Collaboration**

In January 1999, we and Procter & Gamble Pharmaceuticals, or P&G, entered into an exclusive collaboration to develop and commercialize pexelizumab. In 2006, we completed a final Phase III trial of pexelizumab. After reviewing results from that trial, we along with P&G, determined not to pursue further development of pexelizumab. Effective March 30, 2007, we and P&G mutually agreed to terminate the collaboration agreement. As the relevant agreement was terminated in March 2007, the remaining portion of the \$10,000 non-refundable up-front license fee, or \$5,343, was recognized as revenue in the year ended December 31, 2007 and is included in contract research revenues.

**License and Research and Development Agreements**

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

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

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

Clinical and manufacturing development agreements generally provide for us to fund manufacturing development and on-going clinical trials. Clinical trial and development agreements include contract services and outside contractor services including contracted clinical site services related to patient enrolment for our clinical trials. Manufacturing development agreements include clinical manufacturing and manufacturing development and scale-up. We have executed a large-scale product supply agreement with Lonza Sales AG for the long-term commercial manufacture of Soliris (Note 11).

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

The minimum fixed payments (assuming non-termination of the above agreements) as of December 31, 2008, for each of the next five years are as follows:

<b>Years Ending December 31,</b>	<b>License Agreements</b>	<b>Clinical and Manufacturing Development Agreements</b>
2009	\$ 400	\$ 3,750
2010	195	7,500
2011	200	7,500
2012	200	7,500
2013	200	3,750
	\$ 1,195	\$ 30,000

The table above does not include amounts owed to OMRF and PDL BioPharma for license and patents rights (Note 6).

**3. Marketable Securities**

The following table summarizes our marketable securities at December 31, 2007. We had no marketable securities at December 31, 2008.

	<b>Amortized Cost Basis</b>	<b>Gross Unrealized Holding Gains</b>	<b>Gross Unrealized Holding Losses</b>	<b>Aggregate Fair Value</b>
<b>December 31, 2007</b>				
Federal agency obligations	\$ 8,711	\$ 3	\$	\$ 8,714
Corporate bonds	1,722		(3)	1,719

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

Total	\$ 10,433	\$ 3	\$ (3)	\$ 10,433
-------	-----------	------	--------	-----------

F-20

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

No realized gains or losses were recorded for the year ended December 31, 2008 and 2007. We utilize the specific identification method in computing realized gains and losses.

We periodically review for impairment those investment securities that have unrealized losses for more than twelve months to determine if such unrealized losses are other than temporary. We intend to hold these related investment securities to maturity and have the ability to do so. As a result, we consider these unrealized losses to be temporary and have not recorded a loss in our consolidated statements of operations.

**4. Other Assets**

Prepaid expenses and other current assets consist of the following:

	<b>December 31, 2008</b>	<b>December 31, 2007</b>
Derivative receivable	\$ 5,409	\$
State tax receivable	2,060	2,330
Other	4,487	3,373
	\$ 11,956	\$ 5,703

Other non-current assets consist of the following:

	<b>December 31, 2008</b>	<b>December 31, 2007</b>
Leasehold deposits	\$ 1,600	\$ 1,043
Deferred financing costs, net	1,571	2,768
Other	19	
	\$ 3,190	\$ 3,811

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)****5. Property, Plant and Equipment**

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

<b>Asset</b>	<b>December 31, 2008</b>	<b>December 31, 2007</b>
Land	\$ 692	\$ 692
Buildings and improvements	20,585	9,266
Machinery and laboratory equipment	18,144	10,742
Furniture and office equipment	12,215	8,645
Construction-in-progress	110,021	91,305
	161,657	120,650
Less: Accumulated depreciation and amortization	(21,772)	(16,370)
	\$ 139,885	\$ 104,280

Depreciation and amortization of property, plant and equipment was approximately \$5,688, \$4,243 and \$3,028 for the year ended December 31, 2008, 2007 and 2006, respectively.

In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island for the future commercial production of Soliris, for manufacturing development and for manufacturing of future products. Since this date, we have incurred costs related to the construction of the plant to support full-scale commercial manufacturing. We have also capitalized costs related to activities, including engineering runs, necessary to obtain approval of the facility from government regulators.

Through December 31, 2008, we have capitalized \$116,364 related to the manufacturing facility and pilot plant, which includes all costs associated with construction, renovation and upgrades, engineering runs and capitalized interest. Through December 31, 2008, costs incurred in seeking regulatory approval, including engineering runs, was \$42,416, and capitalized interest was \$9,045. See Note 9 for a description of the terms of the related mortgage payable.

We transferred our pilot manufacturing capabilities from New Haven, Connecticut to the Smithfield, Rhode Island facility during 2007, at which time assets related to the pilot plant were placed in service. The cost of assets related to the pilot plant is \$16,354.

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006**

(amounts in thousands, except per share amounts)

**6. Intangible Assets**

Intangible assets and goodwill, net of accumulated amortization, are as follows:

	Range of Estimated Life (months)	December 31, 2008			December 31, 2007		
		Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Licenses	28-72	\$ 24,512	\$ (1,215)	\$ 23,297	\$ 1,731	\$ (794)	\$ 937
Patents	90	10,300	(1,272)	9,028	517	(517)	
<b>Total</b>		<b>\$ 34,812</b>	<b>\$ (2,487)</b>	<b>\$ 32,325</b>	<b>\$ 2,248</b>	<b>\$ (1,311)</b>	<b>\$ 937</b>
Goodwill	Indefinite	\$ 22,855	\$ (2,901)	\$ 19,954	\$ 22,855	\$ (2,901)	\$ 19,954

Amortization of our intangible assets was approximately \$1,176, \$264 and \$0 for the years ended December 31, 2008, 2007 and 2006, respectively. Assuming no changes in the gross costs basis of intangible assets, the estimated amortization of intangible assets for the next five fiscal years is as follows:

Year	
2009	\$ 4,434
2010	4,589
2011	5,254
2012	5,434
2013	6,022

In July 2007, we amended our existing license agreement with the University of Iowa Research Foundation, or UIRF, to prepay our royalty owed to UIRF with respect to sales of Soliris for the treatment of PNH. Under the terms of the amended license agreement, we agreed to pay UIRF \$1,000 in exchange for elimination of the royalty payable on net sales of Soliris for the treatment of PNH. Such payment was made in July 2007. The amount will be amortized in proportion to product sales through 2009, which represents the expiration of the underlying patent. The payment does not affect any other product marketed by Alexion under the license, and net sales of any other product covered by the UIRF license agreement shall be subject to royalties.

In February 2008, we agreed to purchase certain patents related to complement-inhibition technology from Oklahoma Medical Research Foundation, or OMRF. We agreed to pay a total of \$10,000, plus interest, to OMRF for the rights to the patents. In addition to the initial payment of \$3,000 paid in February 2008 and \$4,500 in December 2008, we are required to make a final payment of \$2,500 by July 2009. Interest accrues on the unpaid amount at the rate of 50% of the sum of the prime rate plus 1%, per annum, or 2.125%, at December 31, 2008. We recorded the \$10,000 as an intangible asset which is amortized in proportion to product sales through 2014, which represents the expiration of the acquired patents.



**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

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

**For the Years Ended December 31, 2008, 2007 and 2006**

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

In December 2008, we entered into a definitive license agreement with PDL BioPharma, Inc. on a patent portfolio relating to the humanization of antibodies for \$25,000 (see Note 11). The initial payment of \$12,500 was paid in January 2009, with a final payment of \$12,500 due on June 30, 2009. No additional payments will be owed by Alexion to PDL for these patents in respect of Soliris sales for any indication. As a result of the settlement, we recorded an intangible asset which will be amortized in proportion to product sales through November 2014, which represents the expiration of the PDL patents. Based on the settlement and evaluation of other potential royalties, we recorded a reduction in cost of goods sold of approximately \$1,800 during the fourth quarter of 2008 related to an adjustment of estimated accrued royalties on sales of Soliris prior to the fourth quarter.

In December 2008, we acquired the outstanding shares of Legend K.K. for 100,000 Japanese yen (\$1,124 on acquisition date). The acquisition was treated as an acquisition of an asset with substantially all of the purchase price allocated to a license. The license will be amortized over the remaining useful life of 28 months.

**7. Derivative Instruments and Hedging Activities**

We operate internationally and, in the normal course of business, are exposed to fluctuations in foreign currency exchange rates. The exposures result from portions of our revenues, as well as the related receivables, that are denominated in currencies other than the U.S. dollar, primarily the Euro and British Pound. We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. We do not use derivatives for speculative trading purposes.

Beginning in the third quarter of 2008, we entered into foreign exchange contracts, with durations of 12 months or less, to hedge exposures resulting from portions of our forecasted revenues that are denominated in currencies other than the U.S. dollar. These hedges were designated as cash flow hedges upon inception. As of December 31, 2008, we have open contracts with notional amounts totalling \$100,675 that qualified for hedge accounting and \$4,935 in accumulated other comprehensive income representing the anticipated gain to be reclassified to revenue over the next twelve months as the forecasted transactions occur. During the year ended December 31, 2008, we recognized a gain of \$4,141 in revenue relating to hedged transactions which occurred. During the year ended December 31, 2008, a gain of \$345 was recognized associated with ineffectiveness of cash flow hedges.

Beginning in the first quarter of 2008, we entered into foreign exchange contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities of our foreign subsidiaries. These derivative instruments do not qualify for hedge accounting under SFAS 133. As of December 31, 2008, the notional settlement amount of forward foreign exchange contracts relating to monetary assets and liabilities was \$28,201. We recognized a gain of \$3,177 for the year ended December 31, 2008 associated with these derivative instruments.

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006**

(amounts in thousands, except per share amounts)

**8. Accrued Expenses**

Accrued expenses consist of the following:

	December 31, 2008	December 31, 2007
Payroll and employee benefits	\$ 14,153	\$ 10,610
Royalties	13,343	4,724
Rebates	3,347	1,006
Clinical expense	3,317	3,437
VAT Payable	2,323	1,415
Other	9,717	7,132
	\$ 46,200	\$ 28,324

**Exit Activities**

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

	Employee Related Benefits	Facility Lease Costs	Other Exit Activities	Total Exit Activities
Recorded on exit date	\$ 5,401	\$ 1,379	\$ 539	7,319
Payments and other settlements	(43)			(43)
Balance at December 31, 2006	5,358	1,379	539	7,276
Revision of estimate	21		(144)	(123)
Payments and other settlements	(5,379)	(616)	(395)	(6,390)
Balance at December 31, 2007		763		763
Revision of estimate		(18)		(18)
Payments and other settlements		(149)		(149)
Balance at December 31, 2008	\$	\$ 596	\$	\$ 596

Employee benefits consist of expenses for severance compensation as well as accelerated vesting of share-based grants. Facility lease costs are associated with the lease on our San Diego, California facility as described in Note 10 and other exit activities consist of impairment charges on equipment. The Company remains obligated

F-25

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

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

**For the Years Ended December 31, 2008, 2007 and 2006**

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

for lease payments through 2012. In September 2007, the Company signed a sub-lease for the AAT facility, which provides for sub-lease payments through the term of the lease, or 2012. The accrual for restructuring activities reflects the present value of lease obligations, reduced by estimated sub-lease income. As of December 31, 2008, all remaining costs associated with employee related benefits and other exit activities have been paid or settled.

**9. Debt**  
**Convertible Notes**

In January 2005 we sold \$150,000 principal amount of 1.375% Convertible Senior Notes due February 1, 2012 (the 1.375% Notes) in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 1.375% per annum on the principal amount from January 25, 2005, payable semi-annually in arrears in cash on February 1 and August 1 of each year, beginning August 1, 2005. The 1.375% Notes is convertible into our common stock at an initial conversion rate of 15.8957 shares of common stock (equivalent to a conversion price of approximately \$15.73 per share) per \$1 principal amount of the 1.375% Notes, subject to adjustment, at any time prior to the close of business on the final maturity date of the notes. We do not have the right to redeem any of the 1.375% Notes prior to maturity. The convertible notes payable do not have covenants related to our financial performance. We capitalized deferred financing costs related to this offering of approximately \$4,800 which are amortized as a component of interest expense over the seven-year term of the notes.

In October 2008, certain holders of our convertible notes exercised conversion rights with respect to an aggregate principal amount of \$52,778 of the notes resulting in the issuance of 3,356 shares of common stock. The shares were issued in November 2008. As a result of the conversion of \$52,778 of the notes, we reclassified \$775 from deferred financing costs to equity.

Amortization expense associated with deferred financing costs for the year ended December 31, 2008, 2007 and 2006 was approximately \$733, \$677 and \$677, respectively.

As of December 31, 2008, the market value of our \$97,222, 1.375% Convertible Notes due February 1, 2012, based on quoted market prices, was estimated at \$211,106.

If the holder elects to convert its 1.375% Notes upon the occurrence of a designated event, such as liquidation or change in control, the holder will be entitled to receive an additional number of shares of common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option, are set according to a table within the offering document, and are capped (in no event will the shares issuable upon conversion of a note exceed 21.4550 per \$1 principal amount).

## **Table of Contents**

### **Alexion Pharmaceuticals, Inc.**

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

#### **For the Years Ended December 31, 2008, 2007 and 2006**

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

### **Mortgage Loan**

In July 2006, we entered into a mortgage loan agreement to borrow \$26,000 to finance the purchase and construction of our Smithfield, Rhode Island manufacturing facility. In July 2007, we amended our existing mortgage loan agreement with iStar Financial Inc. to increase the loan amount by \$18,000, resulting in an aggregate principal balance of \$44,000. From the effective date of the amendment, the mortgage loan bears interest at a fixed annual rate of 9.12% and all obligations under the loan agreement are guaranteed by Alexion Pharmaceuticals, Inc. The loan principal is required to be repaid in equal monthly installments of \$489, starting March 2010 and until August 2017, at which time all outstanding balances are due. The loan may not be prepaid in whole or in part prior to July 2009. After that date the loan can be prepaid in whole, but not in part, and must include a prepayment premium as described in the loan agreement. The loan is collateralized by the assets of our Smithfield, RI facility, and the proceeds of the loans were used primarily to finance the construction of our manufacturing facility.

As a condition of the loan, we are required to maintain restricted cash accounts. These accounts must be used specifically for the purchase and construction of the manufacturing facility and to maintain required operating escrow balances. The lender has a first priority security interest and the right to approve all disbursements from the accounts holding restricted cash.

The mortgage loan does not require covenants related to our financial performance.

### **Revolving Credit Facility**

In February 2008, we entered into a Credit Agreement with Bank of America, N.A. to provide for an available \$25,000 revolving credit facility that can be used for working capital requirements and other general corporate purposes. The loan is collateralized by substantially all of Alexion Pharmaceuticals, Inc.'s assets, including the pledge of the equity interests of certain direct subsidiaries, but excluding intellectual property, assets of foreign subsidiaries and assets related to our manufacturing facility in Smithfield, RI. The borrowing base is limited to the lesser of \$25,000 or 80% of eligible domestic receivables. At December 31, 2008, we had no outstanding balance under the revolving credit facility. We have open letters of credit of \$4,165 at December 31, 2008.

We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.75% to 2.25% depending on Alexion's liquidity (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect and (B) the Federal Funds Rate then in effect plus 0.50%, plus an additional 0% to 0.25% depending on Alexion's liquidity. Interest is payable quarterly for Base Rate loans and, in the case of LIBOR-based loans, at the end of the applicable interest period, with the principal due on February 28, 2011, the maturity date.

The revolving credit facility requires that we comply with quarterly financial covenants related to liquidity and profitability ratios, as well as minimum revenue requirements. Further, the agreement includes negative

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

covenants, subject to exceptions, restricting or limiting our ability and the ability of our subsidiaries to, among other things, incur additional indebtedness, grant liens, engage in certain investment, acquisition and disposition transactions, and enter into transactions with affiliates. The agreement also contains customary representations and warranties, affirmative covenants and events of default, including payment defaults, breach of representations and warranties, covenant defaults and cross defaults. If an event of default occurs, the interest rate would increase and the administrative agent would be entitled to take various actions, including the acceleration of amounts due under the loan.

**10. Leases****Capital Leases**

We lease office equipment and software licenses under capital lease agreements expiring in 2010. The assets and liabilities under capital leases are recorded at the lesser of the present value of the minimum lease payments or the fair value of the asset. The assets are amortized over the lower of their related lease terms or their estimated useful lives. Amortization of assets under capital lease is included in depreciation expense. As of December 31, 2008, the cost of equipment under capital lease is \$940 and accumulated amortization is \$517. The weighted-average interest rate on the capital leases is approximately 9.47%.

Minimum future lease payments under capital lease as of December 31, 2008 are:

<u>Year</u>	
2009	\$ 336
2010	213
2011	
2012	
	549
Less: Amount representing interest	51
Present value of minimum lease payments	\$ 498

**Operating Leases**

As of December 31, 2008, we lease our headquarters and primary research and development facilities in Cheshire, Connecticut. The lease is set to expire in May 2017. Monthly fixed rent started at approximately \$162, increasing to approximately \$193 over the term of this lease.

We lease additional research space in San Diego, California, starting at a monthly fixed rent of approximately \$35 and increasing to approximately \$55. In connection with the closure of Alexion Antibody Technologies ( AAT ) in 2006, we accrued the fair value of future payments under the lease (see Note 8). In

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

September 2007, the Company signed a sub-lease for the AAT facility, which provides for sub-lease payments through the term of the lease, or 2012.

Aggregate lease expense for our facilities was \$4,728, \$4,021 and \$2,592 for the years ended December 31, 2007 and 2006, respectively. Lease expense is being recorded on a straight-line basis over the applicable lease terms.

Aggregate future minimum annual rental payments for the next five years and thereafter under non-cancellable operating leases (including facilities and equipment) as of December 31, 2008 are:

2009	\$ 4,699
2010	4,008
2011	3,723
2012	3,097
2013	2,605
Thereafter	8,053

**11. Commitments and Contingencies****Legal Proceedings**

On March 16, 2007, PDL BioPharma, Inc., or PDL, filed a civil action against us in the U.S. District Court for the District of Delaware claiming wilful infringement of certain PDL patents, or the PDL Patents, due to sales of Soliris. We denied such claims and filed counterclaims. In the fourth quarter of 2008, we entered into a Patent License Agreement and Settlement Agreement with PDL for the purpose of resolving all claims previously filed by PDL and all counterclaims previously filed by Alexion.

Pursuant to the License Agreement, we acquired a fully paid, nonexclusive, irrevocable, perpetual worldwide license to some claims of the PDL Patents and a covenant not to sue from PDL for other claims of the PDL Patents, in each case for the commercialization of Soliris for all indications. The agreement requires payments totaling \$25,000 to PDL, \$12,500 of which was paid in the first quarter of 2009 and \$12,500 of which is due in June 2009. No royalties or other amounts are owed to PDL with respect to sales of Soliris for any indication. Upon receipt of the \$25,000 license payment, the previously announced claims filed by PDL and counterclaims filed by us will be dismissed.

Under the terms of the License Agreement PDL separately granted us the right to take a worldwide, royalty-bearing license under the PDL Patents to commercialize additional Alexion humanized antibodies that may be covered by the PDL Patents in the future.

Under the terms of the Settlement Agreement, Alexion and PDL agreed to resolve and settle all claims filed by PDL and all counterclaims filed by Alexion in the U.S. District Court for the District of Delaware.

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)****Product Supply**

The Large-Scale Product Supply Agreement dated December 18, 2002, or the Lonza Agreement, between Lonza Sales AG, or Lonza, and us, relating to the manufacture of Soliris, was amended in June 2007. We amended our supply agreement to provide for additional purchase commitments of Soliris of \$30,000 to \$35,000 from 2009 through 2013. Such commitments may only be cancelled in limited circumstances.

**12. Income Taxes**

The income tax provision (benefit) is based on income (loss) before income taxes as follows:

	2008	2007	2006
U.S.	\$ 23,756	\$ (71,432)	\$ (123,965)
Non-U.S.	10,974	(21,603)	(7,922)
	\$ 34,730	\$ (93,035)	\$ (131,887)

The components of the income tax provision (benefit) are as follows:

	2008	2007	2006
<b>Income Tax Provision (Benefit)</b>			
Domestic			
Current	\$ 2,514	\$ (745)	\$ (373)
Deferred	(2,633)		
	(119)	(745)	(373)
Foreign			
Current	1,902		
Deferred	(202)		
	1,700		
Total			
Current	4,416	(745)	(373)
Deferred	(2,835)		
	\$ 1,581	\$ (745)	\$ (373)

We maintain a full valuation allowance against substantially all U.S. and certain foreign deferred tax assets where realization of those assets is uncertain. Accordingly, we have not reported any tax benefit relating to our remaining net operating loss carryforwards (NOLs) and income tax credit carryforwards related to these jurisdictions. The change in valuation allowance of \$7,213 was primarily related to realization of net



operating losses during 2008. Income tax expense for 2008 and the income tax benefit for 2007 includes the benefits

F-30

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

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

**For the Years Ended December 31, 2008, 2007 and 2006**

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

realized on the exchange of federal and state research and development income tax credits for cash of \$522 and \$686, respectively. In addition, income tax expense for 2008 includes foreign income tax expense of \$1,700. This foreign income tax expense is related to our foreign subsidiaries that became profitable during the year and utilized all of their NOLs.

Due to the amount of our NOLs and income tax credit carryforwards, we do not anticipate paying substantial U.S. federal income taxes in the foreseeable future. We do expect to pay cash taxes in a number of foreign jurisdictions, as well as in certain states, where our net operating losses were fully utilized during 2008. We were subject to the alternative minimum tax during 2008 and expect that we will continue to be subject to the alternative minimum tax in the near term. The payment of an alternative minimum tax amount generates a credit that may be carried forward indefinitely and used to offset our regular income tax liability.

At December 31, 2008, we have federal, state, and foreign net operating loss carryforwards of \$745,102, \$713,040, and \$20,310, respectively. Included in the NOLs are federal and state NOLs of \$142,812 and \$147,432, respectively, attributable to excess tax benefits from the exercise of non-qualified stock options. The tax benefits attributable to these NOLs will be credited directly to additional paid in capital when realized. These NOLs expire between 2009 and 2027. We also have federal and state research and development income tax credit carryforwards of approximately \$18,826 and \$8,834 respectively. These income tax credits expire between 2009 and 2027. Additionally, included in these research and development carryforwards are federal and state research and development credit carryforwards of \$3,430 and \$4,514, respectively, attributable to excess tax benefits from the exercise of non-qualified stock options.

Certain stock option exercises resulted in tax deductions in excess of previously recorded benefits based on the option value at the time of grant. Although these additional tax benefits or windfalls are reflected in net operating loss carryforwards, pursuant to SFAS 123(R), the additional tax benefit associated with the windfall is not recognized until the deduction reduces taxes payable. Accordingly, since the tax benefit does not reduce our current taxes payable due to net operating loss carryforwards, these windfall tax benefits are not reflected in our net operating losses in deferred tax assets for all periods presented.

At December 31, 2007, we had federal, state, and foreign NOL carryforwards of \$732,653, \$707,718, and \$29,845, respectively. Included in the NOLs are federal and state NOLs of \$99,972 and \$105,873, respectively, attributable to excess tax benefits from the exercise of non-qualified stock options. The tax benefits attributable to these NOLs would be credited directly to additional paid in capital when realized. These NOLs expire between 2008 and 2027 and some of these NOLs are subject to an annual limitation under section 382 of the Internal Revenue Code of 1986, as amended. We also had federal and state research and development credit carryforwards of \$18,689 and \$8,443 respectively. These income tax credits expire between 2008 and 2027.

The Tax Reform Act of 1986 contains certain provisions that can limit a taxpayer'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 percent over a three-year period. We have determined that these limiting provisions were

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

triggered during a prior year. However, we believe that such limitation is not expected to result in the expiration or loss of any of our federal NOLs and income tax credit carryforwards.

The provision (benefit) for income taxes differs from the U.S. federal statutory tax rate. The reconciliation of the statutory U.S. federal income tax rate to our effective income tax rate is as follows:

	<b>Year Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Federal statutory rate	35.0%	-35.0%	-34.0%
State and local income taxes	0.9%	-4.1%	-4.3%
Foreign income tax rate differential	-3.3%	6.7%	0.1%
Research & development income tax credits	-2.9%	-3.6%	-3.4%
Foreign income subject to U.S. taxation	8.6%	0.0%	0.0%
Provision (benefit) attributable to foreign currency	4.8%	0.0%	0.0%
Other nondeductible and permanent differences	2.6%	1.3%	0.0%
Provision (benefit) attributable to valuation allowances	-41.1%	33.9%	41.3%
Effective rate	4.6%	-0.8%	-0.3%

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

Provisions have been made for deferred taxes based on the differences between the basis of the assets and liabilities for financial statement purposes and the basis of the assets and liabilities for tax purposes using currently enacted tax rates and regulations that will be in effect when the differences are expected to be recovered or settled. The components of the deferred tax assets and liabilities are as follows:

	<b>Year Ended December 31, 2008</b>	<b>Year Ended December 31, 2007</b>
Deferred tax assets:		
Net operating losses	\$ 242,054	\$ 249,558
Income tax credits	18,205	17,063
Stock compensation	10,854	5,917
Reserves, accruals and other	9,587	2,247
Intangible assets	6,571	122
Depreciable assets		197
Total deferred tax assets	287,271	275,104
Valuation allowance	(267,891)	(275,104)
Total deferred tax assets after valuation allowance	19,380	
Deferred tax liabilities:		
Depreciable assets	(16,072)	
Unrealized (gains) and losses	(484)	
Total deferred tax liabilities	(16,556)	
Net deferred tax asset after valuation allowance	\$ 2,824	\$

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an Interpretation of FASB Statement No. 109 (the Interpretation or FIN 48). The Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109. The Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosures, and transition. The Interpretation was effective for fiscal years beginning after December 15, 2006.

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

We applied the provisions of FIN 48 effective January 1, 2007 and recognized a benefit of \$592 to the January 1, 2007 accumulated deficit balance. In addition, we decreased our fully reserved deferred tax assets by \$6,671 at that point in time. The beginning and ending amounts of unrecognized tax benefits reconciles as follows:

	2008	2007
Beginning of period balance	\$ 6,671	\$ 6,671
Increases for tax positions taken during a prior period	306	
Decreases for tax positions taken during a prior period		
Increases for tax positions taken during the current period	2,817	
Reduction as a result of a lapse of statute of limitations	(225)	
	\$ 9,569	\$ 6,671

We recognize interest and penalties related to unrecognized tax benefits as a component of income tax expense. Due to the amount of our NOL and income tax credit carryforwards, we have not accrued interest relating to these unrecognized tax benefits. Accrued interest and penalties, however, would be disclosed within the related liabilities lines in the consolidated balance sheet. All of our unrecognized tax benefits, if recognized, would impact the effective tax rate.

We file federal and state income tax returns in the U.S. and in numerous foreign jurisdictions. The U.S. and foreign jurisdictions have statute of limitations ranging from 3 to 5 years. However, the statute of limitation could be extended due to our NOL carryforward position in a number of our jurisdictions. The tax authorities, generally, have the ability to review income tax returns for periods where the statute of limitation has previously expired and can subsequently adjust the NOL carryforward or tax credit amounts. Accordingly, we do not expect to reverse any portion of the unrecognized tax benefits within the next year.

There are no cumulative foreign earnings as of December 31, 2008. As such, we have not provided for U.S. deferred income taxes on undistributed earnings of our non-U.S. subsidiaries.

### **13. Stock Options and Restricted Stock**

#### **Stock Options**

At December 31, 2008, we have one stock option plan, the 2004 Incentive Plan ( 2004 Plan ). Under the 2004 Plan, common stock, as well as incentive and non-qualified stock options, may be granted for up to a maximum of 14,937 shares to our directors, officers, key employees and consultants. The amount of shares authorized for granting includes 5,000 initially authorized under then plan, 1,187 shares transferred from the 2000 Plan and an additional 1,550, 2,400 and 4,800 shares authorized by our shareholders in June 2006, May 2007 and May 2008. Stock options granted under all Plans have a maximum contractual term of ten years from

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

the date of grant, have an exercise price not less than the fair value of the stock on the grant date and generally vest over four years.

For the years ended December 31, 2008, 2007 and 2006, we recognized total stock compensation expense of \$18,054, \$16,438 and \$17,601 for stock options and \$5,628, \$3,736 and \$3,014 for restricted stock, respectively. During the year ended December 31, 2008, we capitalized \$1,626 and \$1,215 towards the Rhode Island manufacturing facility and inventory, respectively. During the year ended December 31, 2007, we capitalized \$1,526 and \$325 towards the Rhode Island manufacturing facility and inventory, respectively.

The weighted average fair value at the date of grant for options granted during the years ended December 31, 2008, 2007 and 2006 is \$16.93, \$11.47 and \$9.91 per option, respectively.

As of December 31, 2008, there was \$42,115 of total unrecognized compensation expense related to non-vested share-based compensation arrangements granted under the Plan. The expense is expected to be recognized over a weighted-average period of 1.23 years.

A summary of the status of our stock option plans at December 31, 2008 and 2007, and changes during the years then ended is presented in the table and narrative below:

	Number of shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2005	10,184	\$ 12.08		
Granted	2,925	14.86		
Exercised	(1,851)	7.35		
Forfeited and cancelled	(513)	11.68		
Outstanding at December 31, 2006	10,745	\$ 13.35	6.19	\$ 143,267
Vested and unvested expected to vest at December 31, 2006	10,265	\$ 13.32	6.06	\$ 136,764
Exercisable at December 31, 2006	6,744	\$ 13.21	4.61	\$ 89,065
Outstanding at December 31, 2006	10,745	\$ 13.35		
Granted	2,435	22.58		
Exercised	(4,191)	11.22		
Forfeited and cancelled	(600)	16.85		
Outstanding at December 31, 2007	8,389	\$ 16.82	6.97	\$ 174,054

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006**

(amounts in thousands, except per share amounts)

	Number of shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Vested and unvested expected to vest at December 31, 2007	8,093	\$ 16.76	6.90	\$ 168,437
Exercisable at December 31, 2007	4,225	\$ 15.14	5.25	\$ 94,947
Outstanding at December 31, 2007	8,389	\$ 16.82		
Granted	1,543	36.29		
Exercised	(2,119)	13.64		
Forfeited and cancelled	(770)	22.55		
Outstanding at December 31, 2008	7,043	\$ 21.42	6.65	\$ 106,115
Vested and unvested expected to vest at December 31, 2008	6,769	\$ 21.69	6.75	\$ 103,176
Exercisable at December 31, 2008	3,910	\$ 17.80	5.27	\$ 72,370

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

	Year Ended December 31, 2008	Year Ended December 31, 2007	Year Ended December 31, 2006
Expected life in years	3.67 - 7.73	4.17 - 9.46	6.25
Interest rate	1.44% - 3.53%	3.10% - 4.94%	4.32% - 5.13%
Volatility	40.25% - 61.39%	42.91% - 69.98%	64.36% - 72.20%
Dividend yield	-	-	-

The expected stock price volatility rates are based on historical volatilities of our common stock. The risk-free interest rates are based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. The average expected life represents the weighted average period of time that options granted are expected to be outstanding. We have evaluated three distinct employee groups in determining the expected life assumptions. For the year ended December 31, 2006, the average expected life was determined using the simplified approach as permitted by Staff Accounting Bulletin No. 107, or SAB 107. For the year ended December 31, 2008 and 2007, we estimated the expected life of stock options based on historical experience of exercises, cancellations and forfeitures of our stock options.

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)****Restricted Stock**

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

	<b>Year Ended December 31, 2008</b>	<b>Year Ended December 31, 2007</b>	<b>Year Ended December 31, 2006</b>
Nonvested restricted stock, beginning of the period	909	649	267
Shares issued	518	534	455
Shares cancelled	(208)	(116)	(30)
Shares exercised	(183)	(158)	(44)
Nonvested restricted stock, end of the period	1,034	909	649
Weighted average grant date fair value	\$ 26.14	\$ 17.39	\$ 12.53

**14. Common and Preferred Stock**  
**Preferred Stock**

In February 1997, our Board of Directors declared a dividend of one preferred stock purchase right for each outstanding share of Common Stock (including all future issuances of Common Stock). Under certain conditions, each right may be exercised to purchase one one-hundredth of a share of a new series of preferred stock at an exercise price of \$75.00, subject to adjustment (see below). The rights may be exercised only after a public announcement that a party acquired 20 percent or more of our Common Stock or after commencement or public announcement to make a tender offer for 20 percent or more of our Common Stock. The rights, which do not have voting rights, expire on March 6, 2017, and may be redeemed by us at a price of \$0.01 per right at any time prior to their expiration or the acquisition of 20 percent or more of our stock. The preferred stock purchasable upon exercise of the rights will have a minimum preferential dividend of \$10.00 per year, but will be entitled to receive, in the aggregate, a dividend of 100 times the dividend declared on a share of Common Stock. In the event of liquidation, the holders of the shares of preferred stock will be entitled to receive a minimum liquidation payment of \$100 per share, but will be entitled to receive an aggregate liquidation payment equal to 100 times the payment to be made per share of Common Stock.

On February 23, 2007, our Board of Directors amended the purchase price under the preferred stock purchase rights. Further, as a result of the two-for-one stock split of the Company's outstanding shares of Common Stock effected on August 22, 2008, the number of shares of preferred stock purchasable upon proper exercise of each preferred stock purchase right automatically adjusted from one one-hundredth of a share of preferred stock to one two-hundredth of a share of preferred stock. Therefore, the purchase price, for each one two-hundredth of a share of preferred stock to be issued upon the exercise of each preferred stock purchase right is \$300.00. Except for the increase in the purchase price, the terms and conditions of the rights remain unchanged.



**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

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

**15. Fair Value Measurement**

SFAS 157 establishes a valuation hierarchy for disclosure of the inputs to the valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value.

The following table presents information about our assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2008, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value:

Description	Fair Value Measurement at December 31, 2008			
	Total	Level 1	Level 2	Level 3
<b>Fixed income investments:</b>				
Cash equivalents Money market funds	\$ 129,846	\$	\$ 129,846	\$
<b>Derivatives:</b>				
Foreign exchange contracts	\$ 5,409	\$	\$ 5,409	\$

**Valuation Techniques**

Our cash equivalents classified as Level 2 within the valuation hierarchy consist entirely of an institutional money market fund held at a multinational financial institution and are valued based upon pricing of securities with similar investment characteristics and holdings. Our derivative assets and liabilities include foreign exchange derivatives that are measured at fair value using observable market inputs such as forward rates, interest rates, our own credit risk and our counterparties' credit risks. Based on these inputs, the derivative assets and liabilities are classified within Level 2 of the valuation hierarchy. Based on our continued ability to trade securities and enter into forward contracts, we consider the markets for our fair value instruments to be active.

As of December 31, 2008, there has not been any impact to the fair value of our derivative liabilities due to our own credit risk. Similarly, there has not been any significant adverse impact to our derivative assets based on our evaluation of our counterparties' credit risks.

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)****16. Employee Benefit Plans****Defined Contribution Plans**

We have two qualified 401(k) plans covering all eligible employees. Under the plans, employees may contribute up to the statutory allowable amount for any calendar year. We make matching contributions equal to:

\$1.00 for each dollar contributed up to the first 3 percent; and

\$0.50 for each dollar contributed of the next 2 percent of compensation.

For the years ended December 31, 2008, 2007 and 2006, we recorded matching contributions of approximately \$2,336, \$1,535 and \$406, respectively.

**Defined Benefit Plan**

We maintain defined benefit plans for employees in Switzerland. The assets of the funded plan are held independently of our assets in a legally distinct and independent collective trust fund which serves various unrelated employers. The plan is valued by independent actuaries using the projected unit credit method. The liabilities correspond to the projected benefit obligations of which the discounted net present value is calculated based on years of employment, expected salary increases, and pension adjustments.

The following table sets forth the funded status and the amounts recognized for our defined benefit plans:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Change in benefit obligation:</b>		
Projected benefit obligation, beginning of year	\$ 886	\$
Service cost	238	136
Interest cost	31	
Change in assumptions		(125)
Recognized actuarial net (gain) loss	236	341
Foreign currency exchange rate changes	107	56
Transfers into plan	1,399	478
<b>Projected benefit obligation, end of year</b>	<b>\$ 2,897</b>	<b>\$ 886</b>
 Accumulated benefit obligation, end of year	 2,301	 657

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Change in plan assets:</b>		
Fair value of plan assets, beginning of year	\$ 630	\$
Return on plan assets	26	
Employer contributions	174	63
Plan participants' contributions	96	42
Foreign currency exchange rate changes	95	47
Transfers into plan	1,399	478
 Fair value of plan assets, end of year	 \$ 2,420	 \$ 630
 Funded status at end of year	 \$ (477)	 \$ (256)

At December 31, 2008, we have recorded a liability of \$477 in other non-current liabilities and an accumulated other comprehensive amount of \$471 related to an additional minimum liability.

The weighted average assumptions used to determine the net pension expense are shown below:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Weighted average assumptions:</b>		
Discount rate	3.5%	3.5%
Rate of return on assets	4.0%	4.0%
Rate of compensation increase	1.5%	1.5%

The components of net pension expense are as follows:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Service cost	\$ 238	\$ 136
Interest cost	31	
Expected return on plan assets	(26)	
Employee contributions	(96)	(42)
Amortization and deferral of actuarial gain (loss)	8	
 Net pension expense	 \$ 155	 \$ 94

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

The investment objective of the collective trust is to maximize the overall return from investment income and capital appreciation without resorting to a high risk investment strategy. The weighted average asset allocations for the pension plan are as follows:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Equity securities	28%	25%
Bonds	57%	57%
Real estate	15%	18%

**Estimated Future Benefit Payment**

We expect to pay the following benefit payments for our defined pension benefit plans outside the United States, which reflect future service, as appropriate:

	<b>Estimated Future Benefit Payments</b>
2009	\$ 31
2010	35
2011	37
2012	37
2013	48
2014 to 2018	477

**17. Segment Information**

In accordance with SFAS 131, Disclosures about Segments of an Enterprise and Related Information, we present segment information in a manner consistent with the method we use to report this information to our management. We have determined we operate in a single segment.

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006**

(amounts in thousands, except per share amounts)

Revenues and tangible long-lived assets by significant geographic region are as follows:

Revenues:	Year Ended December 31,		
	2008	2007	2006
United States	\$ 113,204	\$ 51,856	\$ 1,558
Europe	143,645	20,185	
Other	2,155		
	\$ 259,004	\$ 72,041	\$ 1,558

Long-lived assets:	December 31,	
	2008	2007
United States	\$ 189,372	\$ 126,457
Europe	2,792	545
	\$ 192,164	\$ 127,002

**18. Quarterly Financial Information (unaudited)**

The following is condensed quarterly financial information for the years ended December 31, 2008 and 2007:

	March 31	June 30	Quarter Ended September 30	December 31
<b>2008:</b>				
Revenues	\$ 45,641	\$ 59,559	\$ 76,500 (1)	\$ 77,399
Cost of sales	5,464	7,142	8,948	6,812 (2)
Operating expenses	45,390	49,732	46,938	54,064
Operating income (loss)	(5,213)	2,685	20,614	16,523
Net income (loss)	(4,249)	2,374	19,689	15,336
Earnings (loss) per common share				
Basic	(0.06)	0.03	0.26	0.19
Diluted	(0.06)	0.03	0.23	0.17

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2008, 2007 and 2006****(amounts in thousands, except per share amounts)**

	March 31	June 30	Quarter Ended September 30	December 31
<b>2007:</b>				
Revenues	\$ 6,317	\$ 9,756	\$ 22,110	\$ 33,858
Cost of sales	85 (3)	1,067 (3)	2,154 (3)	3,391 (3)
Operating expenses	41,057	37,983	41,850	44,213
Operating loss	(34,825)	(29,294)	(21,894)	(13,746)
Net loss applicable to common shareholders	(32,693)	(27,184)	(20,085)	(12,330)
Net loss per common share, basic and diluted	(0.46)	(0.38)	(0.27)	(0.17)

- (1) During the three months ended September 30, 2008, certain government payors agreed to reimburse for Soliris shipments which were delivered in prior periods. Accordingly, we recognized \$5,300 of net product sales in the third quarter associated with these prior shipments.
- (2) In the fourth quarter of 2008, we entered into a patent license agreement and settlement agreement with PDL BioPharma for a fully paid, perpetual license. As a result of the settlement and evaluation of other potential royalties, we recorded a reduction in cost of goods sold of approximately \$1,800 related to an adjustment of estimated accrued royalties for sales of Soliris prior to the fourth quarter.
- (3) Product sold during the year ended December 31, 2007 included inventory that was previously expensed prior to submission of our BLA, and therefore is not included in the cost of sales during this period. During the fourth quarter of 2007, we exhausted the supply of previously expensed inventory.