

ALEXION PHARMACEUTICALS INC  
Form 10-K  
February 17, 2011  
Table of Contents

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

Washington, D.C. 20549

**FORM 10-K**

**Annual report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934**  
For the fiscal year ended December 31, 2010

or

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

Commission file number: 0-27756

**ALEXION PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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

(Address of Principal Executive Offices) (Zip Code)

**203-272-2596**

(Registrant's telephone number, including area code)

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

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 whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) 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 large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. Check One:

Large accelerated filer  Accelerated filer  Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

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

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based upon the last sale price of the Common Stock reported on The Nasdaq Stock Market LLC on June 30, 2010, was approximately \$4,611,459,750.

The number of shares of Common Stock outstanding as of February 11, 2011 was 91,308,703.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement to be used in connection with its Annual Meeting of Stockholders to be held on May 10, 2011, 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.

**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 indication and any expanded uses, timing and effect of sales of Soliris in various markets worldwide, level of coverage and reimbursement for Soliris, pricing, level of future Soliris sales and collections, plans for acquired companies and programs, timing regarding development and regulatory approvals for additional product candidates and the medical and commercial potential of those product candidates, 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, prospects for regulatory approval, 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, the outcome of challenges and opposition proceedings to our intellectual property, and assertion or potential assertion by third parties that the manufacture, use or sale of Soliris infringes their intellectual property 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, declines in sovereign credit ratings or sovereign defaults in countries where we commercialize our products, delay of collection or reduction in reimbursement due to adverse economic conditions, the short and long term effects of government healthcare measures, and the effect of shifting foreign 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. is a biopharmaceutical company engaged in the discovery, development and commercialization of innovative therapeutic products aimed at treating patients with severe and life-threatening disease states, including those in the therapeutic areas of hematology, nephrology including transplant rejection, neurology, ophthalmology and cancer. Our marketed product Soliris® (eculizumab) is the first and only therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH), an ultra-rare and life-threatening blood disorder. We were incorporated in 1992 and began commercial sale of Soliris in 2007.

## **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 disorders in the therapeutic areas of hematology, nephrology including transplant rejection, neurology and ophthalmology. Soliris is a humanized monoclonal 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 an ultra-rare, debilitating and life-threatening, acquired genetic deficiency blood disorder defined by uncontrolled complement activation leading to 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).

Soliris was approved by the U.S. Food and Drug Administration (FDA) and the European Commission (E.C.) in 2007, by Japan's Ministry of Health, Labour and Welfare (MHLW) in 2010, and has been approved in several other territories. Additionally, Soliris was granted orphan drug designation for the treatment of PNH in the United States, Europe, Japan and several other territories.

In 2009, the FDA and E.C. granted Soliris orphan drug designation for the treatment of patients with atypical Hemolytic Uremic Syndrome (aHUS), an ultra-rare, inherited and life-threatening complement-inhibitor deficiency disease that often progresses to end-stage kidney disease, kidney failure or death.

### ***Recent Developments***

On January 28, 2011, Alexion acquired Taligen Therapeutics, Inc. (Taligen), a privately held development-stage biotechnology company based in Cambridge, Massachusetts, in a transaction accounted for as a business combination. The acquisition was intended to broaden Alexion's portfolio of pre-clinical compounds and to expand Alexion's capabilities in translational medicine. Taligen's pre-clinical compounds include product candidates for the potential treatment of patients with ophthalmic diseases such as age-related macular degeneration (AMD), as well as other novel antibody and protein regulators of the complement inflammatory pathways. Alexion made an upfront cash payment of \$111,000 for 100 percent of Taligen's equity interests. Additional contingent payments would be earned upon reaching various clinical efficacy and product approval milestones in both the U.S. and European Union for up to six product candidates. If all such clinical efficacy and product approval milestones were achieved in both the U.S. and European Union for six product candidates, the total payments would be \$367,000.

On February 10, 2011, Alexion acquired patents and assets from Germany-based Orphatec Pharmaceuticals GmbH (Orphatec) related to an investigational therapy for patients with Type A molybdenum cofactor deficiency (MoCD), an ultra-rare disorder characterized by severe brain damage and rapid death in newborn infants. The acquisition will be accounted for as a business combination. Orphatec is a privately held development-stage biotechnology company with headquarters in Cologne, Germany. Alexion made an upfront cash payment of approximately \$3,000. Additional contingent payments of up to \$42,000 would be earned upon reaching various development, regulatory and commercial milestones. Alexion also established a research collaboration with key MoCD researchers from Orphatec to accelerate development of the investigational therapy.

On January 26, 2011, Novartis Vaccines & Diagnostics, Inc. (Novartis) filed a civil action against Alexion Pharmaceuticals, Inc. and other biopharmaceutical companies in the U.S. District Court for the District of Delaware. Novartis claims willful infringement by Alexion of U.S. Patent No. 5,688,688. Novartis seeks, among other things, monetary damages.

### ***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

**Table of Contents**

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 certain 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.

We have focused certain of 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 terminal complement inhibitor (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 several other territories, we believe that C5 Inhibitors may be useful in the treatment of a variety of other serious diseases and conditions resulting from uncontrolled complement activation.

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

<b>Product</b>	<b>Development Area</b>	<b>Indication</b>	<b>Development Stage</b>	
Soliris	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Commercial	
		PNH Registry	Phase IV	
		Cold Agglutinin Disease (CAD)*	Phase II	
	Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)	Phase II	
		Presensitized Renal Transplant*	Phase II	
		Kidney Transplant for Catastrophic Antiphospholipid Syndrome (CAPS)*	Phase II	
		ABO Incompatible Renal Transplant*	Phase II	
		MPGN II (Dense Deposit Disease or DDD)*	Phase II	
		Neurology	Myasthenia Gravis (MG)	Phase II
		Neuromyelitis Optica (NMO)*	Phase II	
Ophthalmology	Dry Age-Related Macular Degeneration (AMD)*	Phase II		
Samalizumab	Oncology	Chronic Lymphocytic Leukemia (CLL)	Phase I	
		Multiple Myeloma	Phase I	

\* Investigator Initiated Trial

## **Table of Contents**

### ***Soliris***

Soliris is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation associated with chronic disorders in the therapeutic areas of hematology, nephrology including transplant rejection, neurology and ophthalmology. 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.

Soliris was approved by the FDA and the E.C. in 2007, by Japan's MHLW in 2010 and has been approved in several other territories. Additionally, Soliris was granted orphan drug designation for the treatment of PNH in the United States, Europe, Japan and several other territories.

In 2009, the FDA and E.C. granted Soliris orphan drug designation for the treatment of patients with aHUS an ultra-rare, inherited and life-threatening complement-inhibitor deficiency disease that often progresses to end-stage kidney disease, kidney failure or death.

Orphan drug designation generally entitles us to exclusivity for certain periods of time, subject to limited circumstances. 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 restrict the approval of such competitive product.

### ***About Paroxysmal Nocturnal Hemoglobinuria (PNH)***

PNH is an ultra-rare, debilitating and life-threatening blood disorder in which an acquired genetic deficiency causes uncontrolled complement activation which leads to life-threatening complications. 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. Approximately one-half of the patients with PNH die from the disease within 10 to 15 years of diagnosis. Soliris is the only therapy approved for the treatment of patients with PNH.

### ***Eculizumab Development Programs***

We believe that eculizumab may be useful in treating other complement-mediated diseases and conditions of uncontrolled complement activation. Our ongoing eculizumab development programs include:

#### **Hematology**

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

Cold Agglutinin Disease (CAD) is a severe, ultra-rare complement-mediated autoimmune disease characterized by the presence of high concentrations of circulating complement-activating antibodies directed against red blood cells. As observed with PNH patients, CAD patients also suffer from the clinical consequences of severe hemolysis.

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

## **Table of Contents**

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.

We are aware of an independent investigator who has begun evaluating eculizumab for the treatment of patients with cold agglutinin disease.

## **Nephrology**

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

In patients with aHUS, deficiency of naturally occurring complement inhibitors causes uncontrolled complement activation which leads to thrombotic microangiopathy (TMA), the formation of blood clots in small blood vessels throughout the body causing a reduction in platelet count (thrombocytopenia) and life-threatening damage to the kidney, brain, heart and other vital organs. The prognosis for patients with aHUS is generally 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.

Approximately 50% of patients with aHUS have been identified to have genetic mutations in at least 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 April 2010, we completed enrollment of two (each with adolescent and adult patients) multi-national, multi-center clinical trials evaluating eculizumab for the treatment of adolescent and adult aHUS patients with evidence of thrombotic microangiopathy (clotting in small blood vessels). Approximately 37 patients are included in these studies. The studies include patients who had received plasma therapy (PT) chronically and others who were resistant or intolerant to PT. In October 2010, scientific abstracts were published of interim results from these two trials which indicated that the primary and key secondary endpoints were positive. Updated interim results from the chronic PT trial and final results from the PT-resistant trial were presented at the 2010 American Society of Nephrology scientific meeting and demonstrated that the primary endpoints and key secondary endpoints were achieved in each trial with a high degree of statistical significance. We have commenced a new Phase II, open-label trial in adult aHUS patients and, separately, we have also commenced a pediatric aHUS study.

### **Acute Humoral Rejection (AHR) in Presensitized Kidney Transplant Patients**

Patients undergoing solid organ transplantation may experience severe acute humoral rejection (AHR) 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.

AHR results when antibodies in the transplant recipient vigorously attacks the blood vessels of the donor kidney. During severe AHR, 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 AHR inhibits complement activation, tissue damage and transplant rejection.



## **Table of Contents**

We are aware that independent investigators are continuing to enroll patients in clinical trials to evaluate eculizumab in presensitized renal transplant patients at elevated risk for AHR as well as transplant patients with catastrophic antiphospholipid syndrome. We are also aware that an independent investigator has begun enrolling patients in a clinical trial to evaluate eculizumab in kidney transplant patients sensitized to their donor kidney due to an ABO blood group mismatch between donor and recipient. We are developing protocols to initiate multi-national, multi-site controlled clinical trials of eculizumab in presensitized renal transplant patients at elevated risk for acute humoral rejection and are further considering expansion of development efforts to include investigation of eculizumab as a treatment for patients undergoing transplantation of other organs.

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

Dense deposit disease (DDD) also called Type II membrano-proliferative 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 (excess protein in the urine), 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 studies to evaluate eculizumab in patients with DDD as well as patients with a similar disease referred to as C3nef-mediated nephropathy.

## **Neurology**

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

Myasthenia gravis (MG) is a rare autoimmune syndrome characterized by complement activation 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 eyelids, 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.

The FDA authorized our Investigational New Drug Application (IND) for studying the safety and efficacy of eculizumab in treating patients with MG, and enrolment has closed with 14 patients.

### **Neuromyelitis Optica (NMO)**

Neuromyelitis optica (NMO) is a rare autoimmune disease of the central nervous system (CNS) that affects the optic nerves and spinal cord. Individuals with NMO develop optic neuritis, which causes pain in the eye and vision loss, and transverse myelitis, which causes weakness, numbness, and sometimes paralysis of the arms and legs, along with sensory disturbances and loss of bladder and bowel control. In the past, NMO was considered to be a severe variant of multiple sclerosis (MS) because both can cause attacks of optic neuritis and myelitis. The recent discovery of an antibody in the blood of individuals with NMO gives doctors a reliable biomarker to distinguish NMO from MS.

We are aware that independent investigators are examining the role of eculizumab for the treatment of patients with NMO.

## **Ophthalmology**

### **Dry Age-Related Macular Degeneration (AMD)**

Age-related macular degeneration is a medical condition usually affecting older adults in which uncontrolled complement activation results in a loss of vision in the center of the visual field (the macula) and complement-mediated damage to the retina. It is a major cause of visual impairment in older adults.

## **Table of Contents**

We are aware of an independent investigator who continues to enroll patients in a study evaluating the safety and efficacy of eculizumab as a treatment for the dry form of age-related macular degeneration.

### ***Other Development Programs***

In addition to eculizumab programs, we also have development programs related to the following:

#### **Oncology**

The FDA authorized our IND to evaluate the activity of samalizumab, an antibody to the immune regulator CD200, in patients with chronic lymphocytic leukemia (CLL). CLL is a type of cancer of the blood and bone marrow. CLL most commonly affects older adults, though it may occur at any age and rarely can affect children.

Multiple myeloma, also known as plasma cell myeloma, is the second-most common cancer of the blood. It is the most common type of plasma cell neoplasm. Multiple myeloma accounts for approximately 1% of all cancers and 2% of all deaths from cancer.

Enrollment and dosing has now been completed in our Phase I dose-escalation clinical study of samalizumab, our anti-CD200 antibody, in patients with treatment refractory CLL or multiple myeloma. The trial enrolled 26 patients and positive interim results from this trial were reported at the 2010 American Society for Hematology meeting in Orlando, Florida.

#### **Manufacturing**

We currently rely on two facilities, our own facility in Rhode Island and a third party manufacturer, for commercial and clinical quantities of Soliris, as well as for clinical and preclinical quantities of eculizumab, samalizumab and other product candidates. 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 December 2009 and August 2010, the E.C. and FDA, respectively, approved our Rhode Island manufacturing facility for the production of Soliris.

Our most significant agreement with a third party manufacturer is the large-scale product supply agreement with Lonza Sales AG (Lonza), dated December 18, 2002, which has been amended from time to time. This agreement (Lonza Agreement) relates to the manufacture of eculizumab. An amendment to the Lonza Agreement provided for additional production and minimum quantity purchase commitments of Soliris from 2009 through 2017. This amendment has remaining commitments of approximately \$39,000 as of December 31, 2010. Such commitments may be cancelled only in limited circumstances. If we terminate the Lonza Agreement without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we pay Lonza a royalty on sales of Soliris manufactured at our Rhode Island facility.

#### **Sales and Marketing**

We have established an organization to support current and future sales of Soliris in the United States, in the major markets in Europe, Latin America and in Japan and the Asia Pacific region. Our sales force is small compared to other drugs with similar gross revenues; however, we believe that a relatively smaller sales force is appropriate to effectively market Soliris due to the limited PNH patient population. If we receive regulatory approval in new territories, 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 each jurisdiction 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 which supply physician office clinics, hospital outpatient clinics, infusion clinics or home health care providers. 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 2010 and 2009, sales to our single largest customer, AmerisourceBergen, accounted for 21% and 20%, respectively, of our Soliris net product sales, and no other customer individually accounted for more than 10% of total net product sales.

Because of factors such as 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. To date, actual refunds and returns have been negligible.

Please also see Management's Discussion and Analysis - Revenues, and Note 16 of the Consolidated Financial Statements included in this Form 10-K, 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, 2010, we own or in-license over 62 U.S. patents and 35 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. As of December 31, 2010, we own or in-license 47 foreign patents and 147 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 previous or future commercial manufacture and sale of Soliris and our product candidates.

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

---

## **Table of Contents**

We are aware of broad patents owned by others relating to the manufacture, use and sale of recombinant humanized antibodies, recombinant human antibodies, and recombinant human single chain antibodies. Soliris and some 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. For example, in January 2011, Novartis filed a civil action in the U.S. District Court for the District of Delaware alleging that the manufacture of Soliris infringes their U.S. patent number 5,688,688. 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 product 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.

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. 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.

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, we entered into a license agreement with the Medical Research Council (MRC) whereby MRC granted to us 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 we file for bankruptcy or become insolvent, or if we fail to perform our obligations under the agreement and such failure is not remedied within three months after delivery of notice. Under the agreement, we 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.

## **Table of Contents**

In December 2008, we entered into a patent license agreement with PDL BioPharma (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 paid \$25,000 for a 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. Under an existing arrangement with Lonza, we pay Lonza a royalty on sales of Soliris manufactured at our Rhode Island facility.

## **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 (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 of an indication in the U.S. generally include:

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

## **Table of Contents**

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, pharmaco-dynamics and pharmaco-kinetics.

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 for a proposed indication. 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 establishments and for approved products, can be substantial. The BLA review fee alone can exceed \$500,000, subject to certain limited deferrals, waivers and reductions that may be available. Each BLA submitted to 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 at the time of submission. The FDA's established goal is to review 90% of Priority BLA applications in six months and 90% of Standard applications in 10 months, 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 (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.

As part of the newly enacted Patient Protection and Affordable Care Act of 2010 (PPACA), Public Law No. 111-148, under the subtitle of Biologics Price Competition and Innovation Act of 2009 (BPCI), a statutory pathway has been created for licensure, or approval, of biological products that are biosimilar to, and possibly interchangeable with, earlier biological products licensed under the Public Health Service Act. Also under the BPCI, innovator manufacturers of original reference biological products are granted 12 years of exclusive use before biosimilars can be approved for marketing in the United States. The objectives of the BPCI are conceptually similar to those of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly

## **Table of Contents**

referred to as the Hatch-Waxman Act, which established abbreviated pathways for the approval of drug products. The implementation of an abbreviated approval pathway for biological products is under the direction of the FDA and is currently being developed. In late 2010, the FDA held a hearing to receive comments from a broad group of stakeholders regarding the implementation of the BCPI. The approval of a biologic product biosimilar to one of our products could have a material impact on our business and may be significantly less costly to bring to market and may be priced significantly lower than our products.

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, on an ongoing basis, 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.

## **Orphan Drug Designation**

Soliris has received orphan drug designation from the FDA for the treatment of PNH and aHUS. 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 or supplemental 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 an orphan exclusivity period, in which the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances.

Soliris has also received orphan drug designation for the treatment of PNH in several other territories, including Europe, Australia and South Korea, which provides certain regulatory and filing fee advantages, including market exclusivity, except in limited circumstances, for several years after approval. In 2009, the FDA and E.C. also granted Soliris orphan drug designation for the treatment of patients with aHUS.

## **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 (EMA) using the centralized procedure.

## **Table of Contents**

### **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 payors. 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.

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. On a continuous basis, we engage with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country.

### **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.

Several companies have either publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system or have had programs to develop complement inhibitor therapies. We believe that our potential C5 Inhibitors differ substantially from those of our potential competitors due to our compounds' demonstrated ability to specifically intervene in the complement cascade, for potentially prolonged periods of time. We believe this action to be the optimal point so that the disease-causing actions of complement proteins are inhibited, while the normal disease-preventing functions of complement proteins and other aspects of immune function remain intact.





**Table of Contents****Employees**

As of December 31, 2010, we had 792 full-time, world-wide employees, of which 331 were engaged in research, product development, manufacturing, and clinical development, 305 in sales and marketing, and 156 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.

**EXECUTIVE OFFICERS OF THE COMPANY**

The executive officers of the Company and their respective ages and positions as of February 11, 2011 are as follows:

Name	Age	Position with Alexion
Leonard Bell, M.D.	52	Chief Executive Officer, Secretary, Treasurer, Director
Stephen P. Squinto, Ph.D.	54	Executive Vice President and Head of Research and Development
Patrice Coissac	62	Senior Vice President, and President of Alexion Pharma International, Sàrl
Thomas I.H. Dubin, J.D.	48	Senior Vice President and Chief Legal Officer
David L. Hallal	44	Senior Vice President, Global Commercial Operations
Vikas Sinha, M.B.A., C.A., C.P.A.	47	Senior Vice President and Chief Financial Officer

**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 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** has been Corporate Senior Vice President and President of Alexion Pharma International Sàrl since April 2009. He previously served as Senior Vice President and President of Alexion Europe SAS from November 2005 to March 2009. Before joining Alexion, Mr. Coissac founded and ran his own consulting firm

## **Table of Contents**

from 2004-2005. Prior to this time, Mr. Coissac served as President of Pharmacia SAS France and was responsible during his tenure for the integration of Searle (pharma division of Monsanto) with Pharmacia & Upjohn in France. Before 1999 Mr. Coissac held several senior managerial positions at leading pharmaceutical companies as Head of Commercial Operations at Novartis Belgium and President of Boehringer Mannheim Therapeutics France. In 1994 Mr. Coissac also served as Marketing Senior Vice President for global pharmaceutical operations at Corange International. Previously at Sandoz Pharmaceuticals, he held various global marketing positions in several countries including Japan where he was posted during several years, Switzerland at Sandoz World Headquarters and France at the beginning of his career.

**Thomas I.H. Dubin, J.D.** has been Senior Vice President and Chief Legal Officer since January 2010. He was Senior Vice President and General Counsel from August 2005 to December 2009 and 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, Global Commercial Operations since May 2010. From November 2008 to May 2010, he was Senior Vice President, Commercial Operations Americas, and from June 2006 until November 2008 he served as Senior Vice President, US Commercial Operations. Before joining Alexion, Mr. Hallal served as Vice President, Sales at OSI Eyetech from April 2004 until June 2006, where he led the U.S. launch of a first-in-class anti-VEGF therapy for age-related macular degeneration. Prior to OSI Eyetech, from 1992 until 2004, Mr. Hallal held various sales and marketing leadership positions at Amgen and Biogen Idec, where he was involved in multiple product launches in the areas of hematology, oncology, nephrology and immunology. Mr. Hallal received a Bachelor of Arts degree from the University of New Hampshire.

**Vikas Sinha, M.B.A., C.A, CPA.** 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 and a CPA in the United States.

## **Available Information**

Our internet website address is <http://www.alexionpharma.com>. Through our website, we make available, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, any amendments to those reports, proxy and registration statements, and all of our insider Section 16 reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. These SEC reports can be accessed through the Investors section of our website. The information found on our website is not part of this or any other report we file with, or furnish to, the SEC. Paper copies of our SEC reports are available free of charge upon request in writing to Investor Relations, Alexion Pharmaceuticals, Inc., 352 Knotter Drive, Cheshire, CT 06410.

---

**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. If we are unable to increase sales of Soliris or obtain approval or commercialize Soliris in new territories for the treatment of PNH or for additional indications, or if we are significantly delayed or limited in doing so, our business may 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 payors view Soliris as therapeutically effective and safe 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.

We dedicate significant resources to the worldwide expansion of the commercialization of Soliris for the treatment of PNH. We have established sales and marketing capabilities, and are commercializing Soliris in many countries throughout the world. In certain countries, including Canada and certain countries in the European Union, we continue discussions with authorities to finalize operational, reimbursement, price approval and funding processes so that we may, upon conclusion of such discussions, commence commercial sales in those countries. We have submitted applications for marketing authorization of Soliris for the treatment of PNH in additional territories. We cannot guarantee that any such marketing application will be approved in all countries where we seek authorization to sell Soliris for the treatment of PNH, or even if approved, that we will be able to obtain reimbursement for Soliris or that we will be able to successfully commercialize Soliris in any additional countries. As a result, sales in certain countries may be delayed or never occur, or may be subsequently reduced.

In November 2010 we announced that two Phase II clinical studies investigating Soliris as a treatment for patients with aHUS who are resistant to plasma therapy met primary and key secondary endpoints. We cannot guarantee that the data from such studies will be sufficient to proceed with the filing of a BLA for Soliris for the treatment of aHUS. The FDA and other regulatory agencies may have varying interpretations of our clinical trial data, which could delay, limit, or prevent regulatory approval or clearance. Even if the FDA and foreign regulatory authorities do grant marketing approval of Soliris for the treatment of aHUS, they may impose restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. A narrowed indication or other restrictions may limit the market potential for Soliris for the treatment of aHUS.

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

receipt of marketing approvals for Soliris for the treatment of PNH in new territories and the maintenance of marketing approvals for the treatment of PNH in the United States, the European Union, Japan and other territories;

receipt and maintenance of marketing approvals for Soliris for the treatment of aHUS from United States and foreign regulatory authorities,

the number of patients with PNH and, if approved for the treatment of aHUS, aHUS, who are diagnosed with the disease and identified to us;

## Table of Contents

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

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

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

acceptance of Soliris in the medical community;

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

our ability to develop, register and commercialize Soliris for indications other than PNH, including aHUS.

If we are not successful in increasing sales of Soliris in the United States, Europe and Japan and commercializing in the rest of the world, or are significantly delayed or limited in doing so, we may experience a surplus inventory, our business may be materially harmed and we may need to significantly curtail operations.

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

Soliris has been approved for the treatment of PNH and we are advancing our efforts to seek marketing approval of Soliris for the treatment of aHUS. PNH and aHUS are each ultra-rare diseases with small patient populations that have not been definitively determined. There can be no guarantee that any of our programs will be effective at identifying patients and the number of patients in the United States, Europe and elsewhere 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, or maintain at anticipated levels, reimbursement for Soliris from government health administration authorities, private health insurers and other organizations, our pricing may be affected or our product sales, results of operations or financial condition could 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 payors and other third-party payors, 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, determine to provide a lower level of coverage and reimbursement than anticipated, or reduce previously approved levels of coverage and reimbursement, including in the form of higher mandatory rebates, then our pricing or reimbursement for Soliris may be affected and our product sales, results of operations or financial condition could be harmed.

In certain countries where we are seeking or may seek to commercialize Soliris, 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

## Table of Contents

country may include a combination of distinct potential payors, including private insurance and governmental payors. For example, countries in the European Union may 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 from time to time 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 are not able to obtain coverage, pricing or reimbursement on terms acceptable to us or at all, or if such terms should change in any foreign countries, we may not be able to or we may determine not to sell Soliris in such countries, or we could decide to sell Soliris at a lower than anticipated price in such countries, and our revenues may be adversely affected as a result.

Changes in pricing or the amount of reimbursement in countries where we currently commercialize Soliris may also reduce our profitability and worsen our financial condition. In the United States, European countries, and elsewhere, there have been, and we expect there will continue to be, efforts to control and reduce healthcare costs. Government and other third-party payors are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs. For example, during 2010 the German government adopted legislation to increase mandatory discounts on pharmaceutical products and impose a temporary freeze on pharmaceutical pricing, including Soliris. A significant reduction in the amount of reimbursement or pricing for Soliris in one or more countries may have a material adverse effect on our business. See additional discussion below under the headings Government initiatives that affect coverage and reimbursement of drug products could adversely affect our business and The credit and financial market conditions may aggravate certain risks affecting our business. In addition, certain countries establish pricing and reimbursement amounts by reference to the price of the same or similar products in other countries. If coverage or the level of reimbursement is limited in one or more countries, we may be unable to obtain or maintain anticipated pricing or reimbursement in current or new territories.

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

Even in countries where patients have access to insurance, their insurance co-payment amounts or annual or lifetime caps on reimbursements may represent a barrier to obtaining or continuing Soliris. In the United States, we have financially supported non-profit organizations, such as the PNH Fund of the National Organization for Rare Disorders (NORD) which assist patients in accessing treatment for PNH, including Soliris. Such organizations assist patients whose insurance coverage leaves them with prohibitive co-payment amounts or other expensive financial obligations. NORD's, and other similar organizations', ability to provide 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 to patients who have no insurance coverage for drugs for related charitable purposes in the United States and elsewhere. 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 profitability in the future.

We are also focusing development efforts on the use of eculizumab for the treatment of diseases other than PNH, including for the treatment of aHUS. The success of these programs depends on many factors, including those described under the heading Risks Related to Development, Clinical Testing and Regulatory Approval of our Product Candidates, including Eculizumab for Indications Other than PNH. If eculizumab is approved by regulatory agencies for indications other than PNH, the potential increase in the number of patients receiving Soliris may cause third party payers to refuse coverage or reimbursement for Soliris for the treatment of PNH or provide a lower level of coverage or reimbursement than is currently in effect.

---

**Table of Contents**

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

We cannot be certain that Soliris will gain or maintain market acceptance in a particular country among physicians, patients, healthcare payors, and others. Although we have received regulatory approval for Soliris in certain territories, including the United States, Japan and Europe, such approvals do not guarantee future revenue. We cannot predict whether physicians, other healthcare providers, government agencies or private insurers will determine or continue to accept that Soliris is safe and therapeutically effective relative to its cost. Medical doctors' willingness to prescribe, and patients' willingness to accept, Soliris depends 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 Soliris, publicity concerning Soliris, our other product candidates or competing products, our ability to obtain and maintain third-party coverage or reimbursement, and availability of alternative treatments, including bone marrow transplant as an alternative treatment for PNH. If Soliris fails to achieve or maintain market acceptance among the medical community or patients in a particular country, we may not be able to market and sell it successfully in such country, which would limit our ability to generate revenue and could harm our overall business.

***If we or our contract manufacturers fail to comply with continuing United States and foreign regulations, we could lose our approvals to market Soliris or our manufacturers could lose their approvals to manufacture 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 current and 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 territories. These regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, risk mitigation, adverse event reporting requirements, and export of biologics. For example, the risk management program established in 2007 upon the FDA's approval of Soliris for the treatment of PNH was replaced with a Risk Evaluation and Mitigation Strategy Program (REMS) program, approved by the FDA in 2010. The REMS program requires mandatory physician certification in the United States. Each physician must certify that the physician is aware of the potential risks associated with the administration of Soliris and that the physician will inform each patient of these risks using educational material approved by the FDA.

As a condition of approval for marketing Soliris, governmental authorities may require us to conduct additional studies. For example, in connection with the approval of Soliris in the United States, European Union and Japan, we agreed to establish a PNH Registry, monitor immunogenicity, monitor compliance with vaccination requirements, and determine the effects of anticoagulant withdrawal among PNH patients receiving eculizumab, and, specifically in Japan, we agreed to conduct a trial in a limited number of Japanese PNH patients to evaluate the safety of a meningococcal vaccine. In the United States, for example, the FDA can propose to withdraw approval for a product if it determines that such additional studies are inadequate or if new clinical data or information shows that a product is not safe for use in an approved indication. We are required to report any serious and unexpected adverse experiences and certain quality problems with Soliris to the FDA, the European Medicines Agency (EMA), Japan's Ministry of Health, Labour and Welfare (MHLW), and certain other health agencies. We, the FDA, the EMA, the MHLW or another health agency may have to notify healthcare providers of any such developments. The discovery of any previously unknown problems with Soliris, a manufacturer or a facility may result in restrictions on Soliris, a manufacturer or a 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. We and any third party we would use to manufacture Soliris for sale, including Lonza, must also be licensed by applicable regulatory authorities.

## Table of Contents

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

administrative and judicial sanctions, including, warning letters;

finest and other civil penalties;

withdrawal of a previously granted approval for Soliris;

interruption of production;

operating restrictions;

delays in approving or refusal to approve Soliris or a facility that manufactures Soliris;

product recall or seizure;

injunctions; and

criminal prosecution.

***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 tested Soliris in only a small number of patients. As more patients begin to use Soliris, new risks and side effects may be discovered, the rate of known risks or side effects may increase, and risks previously viewed as less significant 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 applicable 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 are studying and expect to continue to study Soliris in diseases other than PNH in controlled clinical settings, and independent investigators are doing so 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



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

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.

## **Table of Contents**

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 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 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 Meningococcal infection. Serious cases of Meningococcal infection can result in severe illness, including but not limited to brain damage, loss of limbs or parts of limbs, kidney failure, or death. Patients in our eculizumab trials all receive vaccination against Meningococcal infection prior to first administration of Soliris and patients who are prescribed Soliris in most countries are required by prescribing guidelines to be vaccinated prior to receiving their first dose; however, vaccination does not eliminate all risk of Meningococcal infection. Some patients treated with Soliris who had been vaccinated have experienced Meningococcal infection, 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 to market and sell Soliris for PNH in the United States, the European Union, Japan and other territories, we cannot guarantee that we will obtain the regulatory approval or reimbursement approval for Soliris for the treatment of PNH or other diseases in each territory where we seek approvals.***

Governments in countries where we seek to commercialize Soliris regulate the distribution of drugs and the facilities where such drugs are manufactured, and obtaining their approvals can 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, even in countries where marketing approval has been obtained. 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 the United States, the European Union, Japan and other territories. We may not receive regulatory approval for Soliris in any other territories 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. 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 in certain countries, the regulatory agencies in other countries 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 prior to obtaining marketing approval in that country.

***Our commercialization of Soliris may be stopped, delayed or made less profitable if we or any other supply vendor fails to provide sufficient quantities of Soliris. Commercial quantities of Soliris can only be manufactured at two facilities, including our own facility in Rhode Island. We are currently entirely dependent on a single third party to manufacture commercial quantities of Soliris for sale in Japan.***

Commercial quantities of Soliris are manufactured by us at our Rhode Island manufacturing facility and by Lonza Sales AG (Lonza). Manufacturing processes must comply with applicable regulations and manufacturing practices, as well as our own quality standards. In particular, the manufacture of Soliris is heavily regulated by governmental authorities around the world, including the FDA, EMA and MHLW. If we or our third-party suppliers fail to comply fully with such regulations then there could be a government-enforced shutdown of production facilities or production lines, which in turn could lead to product shortages.

The manufacture of Soliris is difficult. Manufacture of a biologic requires a multi-step controlled process and even minor problems or deviations could result in defects or failures. We cannot be certain that we or Lonza will be able to perform uninterrupted supply chain services. The failure to manufacture appropriate supplies of Soliris, on a timely basis, or at all, may prevent or interrupt the commercialization of Soliris. If we or Lonza were unable to manufacture Soliris for any period, or if we do not obtain approval of our facility by the applicable regulatory agencies, 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 and experience significant delay in establishing a new arrangement.

Until December 2009, only Lonza was capable of manufacturing commercial quantities of Soliris. The E.C. and the FDA approved the use of our Rhode Island manufacturing facility for the production of Soliris in December 2009 and August 2010, respectively. We are authorized to sell product that is manufactured in our facility in the United States, the European Union and certain other territories. However, we will not be capable of manufacturing Soliris at our own facility in Rhode Island for commercial sale in Japan or other territories until such time as we have received the required regulatory approval for our facility, if ever. We will continue to depend entirely on one company, Lonza, to manufacture Soliris for commercial sale in Japan and such other territories until that time.

We also depend on a limited number of outside vendors for other services with respect to our clinical and commercial requirements, including product finishing, packaging, vialing and labeling. We do not have control over any third-party manufacturer's, vialer's or other third party provider's compliance with the rules and regulations of the FDA, EMA, MHLW or any other applicable regulations or standards. Any difficulties or delays in our third party manufacturing and supply of Soliris and other product candidates, or any failure of our third party providers to maintain compliance with the applicable regulations and standards could increase our costs, constrain our ability to satisfy demand for Soliris from customers, cause us to lose revenue or incur penalties for failure to deliver product, make us postpone or cancel clinical trials, or cause our products to be recalled or withdrawn.

---

**Table of Contents**

***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 specialty pharmacies and specialty 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 twelve months ended December 31, 2010, our single largest customer, AmerisourceBergen, accounted for 21% of our Soliris net product sales, and our three largest customers accounted for approximately 36.2% of our net product sales. As of December 31, 2010, our single largest customer, AmerisourceBergen, accounted for 17.8% 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 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 for the treatment of PNH ourselves in the United States, Europe, Japan and several other territories. We have established commercial capabilities in the United States, Europe and Japan. If we are unable to establish and/or expand our capabilities to sell, market and distribute Soliris for the treatment of PNH or, if approved by the necessary regulatory agencies, other future indications, 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 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

## **Table of Contents**

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 or penalty 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 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 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 payor. 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, 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. Additionally, as part of the Patient Protection and Affordable Care Act, the federal government has enacted the Physician Payment Sunshine provisions. Beginning in 2013, the Sunshine provisions require manufacturers to publicly report gifts and payments made to physicians and teaching hospitals. 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.

---

**Table of Contents**

**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, including 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 approved for any indication other than for the treatment of patients with PNH, and we do not know when or if Soliris will be approved in other indications. 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 further studies or trials are initiated what the scope and phase of the trial will be or that they will be completed, or that if these further studies or trials are completed, that the design or results will provide a sufficient basis 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 design or 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 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.

In November 2010 we announced that two Phase II clinical studies investigating Soliris as a treatment for patients with aHUS who are resistant to plasma therapy met primary and key secondary endpoints. We cannot guarantee that the data from such studies will be sufficient to proceed with the filing of a BLA and regulatory agencies may have varying interpretations of the clinical trial data, which could delay, limit, or prevent regulatory approval or clearance.

**Table of Contents**

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

For human trials, patients must be recruited and each product candidate must be tested at various doses and formulations for each clinical indication. 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. Many of our programs focus on diseases with small patient populations and 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 due to unfavorable results or other reasons, 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.

During the first quarter of 2011, we acquired Taligen Therapeutics, Inc. and certain assets of Orphatec Pharmaceuticals GmbH. We are evaluating our clinical development strategies for the drug candidates acquired from Taligen and Orphatec, which may include additional preclinical testing and initiation of Phase 1 clinical trials.

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; and

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.*

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

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



---

**Table of Contents**

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:

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.

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

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; perceived lack of cost-effectiveness; lack of availability of reimbursement from third-party payors; 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 similar programs in other countries, and other third-party payors. 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 our drug candidates 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, countries in the European Union may 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. The reimbursement or budget identified by a government or non-government payor for Soliris in an indication other than PNH, if obtained, may be adversely affected by the reimbursement or budget for Soliris in PNH and/or adversely affect the reimbursement or budget for Soliris in PNH by that payor.

***Inability to contract with third-party manufacturers and other third parties on commercially reasonable terms, or failure or delay by us or our third-party manufacturers or other third party providers to provide services with respect to 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 samalizumab 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. Due to the highly technical requirements of manufacturing our drug products, we and our third-party collaborators may be unable to manufacture our drug products despite our and their efforts. In addition, 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. Further, we have no experience manufacturing the drug candidates that we acquired from Taligen and Orphatec. We cannot guarantee that we or any third party will be able to manufacture such drug candidates, or that we or a third party will be able to manufacture sufficient quantities to satisfy our requirements.

## **Table of Contents**

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 could have a material adverse effect on our business.

We currently have limited experience in manufacturing drug products in volumes that would be necessary to support commercial sales, and we can provide no assurance that we will be able to do so successfully. We acquired a commercial-scale manufacturing plant in Smithfield, Rhode Island in July 2006. The E.C. and the FDA have approved the use of our facility for the production of Soliris, and we are authorized to sell Soliris manufactured in our facility in the United States, the European Union and certain other territories. The plant is not currently approved by the MHLW or other regulatory agencies to manufacture Soliris and we will not be capable of manufacturing Soliris for commercial sale in Japan on our own until such time as we have received MHLW approval of our manufacturing facility, if ever. Until December 2009, we have depended on a single third party for commercial supply of Soliris, and we are still entirely dependent on this third party for commercial quantities of Soliris for sale in Japan. We have limited experience in developing commercial-scale manufacturing. We can provide no assurance that we will be able to manufacture our drug products at our Rhode Island plant under conditions required by the FDA or foreign regulatory agencies on a timely basis, if at all. Our plant in Rhode Island is subject to approval by other national and regional regulatory agencies before we can begin sales of Soliris or other drug products manufactured in this facility in the applicable countries or regions, and we will continue to be subject to ongoing regulatory inspections 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 may need to find other alternatives, which is likely to be expensive and time consuming, and also may result in reduced revenue during this period. 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 could 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 could 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 could harm our financial condition.

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

*If we cannot obtain new patents, maintain our existing patents and protect the confidentiality and proprietary nature of our trade secrets and other intellectual property, our business and competitive position will be harmed.*

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 have and may in the future obtain patents or the right to practice patents through ownership or license. Our patent applications may not result in the issue of patents in the United States or other countries. Our patents may not afford adequate protection for our products. Third parties

---

**Table of Contents**

may challenge our patents. For example, a third party filed an opposition with the European Patent Office to our European Patent 0758904, which covers Soliris. The opposition argues that essential claims in our European Patent 0758904 should be narrowed or invalidated. If any of our patents are narrowed, invalidated or become unenforceable, including European Patent 0758904, competitors may develop and market products similar to ours that do not conflict with or infringe our patents rights, which could have a material adverse effect on our financial condition. We may also finance and collaborate in research conducted by government organizations, hospitals, universities or other educational or research institutions. Such research partners may be unwilling to grant us exclusive rights to technology or products developed through such collaborations. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties. Soliris and our drug candidates are expensive and time-consuming to test and develop. Even if we obtain and maintain patents, our business may be significantly harmed if the patents are not broad enough to protect our drugs from copycat products.

In addition, 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, or discuss the potential for collaboration with, suppliers, outside scientists and other drug companies. Collaboration and discussion of potential collaboration present 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.

***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. On January 26, 2011, Novartis Vaccines & Diagnostics, Inc. (Novartis) filed a civil action against us and other biopharmaceuticals companies claiming willful infringement by Alexion of its patent. If it is finally determined that we infringe the Novartis patent, we may be required to pay royalties to Novartis on sales of Soliris regarding certain manufacturing technology. Although we do not believe that the manufacture of Soliris infringes a valid patent claim owned by Novartis, we cannot guarantee that we will be successful in defending against such action. 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. In addition to Novartis, other 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 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 tested or are testing various modifications that we believe should not infringe the patents and which should permit commercialization of our product candidates.

---

## **Table of Contents**

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 or any terms at all; 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, use or sell approved forms of Soliris or our product candidates could have a material adverse effect on our business and prospects.

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

***We have had a history of losses and cannot guarantee that we will achieve our financial goals, including our ability 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 have maintained profitability on a quarterly basis since the quarter ended June 30, 2008 and on an annual basis for the years ended December 31, 2010, 2009 and 2008. We believe that we formulate our annual operating budgets with reasonable assumptions and targets, however we cannot guarantee that we will be able to generate sufficient revenues or control expenses to achieve our financial goals, including continued profitability. 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. We may make errors in predicting and reacting to relevant business trends or our business may be subject to factors beyond our control, which could harm our operations. Since we began our business, we have focused on research and development of product candidates. We launched Soliris for sale in the United States and Europe during 2007. We cannot guarantee that we will be successful in marketing and selling Soliris in countries or regions where we have obtained marketing approval, including the United States, Europe and Japan, on a continued basis, and we do not know when we will have Soliris available for sale in territories where we have applied or will apply for marketing approval, if ever. We will have substantial expenses as we continue our research and development efforts, integrate the programs we acquired from Taligen and Orphatec, continue to conduct clinical trials, and continue to develop manufacturing, sales, marketing and distribution capabilities in the United States and abroad. The achievement of our financial goals, including the extent of our future profitability, depends on many factors, including our ability to successfully market Soliris in the United States, Europe and Japan and other territories, our ability to obtain regulatory, pricing, coverage, and reimbursement approvals of Soliris in additional countries and regions, our ability to successfully market Soliris in additional countries and regions, and our ability to successfully manufacture and commercialize our drug candidates.

***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.***

The FDA, E.C. and the MHLW granted orphan drug designation for Soliris in the treatment of PNH, which entitles us to exclusivity for a total of seven years in the United States and for ten years in Europe and Japan. 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

## **Table of Contents**

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 us 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 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 and cash equivalents 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 the United States, Europe, Japan, and several other territories, evaluating and preparing regulatory submissions for Soliris in several 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;

the integration of the Taligen and Orphatec business; and

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

---

**Table of Contents**

We may not receive funding when we need it or funding may only be available on unfavorable terms. Financial markets in the United States, 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, Europe or Japan, grow our operations in any territory, or expand development programs for 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 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. In the first quarter of 2010, we acquired Taligen Therapeutics, Inc. and certain assets of Orphatec Pharmaceuticals GmbH and we may seek additional acquisitions or in-licensing of businesses or products to expand our product and capabilities. Acquisitions of new businesses or products, including the acquisitions of Taligen and Orphatec, and in-licensing of new products involve numerous risks, including:

substantial cash expenditures;

potentially dilutive issuance of equity securities;

---

**Table of Contents**

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

difficulties in assimilating the operations of the acquired companies;

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

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

the potential loss of our key employees or key employees of the acquired companies; and

failure of any acquired businesses or products or in-licensed products to achieve the scientific, medical, commercial or other results anticipated.

We have limited experience in the acquisition and integration of other companies. We cannot assure you that the recent acquisitions of Taligen and Orphatec, or any other 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, such as Taligen or Orphatec, or an acquired or in-licensed product. In addition, the future success of such transactions 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 Taligen or Orphatec, or any other acquired businesses or companies work or be successful.

We compete with pharmaceutical companies that have significantly greater resources than we for many of the same acquisition and in-licensing opportunities. Such pharmaceutical companies may be less leveraged and have better access to capital resources that may preclude us from completing any acquisition or in-licensing. For this and other reasons, 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, 2010, we have approximately \$579.3 million 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. We believe it is more likely than not that we will use the net operating losses. However, 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 \$3.8 million expired in the year ended December 31, 2007. No NOLs expired during the years ended December 31, 2010, 2009 and 2008.

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





## **Table of Contents**

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.

***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 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. 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. In addition, the United States government and other governments are considering and may adopt tax reform measures that significantly increase our worldwide tax liabilities and materially harm our business, financial condition and results of operations.

***Our 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 sales and operations to be limited or disrupted.***

Over the past few years, we have significantly expanded our 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;

political or economic determinations that adversely impact pricing or reimbursement policies;

economic problems or political instability that disrupt healthcare payment systems;

difficulties or inability to obtain financing in 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 recruiting and retaining qualified managers and employees to manage and operate the business in local jurisdictions;

costs and difficulties in managing and monitoring international operations; and

longer payment cycles.

Our business and marketing methods are also subject to regulation by the governments of the countries in which we operate. The United States Foreign Corrupt Practices Act (FCPA) and similar anti-bribery laws in other countries prohibit companies and their representatives from offering, promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business. We have policies and procedures designed to help ensure that we and our representatives, including our employees, comply with such laws, however we cannot guarantee that these policies and procedures will protect us against liability under the FCPA or other anti-

## **Table of Contents**

bribery laws for actions taken by our representatives. Failure to comply with the laws and regulations of the countries in which we operate could materially harm our business.

We conduct, or anticipate that we will conduct, a substantial portion of our business in currencies other than the U.S. dollar, primarily the Euro, Japanese Yen, Swiss Franc and British Pound. 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 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 payors, and also co-payments from individual patients in certain situations. As a result of the current credit and financial market conditions, and the overall financial climate, these governmental organizations and payors, and/or individuals, may reduce or delay initiation of treatment, 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. Payment defaults by a government payor could require us to expense previously recorded revenue as uncollectable, and might cause us to end or restrict sales to patients in that country. Further, the risk of payment default by a government payor could require us to revise our revenue recognition policies in regard to that payor, causing revenue to be recorded only on a cash basis, and we may be required to end or restrict sales to patients in that country.

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

### ***Government initiatives that affect coverage and reimbursement of drug products could adversely affect our business.***

In March 2010, the United States adopted the Affordable Care Act and governments in many foreign countries where we operate have adopted or have shown significant interest in pursuing legislative initiatives to reduce costs of healthcare. Any such government-adopted healthcare measures could adversely impact the pricing of Soliris or the amount of coverage and reimbursement available for Soliris from governmental agencies or other third-party payors. For example, the governments of Germany and Spain each approved increases to mandatory rebates on the sales of pharmaceutical products. The pricing and reimbursement environment for Soliris may become more challenging due to, among other reasons, changes in government policies or new legislation, or the impact of total Soliris reimbursement to any one payor. In many cases, these government initiatives, even if enacted into law, are subject to future rulemaking by regulatory agencies. Although we have evaluated these government initiatives and the impact on our business, we cannot know with certainty whether any such law, rule or regulation will adversely affect coverage and reimbursement of Soliris, or to what extent, until such laws, rules and regulations are promulgated, implemented and enforced. The announcement or adoption of regulatory or legislative proposals could delay or prevent our entry into new markets, affect our reimbursement or sales in the markets where we are already selling Soliris and materially harm our business, financial condition and results of operations.

---

**Table of Contents**

**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, 2008 and December 31, 2010, the closing sales price of our common stock fluctuated from a low of \$25.49 per share to a high of \$82.34 per share. While we cannot predict our future performance, if our stock price continues to fluctuate in a wide range, an investment in our common stock may result in considerable uncertainty for an investor.

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

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

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

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

**Table of Contents****Item 1B. UNRESOLVED STAFF COMMENTS.**

None.

**Item 2. PROPERTIES.**

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

Location	Operations Conducted	Approximate Square Feet	Lease Expiration Date
Cheshire, Connecticut	Executive, sales and research offices	205,554	2017
Smithfield, Rhode Island	Commercial and research manufacturing	56,500	N/A
Lausanne, Switzerland	Regional executive and sales office	26,500	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.

**Item 3. LEGAL PROCEEDINGS.**

As previously reported, on January 26, 2011, Novartis Vaccines & Diagnostics, Inc. (Novartis) filed a civil action against Alexion and other biopharmaceuticals companies in the U.S. District Court for the District of Delaware. Novartis claims willful infringement by Alexion of a Novartis patent and seeks, among other things, monetary damages.

**Item 4. RESERVED**

**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, 2009.

	High	Low
<b>Fiscal 2009</b>		
First Quarter		
(January 1, 2009 to March 31, 2009)	\$ 40.17	\$ 31.65
Second Quarter		
(April 1, 2009 to June 30, 2009)	\$ 41.11	\$ 32.59
Third Quarter		
(July 1, 2009 to September 30, 2009)	\$ 46.67	\$ 36.87
Fourth Quarter		
(October 1, 2009 to December 31, 2009)	\$ 48.82	\$ 43.11
<b>Fiscal 2010</b>		
First Quarter		
(January 1, 2010 to March 31, 2010)	\$ 55.39	\$ 45.50
Second Quarter		
(April 1, 2010 to June 30, 2010)	\$ 56.68	\$ 48.61
Third Quarter		
(July 1, 2010 to September 30, 2010)	\$ 64.98	\$ 49.64
Fourth Quarter		
(October 1, 2010 to December 31, 2010)	\$ 82.34	\$ 63.56

As of February 1, 2011, we had 463 stockholders of record of our common stock and an estimated 61,658 beneficial owners. The closing sale price of our common stock on February 1, 2011 was \$85.65 per share.

**DIVIDEND POLICY**

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

**EQUITY COMPENSATION PLAN INFORMATION (shares in thousands)**

Plan Category	Number of shares of common stock to be issued upon exercise of outstanding options (2)	Weighted- average exercise price of outstanding options	Weighted- average term to expiration of options outstanding	Number of shares of common stock remaining available for future issuance under equity compensation plans
Equity compensation plans approved by stockholders (1)	6,114	30.54	6.87	5,671
Equity compensation plans not approved by stockholders				

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

- (1) Reflects number of shares of common stock to be issued upon exercise of outstanding options under all our equity compensation plans, including our 2004 Incentive Plan. All 5,671 shares of common stock remaining available for future issuance are available under the 2004 Incentive Plan.
  - (2) Does not include 1,061 restricted shares outstanding that were issued under the 2004 Incentive Plan.
- 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 December 31, 2005 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.

**CUMULATIVE TOTAL RETURN**

	12/05	12/06	12/07	12/08	12/09	12/10
Alexion Pharmaceuticals, Inc.	100.00	199.46	370.52	357.43	482.17	795.56
NASDAQ Composite	100.00	111.74	124.67	73.77	107.12	125.93
NASDAQ Biotechnology	100.00	99.71	103.09	96.34	106.49	114.80

**Table of Contents**

Alexion Pharmaceuticals -NASNM  
C000030398

Begin: 12/31/2005  
Period End: 12/31/2010  
End: 12/31/2010

<b>Date*</b>	<b>Transaction Type</b>	<b>Closing Price**</b>	<b>Beginning No. Of Shares***</b>	<b>Dividend per Share</b>	<b>Dividend Paid</b>	<b>Shares Reinvested</b>	<b>Ending Shares</b>	<b>Cum. Tot. Return</b>
31-Dec-05	Begin	10.125	9.88				9.877	100.00
31-Dec-06	Year End	20.195	9.88				9.877	199.46
31-Dec-07	Year End	37.515	9.88				9.877	370.52
31-Dec-08	Year End	36.190	9.88				9.877	357.43
31-Dec-09	Year End	48.820	9.88				9.877	482.17
31-Dec-10	End	80.550	9.88				9.877	795.56

\* Specified ending dates or ex-dividends dates.

\*\* All Closing Prices and Dividends are adjusted for stock splits and stock dividends.

\*\*\* Begin Shares based on \$100 investment.

**Table of Contents****Item 6. SELECTED 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)

**Condensed Consolidated Statements of Operations:**

	Year Ended December 31,				
	2010	2009	2008	2007	2006
<b>Revenues:</b>					
Net product sales	\$ 540,957	\$ 386,800	\$ 259,004	\$ 66,381	\$
Contract research revenue			95	5,660	1,558
<b>Total revenues</b>	<b>540,957</b>	<b>386,800</b>	<b>259,099</b>	<b>72,041</b>	<b>1,558</b>
Cost of sales	64,437	45,059	28,366	6,696	
<b>Operating expenses:</b>					
Research and development	98,394	81,915	62,581	68,961	83,225
Selling, general and administrative	227,488	172,767	133,543	96,142	55,418
<b>Total operating expenses</b>	<b>325,882</b>	<b>254,682</b>	<b>196,124</b>	<b>165,103</b>	<b>138,643</b>
Operating income (loss)	150,638	87,059	34,609	(99,758)	(137,085)
Other income (expense)	(1,627)	(3,745)	121	6,723	5,198
Income (loss) before income taxes	149,011	83,314	34,730	(93,035)	(131,887)
Income tax provision (benefit)	51,981	(211,852)	1,581	(745)	(373)
<b>Net income (loss)</b>	<b>\$ 97,030</b>	<b>\$ 295,166</b>	<b>\$ 33,149</b>	<b>\$ (92,290)</b>	<b>\$ (131,514)</b>
<b>Earnings (loss) per common share</b>					
Basic	\$ 1.09	\$ 3.46	\$ 0.43	\$ (1.27)	\$ (2.07)
Diluted	\$ 1.04	\$ 3.26	\$ 0.39	\$ (1.27)	\$ (2.07)
<b>Shares used in computing earnings (loss) per common share</b>					
Basic	89,271	85,326	77,680	72,622	63,402
Diluted	93,037	90,582	89,967	72,622	63,402

**Condensed Consolidated Balance Sheet Data:**

	As of December 31,				
	2010	2009	2008	2007	2006
Cash, cash equivalents and marketable securities	\$ 361,605	\$ 176,220	\$ 139,711	\$ 106,712	\$ 250,148
Trade accounts receivable, net	168,732	113,731	74,476	46,278	
Inventories, net	62,165	40,885	49,821	32,907	2,314
<b>Total current assets</b>	<b>646,556</b>	<b>373,456</b>	<b>277,101</b>	<b>205,354</b>	<b>236,776</b>
Property, plant and equipment, net	162,240	164,691	139,885	104,280	39,135
<b>Total assets</b>	<b>1,012,037</b>	<b>786,401</b>	<b>477,551</b>	<b>334,357</b>	<b>333,537</b>
Notes payable			27,500		
Mortgage loan			44,000	44,000	26,000
Convertible notes	3,718	9,918	97,222	150,000	150,000
<b>Total stockholders' equity</b>	<b>859,736</b>	<b>688,356</b>	<b>247,001</b>	<b>101,556</b>	<b>124,677</b>



**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 commercialization of biologic therapeutic products aimed at treating patients with severe and life-threatening disease states, including those in the therapeutic areas of hematology, nephrology including transplant rejection, neurology, ophthalmology and cancer. Our marketed product Soliris® (eculizumab) is the first and only therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH), an ultra-rare and life-threatening blood disorder. We were incorporated in 1992 and began commercial sale of Soliris in 2007.

Soliris is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation associated with chronic disorders in the therapeutic areas of hematology, nephrology including transplant rejection, neurology and ophthalmology. Soliris is a humanized monoclonal 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 an ultra-rare, debilitating and life-threatening, acquired genetic deficiency blood disorder defined by uncontrolled complement activation leading to 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).

Soliris was approved by the U.S. Food and Drug Administration (FDA) and the European Commission (E.C.) in 2007, by Japan's Ministry of Health, Labour and Welfare (MHLW) in 2010 and has been approved in several other territories. Additionally, Soliris was granted orphan drug designation for the treatment of PNH in the United States, Europe, Japan and several other territories.

In 2009, the FDA and E.C. granted Soliris orphan drug designation for the treatment of patients with atypical Hemolytic Uremic Syndrome (aHUS), an ultra-rare, inherited and life-threatening complement-inhibitor deficiency disease that often progresses to end-stage kidney disease, kidney failure or death.

**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:

Revenue recognition

---

**Table of Contents**

Contingent liabilities

Inventories

Research and development expenses

Share-based compensation

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, 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 end customer, which is typically a hospital, physician's office, private or government pharmacy or other health care facility. Amounts collected from customers and remitted to governmental authorities, such as 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 which supply physician office clinics, hospital outpatient clinics, infusion clinics or home health care providers. 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.

In addition to sales in countries where Soliris is commercially available, we have also recorded revenue on sales for individual patients through named-patient programs. 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.

Because of factors such as 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. To date, actual refunds and returns have been negligible.

We record estimated rebates payable under governmental programs, including Medicaid in the United States and other programs outside the United States, as a reduction of revenue at the time of product sale. Our calculations related to these rebate accruals require an analysis of historical claim patterns and 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, which may have an impact on revenue in the period in which the adjustment is made. Generally, the length of time between product sale and the processing and reporting of the rebates is three to six months.

In March 2010, United States government healthcare legislation, which contains several provisions that impact rebates payable, was enacted. The provisions in the legislation which relate to rebates payable include an increase in the minimum Medicaid rebate percentages, which is also extended as a discount to 340B institutions, and an extension of the Medicaid rebate to managed care organizations that dispense drugs to Medicaid recipients. We have recorded estimated rebates payable according to the new legislation. If the provisions of this legislation change, we may revise our estimates of rebates payable, which may have an impact on revenue in the period in which the adjustment is made.

**Table of Contents**

We have provided balances and activity in the rebates payable account for the years ended December 31, 2010, 2009 and 2008 as follows:

	<b>Rebates Payable</b>
<b>Balance at December 31, 2007</b>	<b>\$ (1,006)</b>
Current provisions relating to sales in current year	(3,723)
Payments/credits relating to sales in current year	1,189
Payments/credits relating to sales in prior years	193
<b>Balance at December 31, 2008</b>	<b>\$ (3,347)</b>
Current provisions relating to sales in current year	(6,024)
Payments/credits relating to sales in current year	2,165
Payments/credits relating to sales in prior years	3,138
<b>Balance at December 31, 2009</b>	<b>\$ (4,068)</b>
Current provisions relating to sales in current year	(11,314)
Payments/credits relating to sales in current year	6,488
Payments/credits relating to sales in prior years	4,234
<b>Balance at December 31, 2010</b>	<b>\$ (4,660)</b>

We 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 enter into foreign exchange forward contracts to hedge exposures resulting from portions of our forecasted intercompany revenues that are denominated in currencies other than the U.S. dollar. These hedges are designated as cash flow hedges upon inception. We record the effective portion of these cash flow hedges to revenue in the period in which the sale is made to an unrelated third party and the derivative contract is settled.

**Contingent liabilities**

We are currently involved in various claims and legal proceedings. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, we accrue a liability for the estimated loss. Significant judgement is required in both the determination of probability and the determination as to whether an exposure is reasonably estimable. Because of uncertainties related to these matters, accruals are based on our best estimates based on available information. As additional information becomes available, or upon specific events such as the outcome of litigation or settlement of claims, we reassess the potential liability related to pending claims and litigation and may revise our estimates. These revisions in these estimates of the potential liabilities could have a material impact on our consolidated results of operations and financial position.

**Inventories**

Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of inventory using the weighted-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 (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 approval of the facility by regulatory authorities.





## **Table of Contents**

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 realize the carrying value of our 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.

In the future, reduced demand, quality issues or excess supply beyond those anticipated by management may result in an adjustment to inventory levels, which would be recorded as an increase 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 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 enrollment 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.

## **Share-Based Compensation**

We have one share-based compensation plan known as the 2004 Incentive Plan. Under this plan, restricted stock, restricted stock units, 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, the share-based compensation expense that we record in future periods may differ significantly from our prior recorded amounts.

## **Income Taxes**

We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts

**Table of Contents**

and tax basis of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. We provide a valuation allowance when it is more likely than not that deferred tax assets will not be realized.

We follow the authoritative guidance regarding accounting for uncertainty in income taxes, which 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. 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 industry experience. We provide estimates for unrecognized tax benefits which may be subject to material adjustments until matters are resolved with taxing authorities or statutes expire. If our estimates are not representative of actual outcomes, our results of operations could be materially impacted.

In the fourth quarter of 2009, we reversed the valuation allowance recorded against a substantial portion of our deferred tax assets in the United States, resulting in a tax benefit of \$215,516. The decision to reverse the valuation allowance was made after management determined that it was more likely than not that these deferred tax assets would be realized. We made the determination after evaluation of our levels of recent profitability, as well as forecasts of future taxable income which impact utilization of tax attributes, primarily net operating losses and research income tax credits. We also reversed the valuation allowance recorded against certain non-U.S. deferred tax assets in the second quarter of 2010 where realization of those assets was now more likely than not.

We continue to maintain a valuation allowance against certain other deferred tax assets where the realization is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized. We consider many factors when assessing the likelihood of future realization of deferred tax assets, including our recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income, carryforward periods available to us for tax reporting purposes, various income tax strategies and other relevant factors. Significant judgment is required in making this assessment and, to the extent future expectations change, we would assess the recoverability of our deferred tax assets at that time. If we determine that the deferred tax assets are not realizable in a future period, we would record material changes to income tax expense in that period.

**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,		
	2010	2009	2008
Revenues:			
Net product sales	\$ 540,957	\$ 386,800	\$ 259,004
Contract research revenue			95
Total revenues	540,957	386,800	259,099
Cost of sales	64,437	45,059	28,366
Operating expenses:			
Research and development	98,394	81,915	62,581
Selling, general and administrative	227,488	172,767	133,543
Total operating expenses	325,882	254,682	196,124
Operating income	150,638	87,059	34,609
Other income (expense)	(1,627)	(3,745)	121
Income before income taxes	149,011	83,314	34,730
Income tax provision (benefit)	51,981	(211,852)	1,581
Net income	\$ 97,030	\$ 295,166	\$ 33,149
Earnings per common share:			
Basic	\$ 1.09	\$ 3.46	\$ 0.43
Diluted	\$ 1.04	\$ 3.26	\$ 0.39

***Comparison of the Year Ended December 31, 2010 to the Year Ended December 31, 2009*****Revenues**

Revenues by significant geographic region are as follows:

	Year Ended December 31,		
	2010	2009	% Variance
Revenues:			
United States	\$ 205,792	\$ 159,829	29%
Europe	274,919	215,763	27%
Other	60,246	11,208	438%
	\$ 540,957	\$ 386,800	40%

The increase in revenue for fiscal year 2010 versus 2009 was primarily due to an increased number of patients treated with Soliris globally. The increase in treated patients was due to additional patients and physicians requesting Soliris therapy, as well as reimbursement and price

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

approvals in additional territories, including approvals in Japan, included in Other above, which impacted sales in the third and fourth quarters of 2010.

The increase in revenues was offset by the negative impact of approximately \$9,277 for the year ended December 31, 2010 due to changes in foreign currency exchange rates (inclusive of hedging activity), primarily the Euro and British Pound, compared to USD, versus the year ended December 31, 2009. We recorded a gain in revenue of \$8,778 and \$3,363 related to our foreign currency cash flow hedging program, which is included in revenue from outside the United States, for the years ended December 31, 2010 and 2009, respectively.

**Table of Contents****Cost of Sales**

Cost of sales was \$64,437 and \$45,059, or 12% of product revenue, for the years ended December 31, 2010 and 2009, respectively. Cost of sales includes manufacturing costs as well as actual and estimated royalty expenses associated with sales of Soliris.

On January 26, 2011, Novartis filed a civil action against Alexion Pharmaceuticals, Inc. and other biopharmaceuticals companies in the U.S. District Court for the District of Delaware. Novartis claims willful infringement by Alexion of U.S. Patent No. 5,688,688. Novartis seeks, among other things, monetary damages. If it is finally determined that we infringe the Novartis patent, we may be required to pay royalties to Novartis on sales of Soliris regarding certain manufacturing technology. Although we do not believe that the manufacture of Soliris infringes a valid patent claim owned by Novartis, we cannot guarantee that we will be successful in defending against such action. Given the early stages of this litigation, Management does not believe a loss related to this matter is probable and the potential magnitude of such loss, if any, can be reasonably estimated.

**Research and Development Expense**

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 development costs are comprised of costs to conduct and manage clinical trials related to eculizumab and other product candidates. Product development costs are those incurred in performing duties related to manufacturing development and regulatory functions. Discovery research costs are incurred in conducting laboratory studies and performing preclinical research for other uses of eculizumab and other product candidates. Clinical development 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, our product development and 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, 2010	Year Ended December 31, 2009	\$ Variance	% Variance
Clinical development	\$ 26,983	\$ 20,591	\$ 6,392	31%
Product development	10,789	9,674	1,115	12%
Discovery research	2,846	1,776	1,070	60%
<b>Total external direct expenses</b>	<b>40,618</b>	<b>32,041</b>	<b>8,577</b>	<b>27%</b>
Payroll and benefits	47,683	41,122	6,561	16%
Operating and occupancy	4,540	4,935	(395)	-8%
Depreciation and amortization	5,553	3,817	1,736	45%
<b>Total other R&amp;D expenses</b>	<b>57,776</b>	<b>49,874</b>	<b>7,902</b>	<b>16%</b>
<b>Research and development expense</b>	<b>\$ 98,394</b>	<b>\$ 81,915</b>	<b>\$ 16,479</b>	<b>20%</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, 2010	Year Ended December 31, 2009	Accumulated Expenditures since January 1, 2006
<b>External direct expenses</b>			
Eculizumab: PNH program	\$ 6,661	\$ 7,672	\$ 60,087
Eculizumab: non-PNH programs	17,934	11,345	31,615
Samalizumab	1,183	1,222	3,104
Pexelizumab			13,713
Unallocated	1,205	352	9,140
	<b>\$ 26,983</b>	<b>\$ 20,591</b>	<b>\$ 117,659</b>

Prior to January 1, 2006, we 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 we made the decision to cease development of pexelizumab in 2006.

The successful development of our drug candidates is uncertain and subject to a number of risks. 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.

During the year ended December 31, 2010, we incurred research and development expenses of \$98,394, an increase of \$16,479, or 20% versus the \$81,915 incurred during the year ended December 31, 2009. The increase was primarily related to the following:

Increase of \$6,561 in research and development payroll and benefit expense related primarily to global expansion of staff supporting our increasing number of clinical and preclinical programs.

Increase of \$6,392 in external clinical development expenses related primarily to an expansion of studies of eculizumab for non-PNH indications, offset by decreases in spending on PNH programs (see table above).

Increase of \$1,070 in discovery research was primarily due to external research and consulting fees.

Increase of \$1,736 in depreciation and amortization expenses primarily related to depreciation on our Rhode Island Manufacturing facility which placed into service in December 2009.

We expect our research and development expenses to increase, at a lower rate than our revenue, in 2011 due to clinical development and manufacturing costs related to our expanding eculizumab and samalizumab development programs, as well as expenses related to Taligen and Orphatec 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 Expense**

Our selling, general and administrative expense includes commercial and administrative personnel, corporate facility and external costs required to support the marketing and sales of our commercialized products. These selling, general and administrative costs include: corporate facility

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

operating expenses and depreciation; marketing and sales operations in support of Soliris; human resources; finance, legal, information technology and support personnel expenses; and other corporate costs such as telecommunications, insurance, audit and legal expenses.



---

## **Table of Contents**

During the year ended December 31, 2010, we incurred selling, general and administrative expenses of \$227,488, an increase of \$54,721, or 32%, versus the \$172,767 incurred during the year ended December 31, 2009. The increase was primarily related to the following:

During the year ended December 31, 2010, salaries, benefits and other labor expenses increased to \$134,669, an increase of \$34,631, or 35%, versus \$100,038 incurred during the year ended December 31, 2009. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of \$21,487 related to our global commercial operations teams. This increase was also due to increases in payroll and benefits of \$13,144 within our general and administrative functions to support our infrastructure as a global commercial entity.

Increase in external selling, general and administrative expenses of \$20,090 was due primarily to increases in marketing and consulting services of \$11,984, increases in occupancy and depreciation expenses of \$2,978 relating to new and expanded office spaces in Europe, Japan, Canada, Australia and Latin America, increases of \$2,268 relating to our charitable and compassionate care programs and increases of \$1,112 in telecommunications and information technology expenses.

We expect our selling, general and administrative expenses to increase, at a lower rate than our revenue, in 2011, reflecting our growth as a commercial organization throughout the world.

### **Other Income and Expense**

Foreign currency transaction gains and losses relate to changes in the fair value of monetary assets and liabilities denominated in foreign currencies. During the year ended December 31, 2010, we recognized \$2,434 of foreign currency loss, an increase of \$1,904, versus a loss of \$530 incurred during the year ended December 31, 2009. The increase was primarily a result of the fluctuation in exchange rates on the portion of our monetary assets and liabilities that were not fully hedged as part of our hedging programs.

We recognize investment income primarily from our portfolio of cash equivalents and marketable securities. During the year ended December 31, 2010, investment income increased \$725, or 92% to \$1,511 due primarily to higher cash, cash equivalents and marketable securities balances.

We incur interest on our convertible notes, revolving credit facility and capital lease obligations. During the year ended December 31, 2010, interest expense increased \$98, or 16%, to \$704 due primarily to a reduction in capitalized interest associated with our manufacturing plant in Rhode Island, which was placed in service in the fourth quarter of 2009, and fees relating to our amended and restated credit facility, partially offset by the lower principal balance of our convertible notes as a result of the note conversions and exchanges during 2009 and 2010.

We recorded \$3,395 of non-cash debt exchange expense for the year ended December 31, 2009 relating to the exchange of 5,644 shares for \$87,304 principal amount of our 1.375% Convertible Senior Notes. The expense was recorded based on the fair value of the additional shares provided to the note holders over the stated conversion rate.

### **Income Taxes**

During the year ended December 31, 2010, we recorded an income tax provision of \$51,981, compared to a benefit of \$211,852 for the year ended December 31, 2009. The income tax provision for 2010 is principally attributable to the U.S. Federal, state, and foreign income taxes in our profitable operations. The tax benefit reported in 2009 includes a benefit of \$215,516 attributable to the release of valuation allowances against U.S. deferred tax assets, offset principally by income tax provisions for profitable foreign subsidiaries.

The Company was granted an incentive tax holiday in the Canton of Vaud in Switzerland effective January 1, 2010, with a final expiration date in 2019. The tax holiday will exempt the Company from most local corporate income taxes in Switzerland through the end of 2014 and is expected to be renewed for an additional 5 years.

**Table of Contents****Comparison of the Year Ended December 31, 2009 to the Year Ended December 31, 2008****Revenues**

Revenues by significant geographic region are as follows:

Revenues:	Year Ended December 31,		
	2009	2008	% Variance
United States	\$ 159,829	\$ 113,299	41%
Europe	215,763	143,645	50%
Other	11,208	2,155	420%
	\$ 386,800	\$ 259,099	49%

The increases in revenue for fiscal year 2009 versus 2008 were due to an increased number of patients treated with Soliris in the United States and outside the United States.

As additional physicians request Soliris and as governmental reimbursement for Soliris is provided for in more territories, we expect that the number of patients receiving Soliris treatment 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 a gain in revenue of \$3,363 and \$4,141 related to our foreign currency cash flow hedging program, which is included in revenue from outside the United States, for the years ended December 31, 2009 and 2008, respectively.

We recorded no contract research revenues in the year ended December 31, 2009 and \$95 for the year ended December 31, 2008.

**Cost of Sales**

Cost of sales was \$45,059 and \$28,366, or 12% and 11% of product revenue, for the years ended December 31, 2009 and 2008, respectively. Cost of sales includes manufacturing costs as well as actual and estimated royalty expenses associated with sales of Soliris.

**Research and Development Expenses**

The following table provides information regarding research and development expenses:

	Year Ended	Year Ended	\$	%
	December 31,	December 31,		
	2009	2008	Variance	Variance
Clinical development	\$ 20,591	\$ 17,889	\$ 2,702	15%
Product development	9,674	8,258	1,416	17%
Discovery research	1,776	1,201	575	48%
<b>Total external direct expenses</b>	<b>32,041</b>	<b>27,348</b>	<b>4,693</b>	<b>17%</b>
Payroll and benefits	41,122	27,555	13,567	49%
Operating and occupancy	4,935	4,192	743	18%
Depreciation and amortization	3,817	3,486	331	9%
<b>Total other R&amp;D expenses</b>	<b>49,874</b>	<b>35,233</b>	<b>14,641</b>	<b>42%</b>

<b>Research and development expense</b>	<b>\$ 81,915</b>	<b>\$ 62,581</b>	<b>\$ 19,334</b>	<b>31%</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, 2009	Year Ended December 31, 2008
<b>External direct expenses</b>		
Eculizumab: PNH program	\$ 7,672	\$ 14,112
Eculizumab: non-PNH programs	11,345	1,657
Samalizumab	1,222	699
Unallocated	352	1,421
	<b>\$ 20,591</b>	<b>\$ 17,889</b>

During the year ended December 31, 2009, we incurred research and development expenses of \$81,915, an increase of \$19,334, or 31% versus the \$62,581 incurred during the year ended December 31, 2008. The increase was primarily due to the following:

Increase of \$13,567 in research and development payroll and benefit expense related primarily to global expansion of staff supporting our expanding number of clinical programs and manufacturing and product development activities at our production facility in Smithfield RI.

Increase of \$2,702 external clinical development expenses related primarily to an expansion of studies of eculizumab for non-PNH indications, as well as growth of our samalizumab program, offset by decreases in spending on the PNH program (see table above).

Increase of \$1,416 in external product development expenses related primarily to increases in manufacturing development activities at our production facility in Smithfield RI.

**Selling, General and Administrative Expenses**

During the year ended December 31, 2009, we incurred selling, general and administrative expenses of \$172,767, an increase of \$39,224, or 29%, versus the \$133,543 incurred during the year ended December 31, 2008. The increase was primarily due to the following:

During the year ended December 31, 2009, salaries, benefits and other labor expenses increased to \$100,038, an increase of \$24,775, or 33%, versus \$75,263 incurred during the year ended December 31, 2008. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of \$17,962 related to our global commercial operations teams. This increase was also due to increases in payroll and benefits of \$6,813 within our general and administrative functions to support our infrastructure as a global commercial entity.

Increase in external selling, general and administrative expenses of \$14,449 was due primarily to increases in marketing and consulting services of \$5,693, occupancy and depreciation expenses of \$4,901 relating to new and expanded office space in Europe, Japan, Canada, Australia and Latin America and \$1,348 in telecommunications and information technology expenses.

**Other Income and Expense**

During the year ended December 31, 2009, we recognized \$530 of foreign currency loss, an increase of \$248, versus a loss of \$282 incurred during the year ended December 31, 2008. The increase was primarily a result of the fluctuation in exchange rates on the portion of our monetary assets and liabilities that were not fully hedged as part of our hedging programs.

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

During the year ended December 31, 2009, investment income decreased \$2,024, or 72% to \$786 due primarily to reduced interest rates earned in money market funds.

**Table of Contents**

During the year ended December 31, 2009, interest expense decreased \$1,801, or 75%, to \$606 due primarily to lower principal balance of our convertible notes as a result of the note conversion in October 2008 and exchange in April and May 2009.

**Income Taxes**

During the year ended December 31, 2009, we recorded an income tax benefit of \$211,852, compared to a provision of \$1,581 for the year ended December 31, 2008. The tax benefit reported in 2009 includes a benefit of \$215,516 attributable to the release of valuation allowances against U.S. deferred tax assets, offset principally by income tax provisions for profitable foreign subsidiaries. The valuation allowance was reversed after management determined that a significant portion of the deferred tax assets relating to the United States would be realized. We made the determination after evaluation of our levels of recent profitability, as well as forecasts of future taxable income which impact utilization of tax attributes, primarily net operating losses and research income tax credits. The income tax provision for 2008 is principally attributable to entities in certain foreign jurisdictions who achieved profitability during the year, offset by the reversal of valuation allowances in those foreign jurisdictions and the exchange of Federal research credits for cash.

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

Cash, cash equivalents, marketable securities and working capital as of December 31, 2010 and December 31, 2009 were as follows:

**Financial assets:**

	December 31, 2010	December 31, 2009	\$ Variance
Cash and cash equivalents	\$ 267,145	\$ 157,172	\$ 109,973
Marketable securities	94,460	19,048	75,412
Cash, cash equivalents and marketable securities	\$ 361,605	\$ 176,220	\$ 185,385

**Select measures of liquidity and capital resources:**

	December 31, 2010	December 31, 2009	\$ Variance
Current assets	\$ 646,556	\$ 373,456	\$ 273,100
Current liabilities	138,515	85,262	53,253
Working capital	\$ 508,041	\$ 288,194	\$ 219,847
Current ratio	4.67	4.38	

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 and agency bonds and commercial paper in accordance with our investment policy. The stated objectives of our investment policy is to preserve capital, provide liquidity consistent with forecasted cash flow requirements, maintain appropriate diversification and generate returns relative to these investment objectives and prevailing market conditions.

The increase in cash, cash equivalents and marketable securities was primarily attributable to the increase in product sales and the related cash generated from operations. The increase in working capital was primarily due to increases in our cash and cash equivalents, marketable securities, accounts receivable and inventory offset primarily by an increase in accrued expenses.

Financial instruments that potentially expose the Company to concentrations of credit risk are limited to cash equivalents, corporate bonds, commercial paper, accounts receivable and our foreign exchange derivative

**Table of Contents**

contracts. At December 31, 2010, one individual customer accounted for 17.8% of the accounts receivable balance. At December 31, 2009, one individual customer accounted for 20.0% of the accounts receivable balance.

We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. As of December 31, 2010, we have foreign exchange forward contracts with notional amounts totaling \$445,476. These outstanding foreign exchange forward contracts had a net fair value of \$(5,273), of which an unrealized gain of \$9,955 is included in other assets, offset by an unrealized loss of \$15,228 included in other liabilities. The counterparties to these foreign exchange forward contracts are large multinational commercial banks, and we believe the risk of nonperformance is not material.

In January 2010, we amended and restated our existing credit agreement to, among other things, increase our revolving credit facility by \$25,000. The Amended Credit Agreement provides for a \$50,000 revolving credit facility, with up to a \$20,000 sublimit for letters of credit that can be used for working capital requirements and other general corporate purposes. With the consent of the lenders and the administrative agent and subject to satisfaction of certain conditions, we may increase the facility to \$75,000 in accordance with its terms.

As of December 31, 2010, our accrued royalty balance of \$50,133 includes estimates of royalties potentially owed to other third parties. The estimates of amounts potentially owed to other third parties may be influenced by the outcome of future litigation or other claims, if any, the results of which are uncertain. An increase in estimated amounts owed or a requirement to pay these amounts on an accelerated basis may result in a material adverse effect on liquidity.

We expect continued growth in our expenditures, particularly those related to research and product development, clinical trials, regulatory approvals, international expansion, commercialization of products and capital investment. However, we anticipate that cash generated from operations and our existing available cash, cash equivalents and marketable securities should provide us adequate resources to fund our operations as currently planned for the foreseeable future.

**Cash Flows****Change in cash and cash equivalents:**

	Year Ended December 31,		\$ Variance
	2010	2009	
Net cash provided by operating activities	\$ 160,906	\$ 113,841	\$ 47,065
Net cash used in investing activities	(89,318)	(81,423)	(7,895)
Net cash provided by (used in) financing activities	38,867	(14,270)	53,137
Effect of exchange rate changes on cash	(482)	1,012	(1,494)
<b>Net change in cash and cash equivalents</b>	<b>\$ 109,973</b>	<b>\$ 19,160</b>	<b>\$ 90,813</b>
<i>Operating Activities</i>			

The increase in net cash and cash equivalents from December 31, 2010 is primarily due to the net income achieved in 2010 versus the net income achieved in the same period in 2009. The components of cash flows from operating activities, as reported in our Statement of Cash Flows, are as follows:

Our reported net income, adjusted for non-cash items, including depreciation and amortization, share-based compensation expense, non-cash debt exchange expense, deferred taxes, unrealized foreign currency gain, and unrealized loss on foreign exchange forward contracts, was \$188,267 and \$128,080 for the year ended December 31, 2010 and 2009, respectively.

---

**Table of Contents**

Net cash outflow due to changes in operating assets and liabilities was \$27,361 and \$14,239 for the year ended December 31, 2010 and 2009, respectively. The \$27,361 change in operating assets and liabilities primarily relates to increases in accounts receivable of \$59,239 due to the increased number of patients treated with Soliris globally, as well as reimbursement and price approvals in additional territories. Additionally, the increase in inventory of \$14,119 relates to increased production at our manufacturing facility in Rhode Island and resulting inventory buildup to support commercial growth. These increases were offset by an increase of \$47,455 in accounts payable and accrued expenses, which consists primarily of accrued royalties, payroll and taxes.

In 2011, we expect changes in cash from operations to be highly dependent on sales levels, and the related cash collections, from Soliris.

*Investing Activities*

The components of cash flows from investing activities consisted of the following:

Additions to property, plant and equipment were \$12,823 and \$35,275 for the year ended December 31, 2010 and 2009, respectively. The reduction in additions to property, plant and equipment was primarily as a result of the approval of our Rhode Island manufacturing facility by the E.C. in December 2009. Through the approval date, we capitalized costs associated with the construction and validation of our Rhode Island manufacturing facility, and we ceased capitalization of these costs beginning in January 2010.

Purchases of marketable securities of \$129,860 and sales of marketable securities of \$53,387 for the year ended December 31, 2010.

Payments of \$25,000 and \$2,500 related to the final payment for the PDL BioPharma patent settlement and Oklahoma Medical Research Foundation patent purchase agreement for the year ended December 31, 2009.

In January and February 2011, we completed business combinations of Taligen and Orphatec. These acquisitions required us to make upfront payments of approximately \$114,000, which we have paid from our available cash, cash equivalents and marketable securities. After these acquisitions, we continue to expect that cash generated from operations and our existing available cash, cash equivalents and marketable securities should provide us adequate resources to fund our operations as currently planned for the foreseeable future.

In addition to the upfront payments, these purchase agreements also include contingent payments totaling \$367,000 for Taligen and \$42,000 for Orphatec. We do not expect that any contingent payments will be made in the next 12 months and, accordingly, we do not expect these amounts to have an impact on our liquidity in the near-term. As future payments become more probable, we will evaluate methods of funding payments, which could be made from available cash, cash generated from operations or proceeds from other financing.

*Financing Activities*

Net cash flows from financing activities reflected proceeds from the exercise of stock options of \$37,546 and \$30,733 for the years ended December 31, 2010 and 2009, respectively. In 2009, cash from financing activities was reduced by a \$44,000 prepayment on our mortgage loan.



**Table of Contents****Contractual Obligations**

The following table summarizes our contractual obligations at December 31, 2010 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	1-3 Years	3-5 Years	More than 5 Years
<b>Contractual obligations:</b>					
Convertible notes payable	\$ 3,718	\$	\$ 3,718	\$	\$
Interest expense	100	50	50		
Capital leases	1,459	715	744		
Operating leases	38,498	10,274	15,266	8,798	4,160
<b>Total contractual obligations</b>	<b>\$ 43,775</b>	<b>\$ 11,039</b>	<b>\$ 19,778</b>	<b>\$ 8,798</b>	<b>\$ 4,160</b>
<b>Commercial commitments:</b>					
Clinical and manufacturing development	\$ 39,000	\$ 7,800	\$ 11,700	\$ 7,800	\$ 11,700
Licenses	1,570	315	630	625	
<b>Total commercial commitments</b>	<b>\$ 40,570</b>	<b>\$ 8,115</b>	<b>\$ 12,330</b>	<b>\$ 8,425</b>	<b>\$ 11,700</b>

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 in "Risk Factors" and Note 10 in the Consolidated Financial Statements. The table above also does not include a liability for unrecognized tax benefits related to various federal, state and foreign income tax matters of \$8,658 at December 31, 2010. The timing of the settlement of these amounts was not reasonably estimable at December 31, 2010. We do not expect payment of amounts related to the unrecognized tax benefits within the next twelve months.

We also did not include contingent payments related to the Taligen and Orphatec acquisitions, as the timing of payment for these amounts is not reasonably estimable at December 31, 2010. Contingent payments for the business combinations total \$367,000 for Taligen and \$42,000 for Orphatec, and we do not expect to make any contingent payments in the next 12 months.

*Convertible Notes*

As of December 31, 2010, we had outstanding \$3,718 principal amount of 1.375% Convertible Senior Notes due February 1, 2012 (1.375% Notes). We pay interest on these notes on a semi-annual basis on February 1 and August 1 of each year. However, no principal payments are due until February 2012, except under certain circumstances such as liquidation, merger or business combination. The Notes do not contain covenants related to our financial performance.

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.

As of December 31, 2010, \$3,718 principal amount of the 1.375% Notes is outstanding, and the fair value, based on quoted market prices, was estimated at \$18,892. The \$11,840 decrease in fair value from December 31, 2009 is primarily attributable to the exchange of \$6,200 principal amount of the notes for 394,211 shares of common stock during the first half of 2010.

## **Table of Contents**

### *Mortgage Loan*

We had a mortgage loan of \$44,000 to finance the purchase and construction of our manufacturing facility in Smithfield, Rhode Island. In June 2009, we amended the mortgage loan agreement to permit the prepayment of the loan without penalty. We prepaid a portion of the mortgage loan each month beginning in July 2009 and made a final payment of the remaining principal balance in October 2009.

### *Revolving Credit Facility*

In January 2010, we entered into an amended and restated credit agreement, the Amended Credit Agreement, that provides for an available \$50,000 revolving credit facility through January 22, 2013, with up to a \$20,000 sublimit for letters of credit that can be used for working capital requirements and other general corporate purposes. With the consent of the lenders and the administrative agent and subject to satisfaction of certain conditions, we may increase the facility to \$75,000. The loan is collateralized by substantially all of Alexion Pharmaceuticals, Inc.'s assets, including the pledge of the equity interests of certain direct subsidiaries and Rhode Island facility, but excluding intellectual property and assets of foreign subsidiaries.

We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 2.50% to 3.00% depending on the ratio of our cash to liabilities (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect, (B) Federal Funds Rate then in effect plus 0.50%, and (C) Eurodollar Rate then in effect plus 1.00%, plus 0.50% to 1.00% depending on the ratio of our cash to liabilities (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 January 22, 2013, the maturity date.

The Amended Credit Agreement requires us to comply with certain financial covenants on a quarterly basis. 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.

As of December 31, 2010, we had no outstanding amounts under the revolving credit facility. We had open letters of credit of \$6,647 at December 31, 2010.

### *Capital Leases*

We currently lease office equipment under capital lease agreements expiring in 2013. 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 4.02% 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 currently lease 205,554 square feet of space at our headquarters and research and development facility in Cheshire, Connecticut and approximately 26,500 square feet of space at our regional executive and sales offices in Lausanne, Switzerland. Additionally, we lease 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. In September 2007, we entered into a sub-lease for the AAT facility, which provides for sub-lease payments to us through the term of the lease, or 2012.

## **Table of Contents**

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.

### *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 for future levels of manufacturing by Lonza, which depends upon our commercial requirements, the progress of our clinical development programs and the production levels of our Smithfield, Rhode Island manufacturing facility.

We have agreed to purchase certain minimum quantities of product from Lonza under our existing arrangements. As of December 31, 2010, we have remaining contractual commitments of approximately \$39,000. If we terminate the Lonza Agreement without cause, we will be required to pay for batches of product scheduled for manufacture under our arrangement.

### *Additional Commercial Commitments*

Additional payments related to our commercial commitments, such as licenses, aggregating to approximately \$1,350, 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, 2010, we have pre-tax federal and state net operating loss carryforwards of \$579,308, and \$86,138, respectively. These NOLs expire between 2011 and 2029. We also have federal and state income tax credit carryforwards of approximately \$37,913 and \$4,199, respectively. These income tax credits expire between 2011 and 2030. 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 various U.S. states and in foreign jurisdictions where we have operations and have utilized all of our net operating losses. We were again subject to the alternative minimum tax during 2010 and expect that we will continue to be subject to cash payments for 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.

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.

---

**Table of Contents**

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

(amounts in thousands, except per share data)

**Interest Rate Risk**

As of December 31, 2010, we held all of our cash and cash equivalents in bank accounts and money market funds, which are not subject to significant interest rate risk.

As of December 31, 2010, we held \$94,460 in marketable securities with maturity dates of less than one year. These financial instruments are subject to interest rate risk and will decline in value if interest rates increase. However, we expect to hold time-based investments, such as corporate bonds and commercial paper, through maturity. We estimate that a change of 100 basis points in interest rates would result in an increase or decrease of approximately \$29 in the fair value of our cash and investments, which had a weighted average duration of approximately 4.6 months at December 31, 2010.

In January 2010, we entered into a \$50,000 amended and restated revolving credit facility, the Amended Credit Agreement. We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 2.50% to 3.00% depending on the ratio of our cash to liabilities (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect, (B) Federal Funds Rate then in effect plus 0.50%, and (C) Eurodollar Rate then in effect plus 1%, plus 0.50% to 1.00% depending on the ratio of our cash to liabilities (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.

**Foreign Exchange Market Risk**

As a result of our foreign operations, we face exposure to movements in foreign currency exchange rates, primarily the Euro, Japanese Yen, Swiss Franc and British Pound against the U.S. dollar. 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. We have substantial operations based in Switzerland to support our business outside the U.S. and Canada, and accordingly, our expenses are impacted by fluctuations in the value of the Swiss Franc against the U.S. dollar.

We currently have a derivative program in place to achieve the following: 1) limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet, using contracts with durations of up to 30 days and 2) hedge a portion of our forecasted intercompany product sales, using contracts with durations of up to 36 months. The objective of these programs is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. Both programs utilize foreign exchange forward contracts intended to reduce, not eliminate, the impact of fluctuations in foreign currency rates.

As of December 31, 2010, we held foreign exchange forward contracts with notional amounts totaling \$445,476. As of December 31, 2010, our outstanding foreign exchange forward contracts had a net fair value of \$(5,273).

We do not use derivative financial instruments for speculative trading purposes. The counterparties to these foreign exchange forward contracts are multinational commercial banks. We believe 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 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

**Table of Contents**

liabilities and our foreign exchange 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.

**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, 2010. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2010, 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 (COSO) to conduct an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2010. Based on the assessment, management has concluded that, as of December 31, 2010, our internal control over financial reporting is effective.

The effectiveness of our internal control over financial reporting as of December 31, 2010 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

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

There has been no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

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

Not applicable

**Item 9B. OTHER INFORMATION.**

None.

**Table of Contents**

**PART III**

**Item 10. *DIRECTORS, 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 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 the Alexion Pharmaceuticals, Inc. Code of Conduct, or code of ethics, that applies to directors, officers and employees of Alexion and its subsidiaries 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 (<http://ir.alexionpharm.com/governance.cfm>). We amended the code of ethics in September 2009 and any future 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, AND DIRECTOR INDEPENDENCE.***

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 14. *PRINCIPAL ACCOUNTING FEES AND SERVICES.***

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





**Table of Contents**

**PART IV**

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

**Item 15(a)**

**(1) Financial Statements**

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

**(2) Financial Statement Schedules**

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

**(3) Exhibits:**

- 2.1 Agreement and Plan of Merger by and among Alexion, TPCA Corporation, Taligen Therapeutics, Inc., each stockholder of Taligen that signed the Agreement as a seller of Series BI Call Rights, and, only for the limited purposes described therein as Stockholders Representatives (and not in their individual capacities), Nick Galakatos, Ed Hurwitz and Timothy Mills, dated as of January 28, 2011.(1) \*
- 3.1 Certificate of Incorporation, as amended.(2)
- 3.2 Bylaws, as amended.(3)
- 4.1 Specimen Common Stock Certificate.(4)
- 4.2 Rights Agreement between the Company and Continental Stock Transfer & Trust Company, Rights Agent, dated as of February 14, 1997.(5)
- 4.3 Amendment No. 1 to Rights Agreement, dated as of September 18, 2000, between the Company and Continental Stock Transfer and Trust Company.(6)
- 4.4 Amendment No. 2 to Rights Agreement, dated as of December 12, 2001, between the Company and Continental Stock Transfer and Trust Company, which includes as Exhibit B the form of Right Certificate.(7)
- 4.5 Amendment No. 3 to Rights Agreement, dated as of November 16, 2004, between the Company and Continental Stock Transfer and Trust Company.(8)
- 4.6 Amendment No. 4 to Rights Agreement, dated February 23, 2007, between the Company and Continental Stock Transfer and Trust Company.(9)
- 4.7 Indenture, dated January 25, 2005, between the Company and U.S. Bank National Association relating to Alexion Pharmaceuticals, Inc. s 1.375% Convertible Senior Notes due 2012.(10)
- 10.1 Employment Agreement, dated as of February 14, 2006, between the Company and Dr. Leonard Bell.(11)
- 10.2 Amendment No. 1 to the Employment Agreement, dated as of December 23, 2009, between the Company and Dr. Leonard Bell.(12)
- 10.3 Employment Agreement, dated as of February 14, 2006, between the Company and Dr. Stephen P. Squinto.(11)

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

- 10.4 Amendment No. 1 to the Employment Agreement, dated as of December 23, 2009, between the Company and Dr. Stephen P. Squinto.(12)

**Table of Contents**

10.5	Employment Agreement, dated as of February 14, 2006, between the Company and Vikas Sinha.(11)
10.6	Amendment No. 1 to the Employment Agreement, dated as of December 23, 2009, between the Company and Vikas Sinha.(12)
10.7	Employment Agreement, dated November 7, 2005, between the Company and Patrice Coissac.(13)
10.8	Amendment to Employment Agreement, dated July 25, 2007, between the Company and Patrice Coissac.(14)
10.9	Amendment to Employment Agreement, dated January 14, 2008, between the Company and Patrice Coissac.(14)
10.10	Severance Letter Agreement, dated as of November 7, 2005, by and between Alexion Europe SAS and Patrice Coissac. (13)
10.11	Form of Employment Agreement (Senior Vice Presidents). (11)
10.12	Form of Amendment No. 1 to Employment Agreements (Senior Vice Presidents). (12)
10.13	Form of Indemnification Agreement for Officers and Directors. (15)
10.14	Agreement of Lease, dated May 9, 2000, between the Company and WE Knotter L.L.C.(16)
10.15	Company s 2000 Stock Option Plan, as amended.(3)
10.16	Company s 1992 Outside Directors Stock Option Plan, as amended.(17)
10.17	Company s Amended and Restated 2004 Incentive Plan.(18)
10.18	License Agreement dated March 27, 1996 between the Company and Medical Research Council.(19)+
10.19	Research and Development Facility lease, dated February 1, 2002, between the Company and PMSI SRF L.L.C.(20)
10.20	Large-Scale Product Supply Agreement, dated December 18, 2002, between Alexion Pharma International Sarl and Lonza Sales AG, as amended.(21)+
10.21	Amendment No. 13 to the Large-Scale Product Supply Agreement dated December 18, 2002, between Alexion Pharma International Sarl and Lonza Sales AG, dated June 8, 2007.(22)+
10.22	Form of Stock Option Agreement for Directors.(23)
10.23	Form of Stock Option Agreement for Executive Officers (Form A).(24)
10.24	Form of Stock Option Agreement for Executive Officers (Form B).(24)
10.25	Form of Restricted Stock Award Agreement for Executive Officers (Form A).(25)
10.26	Form of Stock Option Agreement (Incentive Stock Options).(22)
10.27	Form of Stock Option Agreement (Nonqualified Stock Options).(22)
10.28	Form of Restricted Stock Award Agreement.(22)
10.29	Form of Restricted Stock Unit Award Agreement.
10.30	Form of Stock Option Agreement for Participants in France.(22)
10.31	Form of Restricted Stock Unit Agreement for Participants in France.(22)
10.32	Patent License Agreement, dated December 31, 2008, between the Company and PDL BioPharma, Inc.(22)+
10.33	Settlement Agreement, dated December 31, 2008, between the Company and PDL BioPharma, Inc.(22)+

**Table of Contents**

10.34	Settlement and Assignment Agreement, dated as of February 8, 2008, between the Company and Oklahoma Medical Research Foundation. (26)
10.35	Amended and Restated Credit Agreement, dated January 22, 2010, between the Company, Bank of America, N.A. as administrative agent, the other lenders party thereto, Banc of America Securities LLC and J.P. Morgan Securities Inc. as joint lead arrangers, and Banc of America Securities LLC as lead book manager. (12)
10.36	Amended and Restated Security Agreement, dated January 22, 2010, between the Company, Bank of America, N.A., and the other loan parties named therein. (12)
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, an Independent Registered Public Accounting Firm
31.1	Certificate of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002.
31.2	Certificate of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
32.1	Certificate of Chief Executive Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.
32.2	Certificate of Chief Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.
101	The following materials from the Alexion Pharmaceuticals, Inc. Annual Report on Form 10-K for the year ended December 31, 2010 formatted in eXtensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Statements of Operations, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) related notes, tagged as blocks of text.

- (1) Incorporated by reference to our Report on Form 8-K, filed on February 3, 2011.
- (2) 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2009.
- (12) Incorporated by reference to our Report on Form 8-K, filed on November 14, 2005.
- (13) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.
- (14) Incorporated by reference to our Report on Form 8-K, filed on September 17, 2010.

**Table of Contents**

- (15) Incorporated by reference to our Registration Statement on Form S-3 (Reg. No. 333-36738) filed on May 10, 2000.
- (16) Incorporated by reference to our Registration Statement on Form S-8 (Reg. No. 333-71879) filed on February 5, 1999.
- (17) Incorporated by reference to our Report on Form 8-K, filed on May 14, 2010.
- (18) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended July 31, 1996.
- (19) Incorporated by reference to our quarterly report on Form 10-Q for the quarter ended January 31, 2002.
- (20) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2003.
- (21) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.
- (22) Incorporated by reference to our report on Form 8-K, filed on December 16, 2004.
- (23) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2005.
- (24) Incorporated by reference to our report on Form 8-K, filed on March 14, 2005.
- (25) Incorporated by reference to our report on Form 8-K, filed on February 14, 2008.

+ Confidential treatment was granted for portions of such exhibit.

\* Confidential treatment requested for portions of such exhibit.

**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 17, 2011**

By: /s/ Vikas Sinha  
**Vikas Sinha, M.B.A., C.A.**

*Senior Vice President and Chief Financial Officer*

**Dated: February 17, 2011**

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

/s/ Leonard Bell <b>Leonard Bell, M.D.</b>	Chief Executive Officer, Secretary, Treasurer and Director (principal executive officer)	February 17, 2011
/s/ Vikas Sinha <b>Vikas Sinha, M.B.A., C.A.</b>	Senior Vice President and Chief Financial Officer (principal financial officer)	February 17, 2011
/s/ Scott Phillips <b>Scott Phillips</b>	Corporate Controller and Chief Accounting Officer (principal accounting officer)	February 17, 2011
/s/ Max Link <b>Max Link, Ph.D.</b>	Chairman of the Board of Directors	February 17, 2011
/s/ William R. Keller <b>William R. Keller</b>	Director	February 17, 2011
/s/ Larry L. Mathis <b>Larry L. Mathis</b>	Director	February 17, 2011

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

/s/ Joseph A. Madri	Director	February 17, 2011
<b>Joseph A. Madri, Ph.D., M.D.</b>		
/s/ R. Douglas Norby	Director	February 17, 2011
<b>R. Douglas Norby</b>		
/s/ Alvin S. Parven	Director	February 17, 2011
<b>Alvin S. Parven</b>		

**Table of Contents**

<i>/s/</i> ANDREAS RUMMELT	Director	February 17, 2011
<b>Andreas Rummelt, Ph.D.</b>		
<i>/s/</i> ANN VENEMAN	Director	February 17, 2011
<b>Ann Veneman</b>		



**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Contents**

**For the Years Ended December 31, 2010, 2009 and 2008**

	Page(s)
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<b>Consolidated Financial Statements</b>	
<u>Consolidated Balance Sheets</u>	F-3
<u>Consolidated Statements of Operations</u>	F-4
<u>Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Income (Loss)</u>	F-5
<u>Consolidated Statements of Cash Flows</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7 to F-33

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, 2010 and December 31, 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010 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, 2010, 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.

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

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

Hartford, Connecticut

February 17, 2011

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

(amounts in thousands, except per share amounts)

	December 31,	
	2010	2009
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 267,145	\$ 157,172
Marketable securities	94,460	19,048
Trade accounts receivable, net	168,732	113,731
Inventories	62,165	40,885
Prepaid manufacturing costs	7,500	5,762
Deferred tax assets	19,643	16,726
Prepaid expenses and other current assets	26,911	20,132
<b>Total current assets</b>	<b>646,556</b>	<b>373,456</b>
Property, plant and equipment, net	162,240	164,691
Intangible assets, net	24,146	28,589
Goodwill	19,954	19,954
Deferred tax assets	154,569	194,308
Other assets	4,572	5,403
<b>Total assets</b>	<b>\$ 1,012,037</b>	<b>\$ 786,401</b>
<b>Liabilities and Stockholders' Equity</b>		
Current Liabilities:		
Accounts payable	\$ 16,026	\$ 11,530
Accrued expenses	107,030	66,915
Deferred revenue	2,896	1,652
Current portion of capital lease obligations	715	422
Other current liabilities	11,848	4,743
<b>Total current liabilities</b>	<b>138,515</b>	<b>85,262</b>
Capital lease obligations, less current portion	744	503
Convertible notes	3,718	9,918
Deferred tax liabilities		204
Other liabilities	9,324	2,158
<b>Total liabilities</b>	<b>152,301</b>	<b>98,045</b>
Commitments and contingencies (Note 10)		
Stockholders' Equity:		
Preferred stock, \$.0001 par value; 5,000 shares authorized, no shares issued or outstanding		
Common stock, \$.0001 par value; 145,000 shares authorized; 91,591 and 89,097 shares issued at December 31, 2010 and 2009, respectively	6	5
Additional paid-in capital	1,173,480	1,093,933
Treasury stock, at cost, 97 shares at December 31, 2010 and 2009	(2,676)	(2,676)
Accumulated other comprehensive loss	(7,140)	(1,942)
Accumulated deficit	(303,934)	(400,964)

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

Total stockholders' equity	859,736	688,356
Total liabilities and stockholders' equity	\$ 1,012,037	\$ 786,401

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

F-3

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

(amounts in thousands, except per share amounts)

	Year Ended December 31,		
	2010	2009	2008
<b>Revenues:</b>			
Net product sales	\$ 540,957	\$ 386,800	\$ 259,004
Contract research revenues			95
<b>Total revenues</b>	<b>540,957</b>	<b>386,800</b>	<b>259,099</b>
Cost of sales	64,437	45,059	28,366
<b>Operating expenses:</b>			
Research and development	98,394	81,915	62,581
Selling, general and administrative	227,488	172,767	133,543
<b>Total operating expenses</b>	<b>325,882</b>	<b>254,682</b>	<b>196,124</b>
<b>Operating income</b>	<b>150,638</b>	<b>87,059</b>	<b>34,609</b>
<b>Other income and expense:</b>			
Investment income	1,511	786	2,810
Interest expense	(704)	(606)	(2,407)
Foreign currency loss	(2,434)	(530)	(282)
Debt exchange expense		(3,395)	
<b>Income before income taxes</b>	<b>149,011</b>	<b>83,314</b>	<b>34,730</b>
<b>Income tax provision (benefit)</b>	<b>51,981</b>	<b>(211,852)</b>	<b>1,581</b>
<b>Net income</b>	<b>\$ 97,030</b>	<b>\$ 295,166</b>	<b>\$ 33,149</b>
<b>Earnings per common share</b>			
Basic	\$ 1.09	\$ 3.46	\$ 0.43
Diluted	\$ 1.04	\$ 3.26	\$ 0.39
<b>Shares used in computing earnings per common share</b>			
Basic	89,271	85,326	77,680
Diluted	93,037	90,582	89,967

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 Income (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
	Shares Issued	Amount		Shares	Amount				
Balances, December 31, 2007	75,746	4	833,534	57	(1,260)	(1,443)	(729,279)	101,556	\$ (93,556)
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	52,184					52,185	
Issuance of common stock from exercise of options	2,120		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
Foreign currency translation						415		415	\$ 415
Net change in unrealized gains on marketable securities						22		22	22
Unrealized loss on pension obligation						(416)		(416)	(416)
Unrealized loss on hedging activities						(4,910)		(4,910)	(4,910)
Conversion of convertible notes to common stock	5,644		89,893					89,893	
Issuance of common stock from exercise of options	1,564		30,733	40	(1,416)			29,317	
Issuance of restricted common stock	357								
Excess tax benefit from stock options			764					764	
Share-based compensation expense			31,104					31,104	
Net income							295,166	295,166	295,166
Balances, December 31, 2009	89,097	\$ 5	\$ 1,093,933	97	\$ (2,676)	\$ (1,942)	\$ (400,964)	\$ 688,356	\$ 290,277
Foreign currency translation						(528)		(528)	\$ (528)
Net change in unrealized gains on marketable securities, net of tax						(12)		(12)	(12)
Unrealized loss on pension obligation, net of tax						(1,898)		(1,898)	(1,898)
Unrealized loss on hedging activities, net of tax						(2,760)		(2,760)	(2,760)
Conversion of convertible notes to common stock	394		6,175					6,175	
Issuance of common stock from exercise of options	1,646	1	37,545					37,546	
Issuance of restricted common stock	454								
Excess tax benefit from stock options			1,970					1,970	
Share-based compensation expense			33,857					33,857	
Net income							97,030	97,030	97,030

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

Balances, December 31, 2010                    91,591    \$   6    \$ 1,173,480    97    \$ (2,676)    \$   (7,140)    \$ (303,934)    \$ 859,736    \$   91,832

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

F-5

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

(amounts in thousands)

	Year Ended December 31,		
	2010	2009	2008
<b>Cash flows from operating activities:</b>			
Net income	\$ 97,030	\$ 295,166	\$ 33,149
Adjustments to reconcile net income to net cash flows from operating activities:			
Loss on disposal of property, plant and equipment	76	271	44
Depreciation and amortization	15,792	12,473	7,608
Share-based compensation expense	32,338	28,731	23,682
Deferred taxes	36,389	(208,726)	
Marketable securities premium amortization	960		
Non-cash debt exchange expense		3,395	
Unrealized foreign currency (gain) loss	(523)	(997)	3
Unrealized loss (gain) on forward contracts	6,205	(2,233)	473
Changes in operating assets and liabilities:			
Accounts receivable	(59,239)	(36,440)	(31,262)
Inventories	(14,119)	14,596	(15,700)
Prepaid expenses and other assets	(2,773)	(6,926)	951
Accounts payable and accrued expenses	47,455	14,131	32,912
Deferred revenue	1,315	400	1,339
Net cash provided by operating activities	160,906	113,841	53,199
<b>Cash flows from investing activities:</b>			
Purchases of marketable securities	(129,860)	(19,026)	
Proceeds from maturity or sale of marketable securities	53,387		9,368
Purchases of property, plant and equipment	(12,823)	(35,275)	(39,733)
Purchase of technology rights	(20)	(27,740)	(8,624)
(Increase) decrease in restricted cash	(2)	618	339
Net cash used in investing activities	(89,318)	(81,423)	(38,650)
<b>Cash flows from financing activities:</b>			
Debt issuance costs		(50)	(312)
Payments on capital leases	(649)	(301)	(273)
Payments on mortgage loan		(44,000)	
Excess tax benefit from stock options	1,970	764	
Payment of taxes in exchange of treasury shares		(1,416)	
Net proceeds from the exercise of stock options	37,546	30,733	28,893
Net cash provided by (used in) financing activities	38,867	(14,270)	28,308
Effect of exchange rate changes on cash	(482)	1,012	(166)
Net change in cash and cash equivalents	109,973	19,160	42,691
Cash and cash equivalents at beginning of period	157,172	138,012	95,321
Cash and cash equivalents at end of period	\$ 267,145	\$ 157,172	\$ 138,012
<b>Supplemental disclosures</b>			
Cash paid for interest (net of amounts capitalized)	\$ 500	\$ 4,282	\$ 6,688
Cash paid for income taxes	\$ 7,953	\$ 4,268	\$

See Notes 4, 5, 8, 9, 11 and 12 for investing and financing non-cash disclosures

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





---

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**For the Years Ended December 31, 2010, 2009 and 2008**

**(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 commercialization of innovative therapeutic products aimed at treating patients with severe and life-threatening disease states, including those in the therapeutic areas of hematology, nephrology including transplant rejection, neurology, ophthalmology and cancer. Our marketed product Soliris® (eculizumab) is the first and only therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH), an ultra-rare and life-threatening blood disorder. We were incorporated in 1992 and began commercial sale of Soliris 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 and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

We have reclassified certain balance sheet amounts for the prior period to conform to the current year presentation.

**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.

**Critical Accounting Estimates**

The preparation of our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We believe the most complex judgments result primarily from the need to make estimates about the effects of matters that are inherently uncertain and are significant to our consolidated financial statements. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. We evaluate our estimates, judgments and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions.

The most significant areas involving estimates, judgments and assumptions used in the preparation of our consolidated financial statements are as follows:

Revenue recognition



**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**For the Years Ended December 31, 2010, 2009 and 2008**

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

Contingent liabilities

Inventories

Research and development expenses

Share-based compensation

Income taxes

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

**Segment Reporting**

We are managed and operated as one business. The entire business is managed by a single management team with reporting to the chief executive officer. We do not operate separate lines of business or separate business entities with respect to our products or product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate product areas or by location and only has one reportable segment.

**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.

**Fair Value of Financial Instruments**

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, other assets, accounts payable, accrued expenses and other liabilities approximate fair value due to their short-term maturities. Our derivative financial instruments are measured at fair value using observable market inputs such as forward rates, interest rates, our own credit risk and our counterparties' credit risks. Our marketable securities, all of which are available-for-sale, are valued based upon pricing of securities with similar investment characteristics and holdings. Our convertible notes and other debt obligations are carried at historical cost (see Notes 8 and 14 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.

F-8

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008****(amounts in thousands, except per share amounts)**

Unrealized gains and losses that are deemed temporary, are included in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. If any adjustment to fair value reflects a significant 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 would mark the security to market through a charge to our statement of operations. Credit losses are identified when we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security. In the event of a credit loss, only the amount associated with the credit loss is recognized in operating results, with the amount of loss relating to other factors recorded in accumulated other comprehensive income (loss).

**Accounts Receivable**

Our standard credit terms vary based on the country of sale and range from 30 to 120 days. Our average 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 payor is government-owned or government-funded, which we consider to be creditworthy. The length of time from sale to receipt of payment in certain countries typically exceeds our credit terms. We make judgments as to our ability to collect outstanding receivables and provide allowances for the portion of receivables if and when collection becomes doubtful.

During the second quarter of 2010, the Greek government announced a plan for repayment of its debt to international pharmaceutical companies. This plan calls for the majority of pharmaceutical industry receivables from 2007 to 2009 to be settled in non-interest bearing bonds issued by the Greek government, with maturity dates ranging from 1 to 4 years.

In countries in which collections from customers extend beyond normal payment terms, we seek to collect interest. We record interest on customer receivables as interest income when collected.

For the year ended December 31, 2010, one individual customer accounted for 18% of the accounts receivable balance. For the year ended December 31, 2009, one individual customer accounted for 20% of the accounts receivable balance. For the year ended December 31, 2010, one individual customer accounted for 21% of net product sales. For the year ended December 31, 2009, one individual customer accounted for 20% of net product sales. No other customer accounted for more than 10% of net product sales or accounts receivable.

**Inventories**

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

The components of inventory are as follows:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Raw materials	\$ 4,835	\$ 2,678
Work-in-process	37,312	6,900
Finished goods	20,018	31,307
	<b>\$ 62,165</b>	<b>\$ 40,885</b>



---

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**For the Years Ended December 31, 2010, 2009 and 2008**

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

*Capitalization of Inventory Costs*

We capitalize inventory produced for commercial sale, including costs incurred prior to regulatory approval but subsequent to the filing of a Biologics License Application (BLA) when the Company has determined that the inventory has probable future economic benefit. Inventory is not capitalized prior to completion of a phase III clinical trial. Raw materials and purchased drug product associated with clinical development programs are included in inventory. This inventory is charged to research and development expense when consumed. We also capitalize the cost of inventory manufactured at our manufacturing plant in property, plant and equipment prior to the approval of the facility by regulatory authorities.

*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 to realize the carrying value of the Soliris inventory.

**Derivative Instruments**

We record the fair value of derivative instruments as either assets or liabilities on the balance sheet. 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 the authoritative guidance to be a qualifying hedge. The effectiveness of the qualifying hedge contract is assessed quarterly to ensure compliance with the authoritative guidance. We record the fair value of the qualifying hedges in other current assets, other assets, other current liabilities and other liabilities. Gains or losses resulting from changes in the fair value of qualifying hedges are recorded in other comprehensive income (loss) 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 and expense.

**Prepaid Manufacturing Costs**

Cash advances paid by us prior to receipt of the inventory are recorded as prepaid manufacturing costs. 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 years



Machinery and laboratory equipment three to fifteen years

F-10

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**For the Years Ended December 31, 2010, 2009 and 2008**

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

Computer hardware and software three to five 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.

**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, 2010, 2009 and 2008.

**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**

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

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 end customer, which is typically a hospital, physician's office, private or government pharmacy or other health care facility. Amounts collected from customers and remitted to governmental authorities, such as 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 which supply physician office clinics, hospital outpatient clinics, infusion clinics or home health care providers. 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.

In addition to sales in countries where Soliris is commercially available, we have also recorded revenue on sales for individual patients through named-patient programs. 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.



**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**For the Years Ended December 31, 2010, 2009 and 2008**

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

Because of factors such as 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. To date, actual refunds and returns have been negligible.

We record estimated rebates payable under governmental programs, including Medicaid in the United States and other programs outside the United States, as a reduction of revenue at the time of product sale. Our calculations related to these rebate accruals require an analysis of historical claim patterns and 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, which may have an impact on revenue in the period in which the adjustment is made. Generally, the length of time between product sale and the processing and reporting of the rebates is three to six months.

In March 2010, United States government healthcare legislation, which contains several provisions that impact rebates payable, was enacted. The provisions in the legislation which relate to rebates payable include an increase in the minimum Medicaid rebate percentages, which is also extended as a discount to 340B institutions, and an extension of the Medicaid rebate to managed care organizations that dispense drugs to Medicaid recipients. We have recorded estimated rebates payable according to the new legislation. If the provisions of this legislation change, we may revise our estimates of rebates payable, which may have an impact on revenue in the period in which the adjustment is made.

We 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 enter into foreign exchange forward contracts to hedge exposures resulting from portions of our forecasted intercompany revenues that are denominated in currencies other than the U.S. dollar. These hedges are designated as cash flow hedges upon inception. We record the effective portion of these cash flow hedges to revenue in the period in which the sale is made to an unrelated third party and the derivative contract is settled.

**Research and Development Expenses**

Research and development expenses are comprised of costs incurred in performing research and development activities including payroll and benefits, pre-clinical, clinical trial and related clinical manufacturing costs, manufacturing development and scale-up costs, product development and regulatory 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.

**Share-Based Compensation**

We have one share-based compensation plan known as the 2004 Incentive Plan. Under this plan, restricted stock, restricted stock units, 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, share-based compensation issued under the plan consists of incentive and non-qualified stock options, restricted stock and restricted stock units. 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, restricted stock and restricted stock units granted to

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008****(amounts in thousands, except per share amounts)**

employees fully vest four years from the grant date. Stock options have a contractual term of 10 years. We recognize share-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.

**Earnings Per Common Share**

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

The following table summarizes the calculation of basic and diluted EPS for years ended December 31, 2010, 2009 and 2008:

	2010	December 31 2009	2008
Net income used for basic calculation	\$ 97,030	\$ 295,166	\$ 33,149
Weighted-average effect of dilutive securities:			
Interest expense and debt financing cost amortization, net of tax, related to our 1.375% convertible senior notes	72	298	1,943
Net income used for diluted calculation	\$ 97,102	\$ 295,464	\$ 35,092
Shares used in computing earnings per common share basic	89,271	85,326	77,680
Weighted-average effect of dilutive securities:			
Shares issuable upon the assumed conversion of our 1.375% convertible senior notes	383	2,459	8,970
Stock awards	3,383	2,797	3,317
Dilutive potential common shares	3,766	5,256	12,287
Shares used in computing earnings per common share diluted	93,037	90,582	89,967
Earnings per common share:			
Basic	\$ 1.09	\$ 3.46	\$ 0.43
Diluted	\$ 1.04	\$ 3.26	\$ 0.39

The following table represents the potentially dilutive shares excluded from the calculation of EPS for the years ended December 31, 2010, 2009 and 2008 because their effect is anti-dilutive:

	December 31
	2010      2009      2008

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

Potentially dilutive securities:			
Options to purchase common stock	1,234	2,240	1,439
Unvested restricted stock	3	7	20
	1,237	2,247	1,459

F-13

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008****(amounts in thousands, except per share amounts)****Income Taxes**

We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax basis of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. We provide a valuation allowance when it is more likely than not that deferred tax assets will not be realized. The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on income tax returns it files if such tax position is more likely than not to be sustained.

**Comprehensive Income (Loss)**

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 foreign currency translation adjustments, changes in pension liabilities, unrealized holding gains and losses on available for sale securities and unrealized gains and losses on hedge contracts. Certain of these changes in equity are reflected net of tax.

**2. Marketable Securities**

The following tables summarize our marketable securities at December 31, 2010 and 2009:

	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Other Than Temporary Impairments	Aggregate Fair Value
<b>December 31, 2010</b>					
Commercial paper	\$ 65,244	\$ 44	\$ (27)	\$	\$ 65,261
Corporate bonds	19,186	6	(8)		19,184
Federal agency obligations	10,003	12			10,015
<b>Total</b>	<b>\$ 94,433</b>	<b>\$ 62</b>	<b>\$ (35)</b>	<b>\$</b>	<b>\$ 94,460</b>
<b>December 31, 2009</b>					
Corporate bonds	\$ 19,026	\$ 22	\$	\$	\$ 19,048
<b>Total</b>	<b>\$ 19,026</b>	<b>\$ 22</b>	<b>\$</b>	<b>\$</b>	<b>\$ 19,048</b>

No realized gains or losses were recorded for the year ended December 31, 2010 and 2009. We utilize the specific identification method in computing realized gains and losses.

**3. Prepaid Expenses and Other Assets**

Prepaid expenses and other current assets consist of the following:

	December 31, 2010	December 31, 2009
Prepaid taxes	\$ 7,411	\$ 7,682
Forward contract receivable	9,365	5,209
Other	10,135	7,241
	\$ 26,911	\$ 20,132

F-14



**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008**

(amounts in thousands, except per share amounts)

Other non-current assets consist of the following:

	December 31, 2010	December 31, 2009
Forward contract receivable	\$ 590	\$ 2,061
Leasehold deposits	2,403	1,913
Other	1,579	1,429
	\$ 4,572	\$ 5,403

**4. Property, Plant and Equipment, Net**

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

Asset	December 31, 2010	December 31, 2009
Land	\$ 692	\$ 692
Buildings and improvements	133,430	132,675
Machinery and laboratory equipment	41,986	38,946
Computer hardware and software	20,012	13,245
Furniture and office equipment	5,340	4,216
Construction-in-progress	3,831	3,294
	205,291	193,068
Less: Accumulated depreciation and amortization	(43,051)	(28,377)
	\$ 162,240	\$ 164,691

Depreciation and amortization of property, plant and equipment was approximately \$11,003, \$7,566 and \$5,688 for the year ended December 31, 2010, 2009 and 2008, respectively.

At December 31, 2010 and 2009, computer software costs included in property, plant and equipment, net, was \$7,368 and \$4,440, respectively. Depreciation and amortization expense for capitalized computer software costs was \$2,883, \$2,091 and \$1,318 for the years ended December 31, 2010, 2009 and 2008, respectively.

In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island for the commercial production of Soliris and development and 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 and inventory production necessary to obtain approval of the facility from government regulators for the production of a commercially approved drug. In December 2009, we received final regulatory approval for production of commercial quantities of eculizumab by the European Commission. Accordingly, our plant was considered substantially complete and ready for its intended use. As a result of the approval, we placed the plant in service. Based on the

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

approval, we expected to sell certain pre-approval inventory, and we therefore reclassified \$4,514 from property, plant and equipment to inventory. In August 2010, the U.S. Food and Drug Administration (FDA) approved our Rhode Island manufacturing facility for the production of Soliris.

We capitalized interest of \$3,427 and \$4,717 in the years ended December 31, 2009 and 2008, respectively.

F-15

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008****(amounts in thousands, except per share amounts)****5. Intangible Assets, Net**

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

	Estimated Life (months)	December 31, 2010			December 31, 2009		
		Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Licenses	28-96	\$ 25,531	\$ (8,251)	\$ 17,280	\$ 25,422	\$ (4,895)	\$ 20,527
Patents	90	10,517	(3,651)	6,866	10,517	(2,455)	8,062
<b>Total</b>		<b>\$ 36,048</b>	<b>\$ (11,902)</b>	<b>\$ 24,146</b>	<b>\$ 35,939</b>	<b>\$ (7,350)</b>	<b>\$ 28,589</b>
Goodwill	Indefinite	\$ 22,855	\$ (2,901)	\$ 19,954	\$ 22,855	\$ (2,901)	\$ 19,954

Amortization of our intangible assets was approximately \$4,552, \$4,663 and \$1,176 for the years ended December 31, 2010, 2009 and 2008, respectively. Assuming no changes in the gross cost basis of intangible assets, the estimated amortization of intangible assets for the next five fiscal years is as follows:

Year	
2011	\$ 4,711
2012	5,696
2013	7,148
2014	6,583
2015	42

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. 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.

**6. 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, and expenses that are denominated in currencies other than the U.S. dollar, primarily the Euro, Japanese Yen, Swiss Franc and British Pound. We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes.

We enter into foreign exchange forward contracts, with durations of up to 36 months, to hedge exposures resulting from portions of our forecasted intercompany revenues that are denominated in currencies other than the U.S. dollar. The purpose of the hedges of intercompany

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

revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. These hedges are designated as cash flow hedges upon contract inception. At December 31, 2010, we have open contracts with notional amounts totaling \$330,019 that qualified for hedge accounting.

F-16

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008**

(amounts in thousands, except per share amounts)

The impact on other comprehensive income (OCI) and earnings from foreign exchange contracts that qualified as cash flow hedges, for the years ended December 31, 2010 and 2009 are as follows:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Loss recognized in OCI, net of tax	\$ (2,760)	\$ (4,910)
Gain reclassified from OCI to net product sales (Effective portion)	\$ 8,778	\$ 3,363
Gain (loss) reclassified from OCI to other income and expense (Ineffective portion)	\$ 668	\$ (258)

Assuming no change in foreign exchange rates from market rates at December 31, 2010, \$55 of a gain recognized in other comprehensive income is expected to be reclassified to revenue over the next twelve months.

We enter into foreign exchange forward contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities of our foreign subsidiaries. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results. These derivative instruments do not qualify for hedge accounting under the guidance; however, gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. As of December 31, 2010, the notional settlement amount of foreign exchange contracts relating to monetary assets and liabilities was \$115.457.

We recognized a gain (loss) of \$9,443 and \$(3,820), in other income and expense, for the years ended December 31, 2010 and 2009, respectively, associated with the foreign exchange contracts not designated as hedging instruments under the guidance. These amounts were largely offset by gains or losses in monetary assets and liabilities.

The following table summarizes the Company's fair value of outstanding derivatives at December 31, 2010:

	<b>Asset Derivatives</b>		<b>Liability Derivatives</b>	
	<b>Balance Sheet</b>	<b>Fair</b>	<b>Balance Sheet</b>	<b>Fair</b>
	<b>Location</b>	<b>Value</b>	<b>Location</b>	<b>Value</b>
<b>Derivatives designated as hedging instruments:</b>				
Foreign exchange forward contracts	Other current assets	\$ 8,015	Other current liabilities	\$ 7,124
Foreign exchange forward contracts	Other non-current assets	590	Other non-current liabilities	3,380
<b>Derivatives not designated as hedging instruments:</b>				
Foreign exchange forward contracts	Other current assets	1,350	Other current liabilities	4,724
<b>Total fair value of derivative instruments</b>		<b>\$ 9,955</b>		<b>\$ 15,228</b>

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008****(amounts in thousands, except per share amounts)****7. Accrued Expenses**

Accrued expenses consist of the following:

	<b>December 31, 2010</b>	<b>December 31, 2009</b>
Royalties	\$ 50,133	\$ 29,177
Payroll and employee benefits	24,034	17,251
Taxes payable	9,580	5,947
Rebates payable	4,660	4,068
Other	18,623	10,472
	<b>\$ 107,030</b>	<b>\$ 66,915</b>

See Note 10 for additional information on accrued royalties.

**8. 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). 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 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 convertible notes payable do not contain covenants related to our financial performance.

In the second quarter of 2009, certain holders of the 1.375% Notes exercised conversion rights with respect to an aggregate principal amount of \$87,304 resulting in the issuance of 5,644 shares of our common stock. In the second quarter of 2009, we recorded a non-cash expense of \$3,395 for the fair value of the additional shares over the stated conversion rate. We reclassified \$1,105 of deferred financing costs to equity in 2009 as a result of the exchange and had a remaining balance of \$272 at December 31, 2009.

In the first quarter of 2010, certain holders of the 1.375% Notes exercised conversion rights with respect to an aggregate principal amount of \$1,000 resulting in the issuance of 63,582 shares of our common stock. In the second quarter of 2010, certain holders of the 1.375% Notes exercised conversion rights with respect to an aggregate principal amount of \$5,200 resulting in the issuance of 330,629 shares of our common stock. At December 31, 2010, \$3,718 of the convertible notes remains outstanding, and the fair value, based on quoted market prices, was estimated at \$18,892.

Amortization expense associated with deferred financing costs for the year ended December 31, 2010, 2009 and 2008 was approximately \$239, \$260 and \$733, respectively.

**Revolving Credit Facility**

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

In January 2010, we entered into an amended and restated credit agreement, the Amended Credit Agreement, that provides for an available \$50,000 revolving credit facility through January 22, 2013, with up to a

F-18

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008****(amounts in thousands, except per share amounts)**

\$20,000 sublimit for letters of credit that can be used for working capital requirements and other general corporate purposes. With the consent of the lenders and the administrative agent and subject to satisfaction of certain conditions, we may increase the facility to \$75,000. The loan is collateralized by substantially all of Alexion Pharmaceuticals, Inc.'s assets, including the pledge of the equity interests of certain direct subsidiaries and Rhode Island facility, but excluding intellectual property and assets of foreign subsidiaries.

We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 2.50% to 3.00% depending on the ratio of our cash to liabilities (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect, (B) Federal Funds Rate then in effect plus 0.50%, and (C) Eurodollar Rate then in effect plus 1.00%, plus 0.50% to 1.00% depending on the ratio of our cash to liabilities (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 January 22, 2013, the maturity date.

The Amended Credit Agreement requires us to comply with certain financial covenants on a quarterly basis. 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.

As of December 31, 2010, we had no outstanding amounts under the revolving credit facility. We had open letters of credit of \$6,647 at December 31, 2010.

**9. Capital Leases**

We lease office equipment and software licenses under capital lease agreements expiring in 2013. 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, 2010, the cost of equipment under capital lease is \$2,642 and accumulated amortization is \$958. The weighted-average interest rate on the capital leases is approximately 4.02%.

Minimum future lease payments under capital lease as of December 31, 2010 are:

<b>Year</b>	
2011	\$ 793
2012	627
2013	181
	1,601
Less: Amount representing interest	142
Present value of minimum lease payments	\$ 1,459





**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**For the Years Ended December 31, 2010, 2009 and 2008**

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

**10. Commitments and Contingencies**

**Contingent liabilities**

We are currently involved in various claims and legal proceedings. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, we accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on our best estimates based on available information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, we may reassess the potential liability related to these matters and may revise these estimates, which could result in a material adverse adjustment to our operating results.

On January 26, 2011, Novartis filed a civil action against Alexion Pharmaceuticals, Inc. and other biopharmaceuticals companies in the U.S. District Court for the District of Delaware. Novartis claims willful infringement by Alexion of U.S. Patent No. 5,688,688. Novartis seeks, among other things, monetary damages. If it is finally determined that we infringe the Novartis patent, we may be required to pay royalties to Novartis on sales of Soliris regarding certain manufacturing technology. Although we do not believe that the manufacture of Soliris infringes a valid patent claim owned by Novartis, we cannot guarantee that we will be successful in defending against such action. Given the early stages of this litigation, Management does not believe a loss related to this matter is probable and the potential magnitude of such loss, if any, can be reasonably estimated.

In addition to Novartis's claim, other 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 genetically engineered antibodies, including recombinant humanized antibodies, recombinant human antibodies, or recombinant human single chain antibodies. In addition to the action 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. We estimate our obligations for probable contingent liabilities based on our assessment of estimated royalties potentially owed to other third parties. A costly license, or inability to obtain a necessary license, could have a material adverse effect on our business. However the amount of such loss, if any, beyond amounts currently accrued cannot be reasonably estimated.

At December 31, 2010, we have recorded \$50,133 of accrued royalties, which includes amounts related to our existing royalty agreements and amounts recorded for contingent liabilities described above. Our cost of sales for the years ended December 31, 2010, 2009 and 2008 also includes amounts recorded for existing royalty agreements and contingent liabilities.

**Operating Leases**

As of December 31, 2010, 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,

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008****(amounts in thousands, except per share amounts)**

increasing to approximately \$193 over the term of this lease. We also lease space for our regional executive and sales offices in Lausanne, Switzerland, as well as in certain other countries to facilitate our operations as a global organization.

Aggregate lease expense for our facilities was \$6,980, \$6,817 and \$4,728 for the years ended December 31, 2010, 2009 and 2008, 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, 2010 are:

<b>Year</b>	
2011	\$ 10,274
2012	8,718
2013	6,548
2014	5,681
2015	3,117
Thereafter	4,160

**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 us to pay 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 (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.

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.

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

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008**

(amounts in thousands, except per share amounts)

The minimum fixed payments (assuming non-termination of the above agreements) as of December 31, 2010, 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>
2011	\$ 315	\$ 7,800
2012	315	3,900
2013	315	7,800
2014	315	3,900
2015	310	3,900
	\$ 1,570	\$ 27,300

**Product Supply**

The Large-Scale Product Supply Agreement dated December 18, 2002 (Lonza Agreement) between Lonza Sales AG (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 from 2009 through 2013. This amendment has remaining commitments of \$39,000 as of December 31, 2010. Such commitments may only be cancelled in limited circumstances.

**11. Income Taxes**

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

	<b>2010</b>	<b>2009</b>	<b>2008</b>
U.S.	\$ 108,226	\$ 86,803	\$ 23,756
Non-U.S.	40,785	(3,489)	10,974
	\$ 149,011	\$ 83,314	\$ 34,730

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

	<b>2010</b>	<b>2009</b>	<b>2008</b>
Income Tax Provision (Benefit)			
Domestic			

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

Current	\$ 5,013	\$ (7,742)	\$ 2,514
Deferred	40,569	(207,604)	(2,633)
	45,582	(215,346)	(119)
Foreign			
Current	9,728	4,601	1,902
Deferred	(3,329)	(1,107)	(202)
	6,399	3,494	1,700
Total			
Current	14,741	(3,141)	4,416
Deferred	37,240	(208,711)	(2,835)
	\$ 51,981	\$ (211,852)	\$ 1,581

F-22

**Table of Contents**

**Alexion Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**For the Years Ended December 31, 2010, 2009 and 2008**

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

We reversed the valuation allowance against certain non-U.S. deferred tax assets in the second quarter of 2010 where realization of those assets was more likely than not. In the fourth quarter of 2009, we also reversed the valuation allowance recorded against a substantial portion of our deferred tax assets in the United States. We continue to maintain a valuation allowance against certain other deferred tax assets where the realization is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized.

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 various U.S. states and foreign jurisdictions where we have operations and have utilized all of our net operating losses. We were subject to the alternative minimum tax during 2010 and expect that we will continue to be subject to cash payments for 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, 2010, we have federal and state net operating loss carryforwards of \$579,308 and \$86,138, respectively. Included in the NOLs are federal and state NOLs of \$225,574 and \$49,644, 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 utilized to offset taxes payable. Our NOLs expire between 2011 and 2029. We also have federal and state income tax credit carryforwards of approximately \$37,913 and \$4,199, respectively. These income tax credits expire between 2011 and 2030. Additionally, included in these income tax credit carryforwards are federal income tax credit carryforwards of \$5,350 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 authoritative guidance, the additional tax benefit associated with the windfall is not recognized until the deduction reduces regular 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 and credit carryforward in deferred tax assets for all periods presented.

At December 31, 2009, we had federal and state net operating loss carryforwards of \$665,740 and \$117,778, respectively. Included in the NOLs were federal and state NOLs of \$174,545 and \$72,070, 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 utilized to offset taxes payable. We also had federal and state income tax credit carryforwards of approximately \$34,208 and \$7,689 respectively. Additionally, included income tax credit carryforwards are federal income tax credit carryforwards of \$4,767, attributable to excess tax benefits from the exercise of non-qualified stock options.

The Company was granted an incentive tax holiday in the Canton of Vaud in Switzerland effective January 1, 2010, with a final expiration date in 2019. The tax holiday will exempt the Company from most local corporate income taxes in Switzerland through the end of 2014 and is expected to be renewed for an additional 5 years.

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****For the Years Ended December 31, 2010, 2009 and 2008**

(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:

	Year Ended December 31,		
	2010	2009	2008
U.S. federal statutory tax rate	35.0%	35.0%	35.0%
State and local income taxes	2.5%	0.8%	0.9%
Foreign income tax rate differential	-4.9%	5.0%	-3.3%
Income tax credits	-1.0%	-12.1%	-2.9%
Foreign income subject to U.S. taxation	1.6%	0.2%	8.6%
Provision (benefit) attributable to foreign currency	0.0%	0.0%	4.8%
Stock option compensation	1.3%	2.0%	0.9%
Other nondeductible and permanent differences	1.1%	0.3%	1.7%
Provision (benefit) attributable to valuation allowances	-0.7%	-285.5%	-41.1%
Effective income tax rate	34.9%	-254.3%	4.6%

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:

	Year Ended December 31, 2010	Year Ended December 31, 2009
Deferred tax assets:		
Net operating losses	\$ 126,111	\$ 174,424
Income tax credits	35,293	34,438
Stock compensation	16,814	12,799
Accruals and allowances	28,728	16,439
Intangible assets	8,013	7,568
	214,959	245,668
Valuation allowance	(2,470)	(3,296)
Total deferred tax assets	212,489	242,372

Deferred tax liabilities:

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

Depreciable assets	(37,805)	(31,090)
Unrealized gains	(471)	(453)
<b>Total deferred tax liabilities</b>	<b>(38,276)</b>	<b>(31,543)</b>
Net deferred tax asset	\$ 174,213	\$ 210,829

We follow authoritative guidance regarding accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax

F-24



**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008****(amounts in thousands, except per share amounts)**

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 beginning and ending amounts of unrecognized tax benefits reconciles as follows:

	2010	2009	2008
Beginning of period balance	\$ 7,305	\$ 9,569	\$ 6,671
Increases for tax positions taken during a prior period	184	59	306
Decreases for tax positions taken during a prior period	(22)	(3,018)	
Increases for tax positions taken during the current period	1,191	695	2,817
Reduction as a result of a lapse of statute of limitations			(225)
	\$ 8,658	\$ 7,305	\$ 9,569

The company recognizes the interest accrued and the penalties related to unrecognized tax benefits as a component of tax expense. The total amount of accrued interest and penalties and the tax expense as of December 31, 2010 is \$52. Unless related to excess tax benefits from stock options, 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 limitations 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.

The Company has not provided for U.S. income taxes on undistributed earnings of our non-U.S. subsidiaries as these earnings are permanently reinvested. These earnings would be taxable if repatriated to the U.S. It is not practicable to estimate the amount of additional tax that might be payable if such earnings were remitted to the U.S.

**12. Stock Options and Restricted Stock**

At December 31, 2010, we have one stock option plan, the 2004 Incentive Plan ( 2004 Plan ). Under the 2004 Plan, restricted stock and restricted stock units (collectively referred to as Restricted Stock), incentive and non-qualified stock options, and other stock-related awards, may be granted for up to a maximum of 14,937 shares to our directors, officers, key employees and consultants. Stock options granted under all Plans have a maximum contractual term of ten years from the date of grant, have an exercise price not less than the fair value of the stock on the grant date and generally vest over four years.

The following table summarizes the components of share-based compensation expense in the consolidated statements of operations:

December 31,

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

	<b>2010</b>	<b>2009</b>	<b>2008</b>
Research and development	\$ 7,878	\$ 9,049	\$ 6,063
Selling, general and administrative	23,194	19,682	17,619
<b>Total share-based compensation expense</b>	<b>\$ 31,072</b>	<b>\$ 28,731</b>	<b>\$ 23,682</b>

F-25

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008****(amounts in thousands, except per share amounts)**

For the year ended December 31, 2010, \$1,266 of share-based compensation expense was recognized in cost of sales that was previously capitalized into inventory. The corresponding amounts recognized in 2009 and 2008 are not material to the results of operations.

The following table summarizes the share-based compensation capitalized to inventory and fixed assets:

	<b>December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Share-based compensation expense capitalized to inventory	\$ 2,785	\$ 1,403	\$ 1,215
Share-based compensation expense capitalized to fixed assets	\$	\$ 970	\$ 1,626

The weighted average fair value at the date of grant for options granted during the years ended December 31, 2010, 2009 and 2008 is \$17.00, \$14.94 and \$16.93 per option, respectively.

As of December 31, 2010, there was \$55,354 of total unrecognized share-based compensation expense related to non-vested share-based compensation arrangements granted under the Plan. The expense is expected to be recognized over a weighted-average period of 2.57 years.

A summary of the status of our stock option plans at December 31, 2010, and changes during the year then ended is presented in the table and narrative below:

	<b>Number of shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (in years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2009	6,474	\$ 24.78		
Granted	1,465	48.07		
Exercised	(1,646)	22.81		
Forfeited and cancelled	(179)	36.80		
Outstanding at December 31, 2010	6,114	\$ 30.54	6.87	\$ 305,777
Vested and unvested expected to vest at December 31, 2010	5,874	\$ 30.09	6.81	\$ 296,417
Exercisable at December 31, 2010	3,684	\$ 23.08	5.84	\$ 211,729

Total intrinsic value of stock options exercised during the years ended December 31, 2010, 2009 and 2008 was \$64,656, \$33,335 and \$52,082, respectively. The Company primarily utilizes newly issued shares to satisfy the exercise of stock options. The total fair value of shares vested during the years ended December 31, 2010, 2009 and 2008 was \$20,039, \$20,734 and \$20,034, respectively.

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:

	<b>Year Ended December 31, 2010</b>	<b>Year Ended December 31, 2009</b>	<b>Year Ended December 31, 2008</b>
Expected life in years	3.55 - 5.90	3.67 - 6.24	3.67 - 7.73
Interest rate	0.84% - 2.16%	1.41% - 2.19%	1.44% - 3.53%
Volatility	40.70% - 42.48%	40.30% - 48.03%	40.25% - 61.39%
Dividend yield	-	-	-

F-26

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008****(amounts in thousands, except per share amounts)**

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, and we estimate the expected life of stock options based on historical experience of exercises, cancellations and forfeitures of our stock options.

A summary of the status of our non-vested Restricted Stock and changes during the period then ended is as follows:

	<b>Year Ended December 31, 2010</b>
Nonvested restricted stock, beginning of period	944
Shares issued	514
Shares cancelled	(56)
Shares vesting	(341)
<b>Nonvested restricted stock, end of period</b>	<b>1,061</b>
Weighted average grant date fair value	\$ 46.89

### **13. 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****For the Years Ended December 31, 2010, 2009 and 2008****(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.

**14. Fair Value Measurement**

Authoritative guidance 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 tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2010 and 2009, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

		<b>Fair Value Measurement at December 31, 2010</b>			
<b>Balance Sheet Classification</b>	<b>Type of Instrument</b>	<b>Total</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
Cash equivalents	Money market funds	\$ 186,565	\$	\$ 186,565	\$
Marketable securities	Commercial paper	\$ 65,261	\$	\$ 65,261	\$
Marketable securities	U.S. Corporate bonds	\$ 19,184	\$	\$ 19,184	\$
Marketable securities	Federal agency obligations	\$ 10,015	\$	\$ 10,015	\$
Other current assets	Foreign exchange forward contracts	\$ 9,365	\$	\$ 9,365	\$
Other assets	Foreign exchange forward contracts	\$ 590	\$	\$ 590	\$
Other current liabilities	Foreign exchange forward contracts	\$ 11,848	\$	\$ 11,848	\$
Other liabilities	Foreign exchange forward contracts	\$ 3,380	\$	\$ 3,380	\$

		<b>Fair Value Measurement at December 31, 2009</b>			
<b>Balance Sheet Classification</b>	<b>Type of Instrument</b>	<b>Total</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
Cash equivalents	Money market funds	\$ 87,971	\$	\$ 87,971	\$
Marketable securities	U.S. Corporate bonds	\$ 19,048	\$	\$ 19,048	\$
Other current assets	Foreign exchange forward contracts	\$ 5,209	\$	\$ 5,209	\$
Other assets	Foreign exchange forward contracts	\$ 2,061	\$	\$ 2,061	\$
Other current liabilities	Foreign exchange forward contracts	\$ 4,742	\$	\$ 4,742	\$

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008****(amounts in thousands, except per share amounts)****Valuation Techniques**

Items classified as Level 2 within the valuation hierarchy, consisting of an institutional money market fund held at a multinational financial institution and corporate and federal agency bonds and commercial paper, 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.

As of December 31, 2010, 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.

**15. Employee Benefit Plans****Defined Contribution Plan**

We have one qualified 401(k) plans covering all eligible employees. Under the plan, 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 of an individual's base salary and incentive cash bonus; and

\$0.50 for each dollar contributed of the next 2 percent of such compensation.

For the years ended December 31, 2010, 2009 and 2008, we recorded matching contributions of approximately \$1,893, \$1,552 and \$1,298, respectively.

**Defined Benefit Plan**

We maintain defined benefit plans for employees outside the United States, including a retirement benefit plan required by local law. The plans are 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 defined benefit plans:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Change in benefit obligation:</b>		
Projected benefit obligation, beginning of year	\$ 5,655	\$ 2,897
Prior service cost	76	
Service cost	2,240	763



Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-K

Interest cost	266	105
Change in assumptions	1,055	70
Recognized actuarial net loss	1,017	351
Foreign currency exchange rate changes	929	194
Transfers into plan	2,120	1,275
Projected benefit obligation, end of year	\$ 13,358	\$ 5,655
Accumulated benefit obligation, end of year	11,110	4,598

F-29

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008**

(amounts in thousands, except per share amounts)

	December 31,	
	2010	2009
<b>Change in plan assets:</b>		
Fair value of plan assets, beginning of year	\$ 4,737	\$ 2,420
Return on plan assets	108	107
Employer contributions	1,646	508
Plan participants' contributions	666	264
Foreign currency exchange rate changes	945	163
Transfers into plan	1,440	1,275
Fair value of plan assets, end of year	\$ 9,542	\$ 4,737
Funded status at end of year	\$ (3,816)	\$ (918)

The following table provides information about the fair value of the plan assets per asset category:

	December 31, 2010		December 31, 2009	
	Fair Value (Level 2)	as % of total plan assets	Fair Value (Level 2)	as % of total plan assets
Cash and cash equivalents	\$ 921	10%	\$	
Equity security funds	2,473	26%	1,326	28%
Debt security funds	4,934	52%	2,700	57%
Real estate funds	1,214	12%	711	15%
	<b>\$ 9,542</b>	<b>100%</b>	<b>\$ 4,737</b>	<b>100%</b>

At December 31, 2010, we have recorded a liability of \$3,816 in other non-current liabilities and a charge to accumulated other comprehensive income of \$3,018 related to an additional minimum liability.

The following table provides the weighted average assumptions used to calculate net periodic benefit cost and the actuarial present value of projected benefit obligations:

	December 31,	
	2010	2009
<b>Weighted average assumptions:</b>		
Discount rate	2.7%	3.5%
Long term rate of return on assets	4.0%	4.0%
Rate of compensation increase	1.5%	1.5%

The expected long-term rate of return on plan assets represents a weighted average of expected returns per asset category. It considers historical and estimated future risk free rates of return as well as risk premiums for the relevant investment categories.



**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008****(amounts in thousands, except per share amounts)**

The components of net pension expense are as follows:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Service cost	\$ 2,240	\$ 763
Interest cost	266	105
Expected return on plan assets	(265)	(99)
Employee contributions	(666)	(264)
Amortization of prior service costs	8	
Amortization and deferral of actuarial gain (loss)	35	12
<b>Net pension expense</b>	<b>\$ 1,618</b>	<b>\$ 517</b>

The investment objective of the collective trust is to maximize the overall return from investment income and capital appreciation considering investment strategies and asset allocation limits as determined by pension law. The targeted allocation for these funds (if any) is as follows:

	<b>Target Allocation Ranges in %</b>
Cash and notes receivable issued by banks or insurance companies	0-10%
Equity securities	16-40%
Debt securities	38-76%
Real estate	10-20%

Other changes in plan assets and benefit obligations recognized in other comprehensive income (OCI) for the year ended December 31, 2010 are as follows:

Amount included in OCI-beginning of year	\$ (886)
Prior service cost	(76)
Net gain (loss) arising during the period	(1,017)
Change in assumptions	(1,055)
Amortization of net gain (loss)	43
Plan assets losses	(157)
Taxes	130
<b>Amount included in OCI-end of year</b>	<b>\$ (3,018)</b>

We estimate that we will pay employer contributions of approximately \$2,372 in 2011. The expected future cash flows to be paid in respect of the pension plans as of December 31 were as follows:

**Estimated future benefit payments**

2011	\$ 612
2012	649
2013	779
2014	693
2015	724
2016 to 2020	3,423

F-31

**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008****(amounts in thousands, except per share amounts)****16. Revenue and assets by geography**

Revenues and tangible long-lived assets by significant geographic region are as follows:

Revenues:	Year Ended December 31,		
	2010	2009	2008
United States	\$ 205,792	\$ 159,829	\$ 113,299
Europe	274,919	215,763	143,645
Other	60,246	11,208	2,155
	\$ 540,957	\$ 386,800	\$ 259,099

  

Long-lived assets (1):	December 31,	
	2010	2009
United States	\$ 154,227	\$ 158,621
Europe	6,557	5,637
Other	1,456	433
	\$ 162,240	\$ 164,691

(1) Long-lived assets consist of property, plant and equipment.

**17. Subsequent Events**

On January 28, 2011, Alexion acquired Taligen Therapeutics, Inc. (Taligen), a privately held development-stage biotechnology company based in Cambridge, Massachusetts, in a transaction accounted for as a business combination. The acquisition was intended to broaden Alexion's portfolio of pre-clinical compounds and to expand Alexion's capabilities in translational medicine. Taligen's pre-clinical compounds include product candidates for the potential treatment of patients with ophthalmic diseases such as age-related macular degeneration (AMD), as well as other novel antibody and protein regulators of the complement inflammatory pathways. Alexion made an upfront cash payment of \$111,000 for 100 percent of Taligen's equity interests. Additional contingent payments would be earned upon reaching various clinical efficacy and product approval milestones in both the U.S. and European Union for up to six product candidates. If all such clinical efficacy and product approval milestones were achieved in both the U.S. and European Union for six product candidates, the total payments would be \$367,000.

On February 10, 2011, Alexion acquired patents and assets from Germany-based Orphatec Pharmaceuticals GmbH (Orphatec) related to an investigational therapy for patients with Type A molybdenum cofactor deficiency (MoCD), an ultra-rare disorder characterized by severe brain damage and rapid death in newborn infants. The acquisition will be accounted for as a business combination. Orphatec is a privately held development-stage biotechnology company with headquarters in Cologne, Germany. Alexion made an upfront cash payment of approximately \$3,000. Additional contingent payments of up to \$42,000 would be earned upon reaching various development, regulatory and commercial milestones. Alexion also established a research collaboration with key MoCD researchers from Orphatec to accelerate development of the investigational therapy.



**Table of Contents****Alexion Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2010, 2009 and 2008**

(amounts in thousands, except per share amounts)

**18. Quarterly Financial Information (unaudited)**

The following condensed quarterly financial information is for the years ended December 31, 2010 and 2009:

	Quarter Ended			
	March 31	June 30	September 30	December 31
<b>2010:</b>				
Revenues	\$ 117,578	\$ 125,834	\$ 141,569	\$ 155,976
Cost of sales	13,999	13,721	16,495	20,222
Operating expenses	73,009	79,788	82,361	90,724
Operating income	30,570	32,325	42,713	45,030
Net income	\$ 20,934	\$ 21,773	\$ 27,873	\$ 26,450
Earnings per common share				
Basic	\$ 0.24	\$ 0.24	\$ 0.31	\$ 0.30
Diluted	\$ 0.23	\$ 0.24	\$ 0.30	\$ 0.27
	March 31	June 30	September 30	December 31
<b>2009:</b>				
Revenues	\$ 81,267	\$ 92,256	\$ 102,628	\$ 110,649
Cost of sales	9,959	10,313	11,895	12,892
Operating expenses	55,741	60,993	62,846	75,102
Operating income	15,567	20,950	27,887	22,655
Net income	\$ 14,506	\$ 16,802	\$ 26,731	\$ 237,127(1)
Earnings per common share				
Basic	\$ 0.18	\$ 0.20	\$ 0.31	\$ 2.70
Diluted	\$ 0.16	\$ 0.19	\$ 0.29	\$ 2.59

- (1) In the fourth quarter of 2009, we determined that it was more likely than not that a significant portion of our deferred tax assets in the United States, primarily net operating losses and research and development credits, would be realized. Accordingly, we recorded a tax benefit of \$215,516 as a result of reversing the valuation allowance on these deferred tax assets.