

ALEXION PHARMACEUTICALS INC

Form 10-K

February 23, 2009

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

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

or

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

Commission file number: 0-27756

ALEXION PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

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

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

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

Large Accelerated Filer: Accelerated Filer: Non-Accelerated Filer:

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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PART I

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

Note Regarding Forward-Looking Statements

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

Item 1. BUSINESS.

Overview

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

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

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

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

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

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

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

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

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

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

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

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

Litigation

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

Matters Relating to our Common Stock

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

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

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

Products and Development Programs

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

harmful micro-organisms;

cells containing foreign proteins known as antigens; and

potential disease-causing combinations of antigens and antibodies known as immune complexes.

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

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

PNH;

myasthenia gravis;

multifocal motor neuropathy;

asthma;

autoimmune and other hemolytic anemias;

atypical hemolytic uremic syndrome;

transplantation;

cold agglutinin disease;

membranoproliferative glomerulonephropathy type II (dense deposit disease);

Guillain-Barré syndrome;

rheumatoid arthritis;

age-related macular degeneration;

antiphospholipid antibody syndrome including the catastrophic form;

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autoimmune kidney disease;

lupus;

inflammatory skin and muscle disorders; and

specific types of multiple sclerosis.

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

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

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

* Investigator sponsored program

C5 Inhibitors

Complement proteins are a series of inactive proteins circulating in the blood. When activated by stimuli, including those associated with both acute and chronic inflammatory disorders, these inactive complement proteins are split by enzymes known as convertases into activated byproducts through the complement cascade.

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

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

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

activation and destruction of muscle and other tissue cells;

activation of white blood cells;

attraction of white blood cells into inflamed tissues;

production of inflammatory chemicals including tumor necrosis factor-alpha;

activation of blood-clotting systems;

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

activation of kidney cells; and

initiation of cell suicide programs in heart cells.

The following diagram illustrates the complement cascade:

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

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

reduction of red blood cell destruction (hemolysis);

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

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improvement of severe anemia;

improvement of disabling fatigue and other quality of life outcomes;

decrease or elimination of blood transfusion requirements;

reduction of inflammation and blood clotting activation;

reduction in chronic kidney disease; and

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

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

prevention and amelioration of asthmatic attacks;

enhancement of survival in organ transplantation models;

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

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

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

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

enhancement of survival in a model of lupus; and

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

Soliris

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

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

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

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

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

About Paroxysmal Nocturnal Hemoglobinuria, or PNH

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

C5 Inhibitor Immunotherapeutic Product Candidates

Eculizumab Development Programs: Chronic Hemolytic and Thrombotic Disorders

Atypical Hemolytic Uremic Syndrome (aHUS)

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

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

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

Catastrophic Antiphospholipid Syndrome (CAPS)

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

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

Cold Agglutinin Disease (CAD)

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

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

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

Eculizumab Development Programs: Nephrology

Antibody-Mediated Rejection (AMR)

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

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

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

Dense Deposit Disease (DDD)

Dense deposit disease, or DDD, also called Type II 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, often accompanied by nephrotic syndrome which is refractory to immunosuppressant therapy. In most cases, the disease evolves into chronic renal failure, requiring dialysis and renal transplantation.

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

Eculizumab Development Programs: Chronic and Debilitating Neurological Disorders

Myasthenia Gravis (MG)

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

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

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

Multifocal Motor Neuropathy (MMN)

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

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

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Eculizumab: New Formulation

Asthma

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

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

Other Product Candidates

Anti-CD200 Antibody: Oncology Programs

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

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

Antibody Discovery Technology Platform

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

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

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

Manufacturing

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

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

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

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

Sales and Marketing

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

Table of Contents**Customers**

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

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

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

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

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

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

Patents and Proprietary Rights

Patents and other proprietary rights are important to our business. Our policy is to file patent applications to protect technology, inventions and improvements to our technologies that are considered important to the development of our business. We also rely upon our trade secrets, know-how, and continuing technological innovations, as well as patents that we have licensed or may license from other parties, to develop and maintain our competitive position.

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

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

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

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

our products do not infringe the patents;

the patents are not valid; or

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

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

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It is our policy to require our employees, consultants and parties to collaborative agreements to execute confidentiality agreements upon the commencement of employment or consulting relationships or collaborations with us. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us is to be kept confidential and not to be disclosed to third parties except in specific circumstances. In the case of employees, the agreements also provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law.

License Agreements

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

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

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

Government Regulation

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

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

- (1) preclinical laboratory tests and animal tests;

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

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

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

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

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

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

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

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Orphan Drug Designation

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

Foreign Regulation

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

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

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

Reimbursement

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

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

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

Competition

There are currently no approved drugs other than Soliris for the treatment of PNH. However, many companies, including major pharmaceutical and chemical companies as well as specialized biotechnology companies, are engaged in activities similar to our activities. Universities, governmental agencies and other public and private research organizations also conduct research and may market commercial products on their own or through joint ventures. Many of these entities may have:

substantially greater financial and other resources;

larger research and development staffs;

lower labor costs; and/or

more extensive marketing and manufacturing organizations.

Many of these companies and organizations have significant experience in preclinical testing, human clinical trials, product manufacturing, marketing, sales and distribution and other regulatory approval and commercial procedures. They may also have a greater number of significant patents and greater legal resources to seek remedies for cases of alleged infringement of their patents by us to block, delay, or compromise our own drug development process.

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

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

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

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

Employees

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

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Item 1A. RISK FACTORS

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

Risks Related to Our Lead Product Soliris

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

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

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

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

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

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

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

acceptance of Soliris in the medical community;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

administrative and judicial sanctions, including, warning letters;

finest and other civil penalties;

withdrawal of a previously granted approval;

interruption of production;

operating restrictions;

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

product recall or seizure;

injunctive; and

criminal prosecution.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

long treatment time required to demonstrate effectiveness;

lack of sufficient supplies of the product candidate;

disruption of operations at the clinical trial sites;

adverse medical events or side effects in treated patients;

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

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

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

lack of sufficient funds;

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

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

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

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

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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.

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

Our business requires using sensitive technology, techniques and proprietary compounds that we protect as trade secrets. However, we may also rely heavily on collaboration with suppliers, outside scientists and other drug companies. Collaboration presents a strong risk of exposing our trade secrets. If our trade secrets were exposed, it would help our competitors and adversely affect our business prospects.

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

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

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

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

Soliris and our product candidates do not infringe the patents;

the patents are not valid; or

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

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

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

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Risks Related to Our Operations

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

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

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

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

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

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

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

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

the cost necessary to sell, market and distribute Soliris;

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

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

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

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

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

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

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

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

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

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

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

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territory, or expand development programs for of our product candidates, or that there will not be a further deterioration in financial markets and confidence in economies. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back or eliminate our research and development activities or future operations. We might have to license our technology to others or relinquish commercialization rights. This could result in sharing revenues that we might otherwise retain for ourselves. Any of these actions would harm our business.

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

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

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

We are significantly leveraged.

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

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

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

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

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

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

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

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

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

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

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

substantial cash expenditures;

potentially dilutive issuance of equity securities;

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

difficulties in assimilating the operations of the acquired companies;

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

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

the potential loss of our key employees or key employees of the acquired companies.

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

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

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

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

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

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

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

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

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

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

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

fluctuations in currency exchange rates;

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