ALEXION PHARMACEUTICALS INC Form 10-K February 29, 2008 Table of Contents

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-K**

## FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(D)

**OF** 

## THE SECURITIES AND EXCHANGE ACT OF 1934

x Annual report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934 For the fiscal year ended December 31, 2007

or

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

Commission file number: 0-27756

## ALEXION PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(Address of Principal Executive Offices) (Zip Code)

203-272-2596

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, par value \$0.0001 Rights to Purchase Junior Participating Cumulative Preferred Stock

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 x 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 x

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 x 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. x

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

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: x Accelerated Filer: "Non-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, 2007, was approximately \$1,658,668,873.68.

The number of shares of Common Stock outstanding as of February 25, 2008 was 38,106,662.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s Definitive Proxy Statement to be used in connection with its Annual Meeting of Stockholders to be held on May 9, 2008, 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. a its subsidiaries.

## **Note Regarding Forward-Looking Statements**

This annual report on Form 10-K contains forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management s beliefs and certain assumptions made by our management, and may include, but are not limited to, statements regarding the potential benefits and commercial potential of Soliris® (eculizumab), timing and effect of sales of Soliris in various European markets, status of reimbursement, price approval and funding processes in Europe, progress in developing commercial infrastructure and interest and sense of urgency 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, including pending litigation, the sufficiency of our existing capital resources and projected cash needs, results of pending litigation, assessment of impact of recent accounting pronouncements as well as assumptions relating to the foregoing. Words such as anticipates, expects, intends, 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

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

Since our incorporation in January 1992 until April 2007, we have devoted most of our resources to drug discovery, research, and product and clinical development. In March 2007, the Food and Drug Administration, or

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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. We are engaging with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country. We are more complete in those processes in certain countries such as Germany and in earlier stages in other countries such as the United Kingdom. In some European countries, we continue meaningful sales to individual patients through approved named-patient programs.

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 European headquarters in Paris, France, Alexion International S.a.r.l., our European shared service center in Lausanne, Switzerland, and additional sales and marketing subsidiaries in Belgium, France, Germany, Italy, Spain, Switzerland and the United Kingdom.

We have submitted an application for marketing authorization in Australia for Soliris for the treatment of patients with PNH. The application was accepted for priority review. Soliris has received Orphan Drug Designation in Australia, which provides certain regulatory and filing fee advantages, including market exclusivity for several years after approval. We have been authorized by the Pharmaceutical and Medical Devices Agency in Japan to begin a clinical trial of Soliris for PNH, and have commenced dosing in January 2008.

We are also focusing our research efforts on the use of eculizumab in other indications, including use in rare and severe complement-mediated conditions and in chronic and debilitating neurological disorders. Separate studies on the effectiveness of eculizumab in treating myasthenia gravis and multifocal motor neuropathy are expected to begin in 2008. We are also aware that independent investigators have commenced a study to evaluate eculizumab in organ transplantation. In Canada, we received regulatory approval from Health Canada to begin testing intravenous eculizumab in severe asthma patients and commenced dosing during the fourth quarter of 2007.

In addition, we anticipate beginning a clinical study of the safety and efficacy of an antibody to the immune regulator CD200 in chronic lymphocytic leukemia in 2008.

We have incurred operating losses since our inception. As of December 31, 2007, we had an accumulated deficit of \$729 million. We expect to incur operating losses and negative cash flow for additional future periods due to costs associated with the commercialization of Soliris in the United States and Europe, pre-commercialization activities and anticipated commercialization activities in other countries, development of our manufacturing plant in Rhode Island, including engineering and validation runs, product research and development, preclinical studies and clinical testing, regulatory activities, commercial-scale manufacturing at our third party contractor and at our own manufacturing plant when that site is approved to manufacture Soliris, and other infrastructure support costs.

Until we can generate sufficient levels of cash from our operations, we expect to continue to finance future cash needs primarily through the use of available cash, cash equivalents and short-term investments, availability

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under our credit agreement and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements.

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.

#### Recent Developments

In February 2008, we agreed to purchase certain patents related to complement-inhibition technology from Oklahoma Medical Research Foundation, or OMRF. We will pay \$10 million, plus interest, to OMRF for the rights to the patents, in various amounts to be remitted in 2008 and the first half of 2009. No further amounts, including royalties, will be owed to OMRF in respect of sales of Soliris or other use of the patents. Accordingly, the previously announced claims filed by OMRF and counterclaims filed by Alexion in the U.S. District Court for the Northern District of Oklahoma will be dismissed.

In February 2008, we entered into a credit agreement with Bank of America, N.A.. The agreement provides for an available \$25 million revolving credit facility that can be used for working capital requirements and other general corporate purposes. The loan is collateralized by substantially all of Alexion Pharmaceuticals, Inc.'s assets, including the pledge of the equity interests of certain direct subsidiaries, but excluding intellectual property, assets of foreign subsidiaries and assets related to our manufacturing facility in Smithfield, Rhode Island. The borrowing base is limited to 80% of eligible domestic accounts receivables, as defined. We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.75% to 2.25% depending on Alexion's liquidity (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect and (B) the Federal Funds Rate then in effect plus 0.50%, plus 0% to 0.25% depending on Alexion's 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.

## **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

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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;
other hemolytic diseases;
myasthenia gravis;
multifocal motor neuropathy;
asthma;
transplantation;
Guillain-Barre syndrome;
rheumatoid arthritis;
age-related macular degeneration;
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 State and Europe, 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 are as follows:

**Program** Indication Stage Soliris (eculizumab) Paroxysmal Nocturnal Hemoglobinuria Approved (U.S. and E.U.) (PNH) Eculizumab (intravenous) Myasthenia Gravis Preclinical Preclinical Multifocal Motor Neuropathy Asthma Phase I/II Preclinical Eculizumab (intravitreal) Age-Related Macular Degeneration CD200 Mab CLL, Multiple Myeloma Phase I Preclinical DC-SIGN Mab Cancer Vaccine C5 Inhibitors

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

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

lysis, or destruction, of red blood 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 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.

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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;

improvement of severe anemia;

improvement of disabling fatigue and other quality of life outcomes; and

decrease or elimination of blood transfusion requirements.

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 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.

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#### **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. Soliris is a humanized antibody that, at the doses currently prescribed, blocks complement activity for one to two weeks after a single dose. The initial indication for which we have received FDA and E.C. approval for Soliris was PNH.

The FDA granted marketing approval for Soliris for patients with PNH in March 2007 and the E.C. approved the use of Soliris for patients with PNH in the European Union in June 2007. 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 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 in the United States and in the European Union with our own sales force. We are engaging with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country. We are more complete in those processes in certain countries such as Germany and in earlier stages in other countries such as the United Kingdom. In some European countries, we continue meaningful sales to individual patients through approved named-patient programs.

We submitted an application for marketing authorization in Australia for Soliris for the treatment of patients with PNH and the application was accepted for priority review. Soliris has received Orphan Drug Designation in Australia, which provides certain regulatory and filing fee advantages, including market exclusivity for several years after approval. In addition, we the Pharmaceutical and Medical Devices Agency in Japan authorized us to begin our clinical trial of Soliris for PNH and we commenced dosing in January 2008.

## 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 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.

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## **Eculizumab Development Programs**

#### Asthma

Asthma is a chronic respiratory disease that results in bronchial inflammation and airway constriction that prompts asthma shallmark symptoms shortness of breath, chest tightness and wheezing.

In May 2005, we announced the results of an animal model study which demonstrated that treatment with an anti-C5 complement blocking antibody significantly reduced bronchial inflammation and airway constriction. The study, conducted by our researchers, the Yale University School of Medicine, and the Brigham and Women s Hospital, was published in the June 2005 issue of the Journal of Clinical Investigation.

The study suggested that both C5a and C5b-9 contribute to the initiation of airway inflammation and in immediate and sustained airway hyperreactivity. 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.

The anti-C5 blocking antibody, unlike existing asthma therapies high-dose inhaled and oral corticosteroids blocked a wide range of inflammatory mediators known to contribute to the severity and persistence of asthma, including white blood cells and inflammatory mediators from eosinophils and neutrophils. These data suggest a direct role for complement-mediated inflammation in the pathogenesis of severe asthma.

In Canada, we received regulatory approval from Health Canada to begin testing intravenous eculizumab in severe asthma patients. We began dosing patients for this trial during the fourth quarter of 2007.

## Myasthenia Gravis

Myasthenia gravis, or MG, is a rare autoimmune syndrome characterized by the failure of neuromuscular transmission. Patients with MG produce antibodies that damage communication between an individual's nerve ending and muscle. 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.

Acetylcholine is a chemical that travels across the space between the nerve ending and the muscle. Acetylcholine then attaches to many receptor sites on the muscle, causing the muscle to contract due to activation of the receptor sites by the acetylcholine. An antibody present in patients with MG binds to the receptor sites, resulting in a substantial reduction in muscle activation.

Several lines of evidence suggest that complement activation at the neuromuscular junction might be the primary cause of acetylecholine receptor damage and failure of neuromuscular transmission. Therefore, we are studying inhibition of complement activation as a potential approach to prevent the neuromuscular damage caused in MG.

We have collaborated with researchers at Case Western Reserve University to evaluate the potential utility of complement inhibition in MG. In an experimental rodent model of MG, a surrogate anti-C5 antibody

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prevented experimentally acquired MG, and inhibited progression of disease in two-thirds of the subject rodents. The investigators concluded that C5 blockade protects against the development of severe experimentally acquired MG and provides support that complement inhibition is a viable treatment approach for human MG. This data has recently been published in the *Journal of Immunology* (2007;179:8562 8567).

During the fourth quarter of 2007, we began planning a new clinical development program for eculizumab in severe MG. We have obtained expert consultation from several leading neurologists in order to design a rational proof of concept trial in MG. We plan to initiate clinical development of eculizumab in MG in 2008.

#### Multifocal Motor Neuropathy

Multifocal motor neuropathy, or MMN, is a rare immune-mediated disorder of motor nerve fibers. MMN can be categorized as one of many autoimmune neuropathies, which include Guillain-Barre Syndrome, or GBS, and its variants, as well as chronic inflammatory demyelinating polyneuropathies. Demyelination is the removal of the insulating and protective protein, which covers nerve cells.

Patients with MMN demonstrate a slow, progressive asymmetrical weakness of limbs, muscle cramping and muscle twitching. Complement-activating antibodies have been identified as causing these conditions. Injury or destruction to the myelin sheath or the nerve cell results in decreased nerve conduction. The membrane attack complex, or MAC, or C5b-9, has been localized to nerve cells in MMN and complement-mediated nerve and muscle damage has been demonstrated.

Through a collaboration with neurology researchers at the University of Glasgow, the potential utility of anti-C5 antibody has been evaluated in a preclinical model. This model demonstrated that terminal complement is pathogenic in the nerve tissues and that inhibition with anti-C5 prevents complement-mediated nerve damage. In addition, clinical measurements of neuropathy were markedly improved. This data has been recently published in the January 2008 issue of the journal *Brain*.

During the fourth quarter of 2007, we began planning a new clinical development program for eculizumab in MMN. We plan to initiate clinical development of eculizumab in MMN in Europe in 2008.

## **Anti-CD200 Antibody**

We are developing an antibody for the treatment of B-Chronic Lymphocytic Leukemia, or B-CLL, an incurable chronic cancer that results from expansion of B-lymphocytes and other myeloid tumors such as multiple myeloma, or MM. Our antibody binds to CD200, a molecule 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. We have demonstrated the potent anti-tumor activity of our anti-CD200 antibody in a model of CLL, which was published in the January 2006 issue of the Proceedings of the National Academy of Sciences and presented at the 2006 meeting of the American Society for Clinical Oncology. Our anti-CD200 antibody drug candidates may have therapeutic application in patients suffering from B-CLL, MM and other blood and solid tumors with elevated CD200 expression.

We anticipate beginning a clinical study of Anti-CD200 antibody in chronic lymphocytic leukemia in 2008.

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## **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 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, autoimmune and inflammatory 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.

#### **Dendritic Cell Antibodies**

We are developing humanized antibodies to cell surface proteins, DC-SIGN, found exclusively on human dendritic cells, a type of human immune cell, and a related receptor, L-SIGN. Under the exclusive worldwide license agreement and research alliance with the University Medical Center of Nijmegen, The Netherlands, we received rights related to these molecules and any associated therapeutic product candidates, including already identified monoclonal antibodies. These products may have broad therapeutic application in several clinical settings including different cancers and infectious diseases, and in certain inflammatory disorders. This alliance broadens our interest in immune system modulation to also include human dendritic cells.

Dendritic cells have been identified as critical controllers of the immune system. In order for an immune response against foreign antigens to occur, these antigens must be displayed by antigen-presenting cells. While dendritic cells are an extremely rare immune cell type, they are the most potent of all the antigen presenting cells. Dendritic cells capture antigens in the peripheral tissues, process and display the antigen fragments on their cell surface, and then migrate from the periphery to the T-cell areas of the lymphoid organs. There they attract resting T-cells and present their antigen load, thus activating the T-cells to begin an immune response. This process appears to be controlled in part by the molecule DC-SIGN. We have recently demonstrated that our DC-SIGN antibody potently activates the immune system and exhibits significant anti-tumor activity in a model system.

## Strategic Alliance with Procter & Gamble

During 2006, we completed a final Phase III trial of another product candidate known as pexelizumab under a license and collaboration agreement with Procter & Gamble Pharmaceuticals, or P&G. After reviewing results from that trial, we along with P&G, determined not to pursue further development of pexelizumab for the cardiovascular indications being studied, and in March 2007, we and P&G terminated our license and collaboration agreement. Alexion retains ownership of pexelizumab without further obligations to P&G.

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## 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, manufacturing development and manufacturing of future products. We transferred our pilot manufacturing capabilities from New Haven, Connecticut to Smithfield, Rhode Island during 2007, and we expect to use 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. As required by the Lonza Agreement, we have remitted cash advances aggregating \$13.8 million through December 31, 2007. We executed the latest amendment to the Lonza Agreement in June 2007 to provide for additional purchase commitments of Soliris of \$30 million to \$35 million through 2013. Such commitments may only be cancelled in limited circumstances. We have agreed to purchase certain minimum quantities of product from Lonza under our existing arrangements. If we terminate the Lonza Agreement without cause, we will be required to pay for batches of product scheduled for manufacture under our arrangement.

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 and in the major markets in Europe. Our sales force is small in both the United States and Europe compared to other drugs with similar gross revenues; however, we believe the size of our 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 and Europe, we may create our own commercial organizations in such territories and market and sell Soliris through our own sales force. However, we will evaluate each jurisdiction on a country-by-country basis, and it is possible that we may 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 other countries.

## 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. Soliris is generally shipped directly from our third party warehouse to the patients health-care provider, who is not typically our direct customer.

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In European countries in which Soliris is currently commercially available and will be commercially available in the future, our customers are expected to be primarily hospitals, pharmacies and other healthcare facilities. In the United Kingdom, we have also entered into an agreement in which we will sell Soliris to a distributor. Until Soliris is commercially available in other European countries, we have entered into transitional agreements with a distributor to distribute Soliris, primarily under named-patient programs.

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 percent of net sales:

AmerisourceBergen 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 return rights, Soliris customers generally carry limited inventory.

## **Patents and Proprietary Rights**

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

We have filed several U.S. patent applications and international counterparts of certain of these applications. In addition, we have in-licensed several additional U.S. and international patents and patent applications. As of January 31, 2008, we own or in-license over 73 U.S. patents and 39 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, the dendritic cell program, and other technologies. We own or in-license 64 foreign patents and 138 pending foreign patent applications. We owe royalties and other fees to the licensors of some of those patents and patent applications in connection with Soliris for PNH, and we may owe royalties and fees with respect to any future commercial manufacture and sale of our product candidates.

We record actual and estimated royalties to third parties related to the sale and commercial manufacture of Soliris. These estimates may be influenced by the outcome of current litigation, the results of which are uncertain (see Note 9 of the Consolidated Financial Statements included in this Form 10-K beginning on page F-21). On a periodic basis and based on events such as the outcome of litigation, we may reassess these estimates, resulting in adjustments to cost of sales.

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

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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 humanized single chain antibodies, recombinant human antibodies, or recombinant human single chain antibodies. In addition to the legal actions filed by PDL BioPharma, Inc., OMRF, and SB2, Inc. (please see a description of the claims under the heading Legal Proceedings), we have received notices from the owners of other 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:

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.

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 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.

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## **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;
- (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
- (5) 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 are closely monitored and 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.

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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.

Under the Special Protocol Assessment procedure, a sponsor may seek the FDA is agreement on the design and size of a clinical trial intended to form the primary basis of an effectiveness claim. If the FDA agrees in writing, its agreement may not be changed after the trial begins, except in limited circumstances. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on it as the primary basis for approval with respect to effectiveness. The Phase III clinical program for Soliris for the PNH indication was conducted pursuant to an SPA. For future clinical trials related to other indications for Soliris or for other products, there can be no assurance that the FDA will agree to the design and size of future clinical trials, and there can be no assurance that any trial will have a successful outcome.

The results of the 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 FDA for reviewing a BLA, as well as annual fees for commercial manufacturing establishments and for approved products, can be substantial. The BLA review fee alone can exceed \$500,000, subject to certain limited deferrals, waivers and reductions that may be available. Each BLA submitted to 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 BLAs is six months for Priority applications and 10 months for Standard applications, whereupon a review decision is 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

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occur following initial marketing. Finally, 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 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, monies, and effort to maintain cGMP compliance.

#### **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

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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 to the European Medicines Agency, or EMEA, for Soliris for the treatment of PNH using the centralized procedure.

In June 2007, the 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. We are engaging with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country. We are more complete in those processes in certain countries such as Germany and in earlier stages in other countries such as the United Kingdom. In some European countries, we continue meaningful sales to individual patients through approved named-patient programs.

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.

#### 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 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 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.

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.

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## 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. Many biotechnology companies have focused their developmental efforts in the human therapeutics area, and many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or have made commercial arrangements with other biotechnology companies. A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us; in some instances, these products have already entered clinical trials or are already being marketed. Other companies are engaged in research and development based on complement proteins.

Each of Adprotech Ltd., Avant Immunotherapeutics, Inc., XOMA, Ltd., Novo Nordisk A/S, Archemix Corporation, Evolutec Ltd., Amgen Inc., Genentech, Inc., Pharming Group N.V., CSL-Behring, Peptech Ltd., Lev Pharma, Inc., Optherion, Inc., Jerini AG, 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, 2007, we had 434 full-time, world-wide employees, of which 226 were engaged in research, development, manufacturing, and clinical development, 114 in sales and marketing, and 94 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 Business

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. If we are unable to successfully commercialize and sell Soliris 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 successful commercialization of Soliris in the United States and in Europe and whether physicians, patients and healthcare payers view Soliris as therapeutically and cost effective. For the year ended December 31, 2007, sales related to Soliris constituted approximately 92% of our total revenue, and we expect that Soliris product sales will continue to contribute to a significant percentage of our total revenue over the next several years.

The commercial success of Soliris 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 the product;

successful launch of commercial sales of the product in Europe and successful continuation of commercial sales in the United States;

acceptance of the product in the medical community;

ability to effectively market and distribute the product in the United States and Europe;

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

receipt of marketing approvals from foreign regulatory authorities; and

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

We obtained marketing approval for Soliris in Europe in June 2007. We are engaging with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country. We are more complete in those processes in certain countries such as Germany and in earlier stages in other countries such as the United Kingdom. In some European countries, we continue meaningful sales to individual patients through approved named-patient programs. We cannot guarantee that reimbursement and other processes will be concluded successfully or on a timely basis and, as a result, sales in certain European countries may be delayed or never occur. If we are not successful in commercializing Soliris in the United States and in Europe, 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.

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Because the target patient population for Soliris 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 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.

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. 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. 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 may not be able to gain market acceptance among the medical community or patients which would prevent us from becoming profitable.

We cannot be certain that Soliris will gain market acceptance among physicians, patients, healthcare payers, and others. Although we have received regulatory approval for Soliris in the United States and Europe, it does 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 third-party coverage or reimbursement, and availability of alternative treatments, including bone marrow transplants. If Soliris fails to 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.

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.

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. However, for year ended December 31, 2007, our three top customers accounted for approximately 40%, 25% and 11% of our net product sales, and 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

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Soliris to patients. Although a number of specialty distributors and specialty pharmacies who supply physician office clinics, hospital outpatient clinics, infusion clinics or home health care providers and governmental organizations distribute Soliris, they generally carry a very limited inventory and may be reluctant to distribute Soliris in the future if demand for the product does not increase. Further, it is possible that our distributors could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to distribute smaller volume products such as Soliris, or cause higher product distribution costs, lower margins or the need to find alternative methods of distributing our product. Although we believe we can find alternative distributors on a relatively short notice, our revenue during that period of time may suffer and we may incur additional costs in switching from one distributor to another. 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 and maintain capabilities to sell, market and distribute our product, either through our own capabilities or by entering into agreements with others, 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. In Europe, regulatory and commercial requirements vary on a country by country basis and we cannot guarantee that we will have the capabilities or resources to successfully conclude the necessary processes and commercialize Soliris in every country in Europe. Reimbursement sources are different in each European country and in each country may include a combination of distinct potential payers, including private insurance and governmental payers. Even if we hire the qualified sales and marketing personnel we need in the United States and in Europe, 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 our product. Establishing and maintaining sales, marketing and distribution capabilities is expensive and time-consuming. Our expenses associated with building up and maintaining the sales force and distribution capabilities may be disproportional compared to the revenues we may be able to generate on sales of our product. We cannot guarantee that we will be successful in commercializing Soliris.

If we are unable to obtain 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.

Our future revenues and profitability will be adversely affected if we cannot depend on governmental, private third-party payers and other third-party payers, including Medicare and Medicaid in the United States and country specific governmental organizations in Europe, to defray the cost of Soliris to the consumer. If these entities refuse to provide coverage and reimbursement with respect to Soliris or determine to provide an insufficient level of coverage and reimbursement, Soliris may be too costly for general use, and physicians may

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not prescribe it. Soliris is significantly more expensive than traditional drug treatments. 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 our products 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.

Since Soliris is too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers is not available, our ability to successfully commercialize Soliris may be adversely impacted. Any limitation on the use of Soliris or any decrease in the price of Soliris will have a material adverse effect on our ability to achieve profitability.

Even where patients have access to insurance, their insurance co-payment amounts may be too expensive for them to afford. In the United States, Alexion will financially support 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 may be dependent on funding from Alexion, and we cannot guarantee that such funding will be provided by Alexion or other parties at adequate levels, if at all. We also anticipate that Alexion will provide 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 achieve profitability.

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

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. 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. We are currently engaging the appropriate authorities in major European markets on the operational, reimbursement, price approval and funding processes that are separately required by each European country. Our results of operations may suffer if we are unable to successfully and timely conclude such processes and begin to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

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If the use of our products harms people, or is perceived to harm patients even when such harm is unrelated to our products, our regulatory approvals could be revoked or otherwise negatively impacted, physicians may become less likely to prescribe our products, 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 our products could (1) lessen the frequency with which physicians decide to prescribe our products, (2) encourage physicians to stop prescribing our products to their patients who previously had been prescribed our products, (3) cause serious adverse events and give rise to product liability claims against us, and (4) result in our need to withdraw or recall our products 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. As a result, 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 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 covered types of 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 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 regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to Soliris, the investigation into the circumstance may be time consuming or 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.

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 the Neisseria bacteria prior to first administration of Soliris and all patients who are prescribed Soliris in the United States and

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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 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. Determination of significant complications associated with the delay or discontinuation of Soliris could have a material adverse effect on our ability to sell eculizumab for PNH.

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.

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 successfully. We depend on a few outside suppliers for manufacturing and a single manufacturer for commercial supply. 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 or our other drug candidates. We expect that it will be at least eighteen to twenty-four months 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 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 in Europe that is manufactured in this facility and we will continue to be subject to ongoing European regulatory inspection thereafter.

We have executed a commercial-scale product supply agreement with Lonza for the long-term manufacture of eculizumab on which we will be relying for manufacturing commercial sale quantities of Soliris. The failure of Lonza to manufacture appropriate supplies of eculizumab, on a timely basis, or at all, may prevent or impede the commercialization of Soliris. Lonza or we will be required to manufacture substantially more material than we have required for clinical and preclinical trials. 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.

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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 profitability would be materially and adversely affected.

Manufacture of drug products, including the need to develop and utilize manufacturing processes that consistently produce our drug products to their required quality specifications, is highly regulated by the FDA and other domestic and foreign authorities. 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 materially adverse effect on our business.

Manufacture of our drug products is highly technical and only a few third-parties have the ability and capacity to manufacture our drug products for our development and commercialization needs. We cannot assure you that these potential third-party collaborators will agree to manufacture our products on our behalf on commercially reasonable terms, if at all. If we do achieve agreement from one or more third parties to manufacture our drug products, we cannot assure you that they will be able or willing to honor the terms of the agreements, including any obligations to manufacture the drug products in accordance with regulatory requirements and to our quality specifications and volume requirements. Due to the highly technical requirements of manufacturing our drug products, our third-party collaborators and we may be unable to manufacture our drug products despite their and our efforts.

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. We could owe substantial penalty payments to Lonza if we were not to use the manufacturing capacity for which we 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.

If we continue to incur operating losses, we may be unable to continue our operations.

We have incurred losses since we started our company in January 1992. As of December 31, 2007, we had an accumulated deficit of approximately \$729 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. Since we began our business, we have focused on research and development of product candidates. We 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 commercializing Soliris in the United States and Europe, and we do not know when we will have products available for sale in other countries and regions, if ever. We expect to continue to operate at a net loss for additional periods as we transition from a research and development company to a sales and

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marketing company, 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 approval of Soliris in other countries, and our ability to successfully manufacture approved drugs. The extent and the timing of our future losses and our profitability, if we are ever profitable, are highly uncertain.

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 the development and continue the commercialization of our products and product candidates. We are currently selling and preparing for the commercialization of Soliris in several countries in Europe and conducting or evaluating several clinical trials. Funding needs may shift between projects and potentially accelerate and increase as we continue launch and commercialization activities throughout Europe 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 regulatory approvals for Soliris outside the United States and Europe and for eculizumab for other indications;

the ability to obtain 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 the necessary regulatory approvals for those facilities;

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

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

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

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

We may not receive funding when we need it or funding may only be available on unfavorable terms. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back or eliminate

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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 are unable to engage and retain third-party collaborators, our research and development efforts may be delayed.

In March 2007, we announced the termination of our collaboration with P&G relating to the joint development of pexelizumab in cardiovascular indications. Currently, none of our product candidates are being jointly developed with third party collaborators. We may experience significant delays in the development of our product candidates if we cannot engage additional collaborators when required. We would be required to devote additional funds or other resources to these activities or to terminate them. Either of these events would divert funds or other resources from other parts of our business.

We cannot assure you that:

we will be able to negotiate acceptable collaborative agreements to develop or commercialize our product candidates;

any arrangements with third parties will be successful; or

potential collaborators will not pursue treatments for other diseases or seek other ways of developing treatments for our disease targets.

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

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 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. Each of Adprotech Ltd., Avant Immunotherapeutics, Inc., XOMA, Ltd., Novo Nordisk A/S, Archemix Corporation, Evolutec Ltd., Amgen Inc., Genentech, Inc., Pharming Group N.V., CSL-Behring, Peptech Ltd., Lev Pharma, Inc., Optherion, Inc., Jerini AG, 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. 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. These and other pharmaceutical 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 even before we are able to finish our clinical trials. Other pharmaceutical companies also compete with us to attract academic research institutions as drug development partners, including for licensing these institutions proprietary technology. If

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our competitors successfully enter into such arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may not be able to find equivalent opportunities elsewhere.

If we fail to recruit and retain personnel, 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, David W. Keiser, our President, Chief Operating Officer and a member of our Board of Directors, and Stephen P. Squinto, Ph.D., our Executive Vice President and Head of Research. There is intense competition in the 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, Mr. Keiser, and Dr. Squinto. None of our key personnel is nearing retirement age or to our knowledge, planning to retire. To our knowledge, there is no tension between any of our key personnel and the Board of Directors. If we 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, 2007, we had outstanding \$150 million principal amount of 1.375% convertible senior notes which will mature on February 1, 2012. Our subsidiary Alexion Manufacturing borrowed \$44 million 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 credit agreement with Bank of America and may borrow up to \$25 million, with up to a \$5 million 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.

Our 1.375% convertible senior notes, the mortgage loan and the revolving credit facility 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 other purposes on favorable terms, if at all;

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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 that could disrupt our business and harm our financial condition.

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions to do so. Acquisitions involve numerous risks, including:

substantial cash expenditures;

potentially dilutive issuance of equity securities;

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

difficulties in assimilating the operations of the acquired companies;

diverting our management s attention away from other business concerns;

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

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

We cannot assure you that any acquisition will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions. We cannot assure you that we will be able to make the combination of our business with that of acquired businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired business or companies may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our 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.

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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.

As of December 31, 2007, we had approximately \$733 million of net operating loss carry forwards, or NOLs, available to reduce taxable income in future years. We believe that some of these NOLs are currently subject to an annual limitation under section 382 of the Internal Revenue Code of 1986, as amended.

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

#### **Risks Related to Our Industry**

We are subject to extensive government regulation and, if we do not maintain our regulatory approvals in the United States or in Europe, we will not be able to sell Soliris in such market.

We and our partners cannot sell or market our products without regulatory approval. We obtained marketing approval of Soliris in the United States and in Europe for PNH. 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. In the United States, we or our partners must obtain and maintain approval from the FDA for each indication for each drug that we intend to sell and for each facility where such drug is manufactured. Obtaining FDA approval is typically a lengthy and expensive process, and although we obtained approval for Soliris in PNH, approval is highly uncertain for our other drug candidates. Governments in Europe also regulate drugs distributed outside the United States and facilities outside the United States 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 in Europe, 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 may not receive regulatory approval for Soliris outside the United States and Europe or for any of our product candidates for at least the next several years, if ever.

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services from the market.

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 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. We are required to report any serious and unexpected adverse experiences and certain quality problems with Soliris to the FDA and the EMEA. We, the FDA or the EMEA may have to notify healthcare providers of any such developments. The discovery of any previously unknown problems with a product, manufacturer or facility may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product 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 our products 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 our products 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;
fines and other civil penalties;
delays in approving or refusal to approve a product candidate;
withdrawal of a previously granted approval;
product recall or seizure;
interruption of production;
operating restrictions;
injunctions; and
criminal prosecution

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The discovery of previously unknown problems with a product 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 one or more of our products or

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

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 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. In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. 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.

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 other indications for Soliris, our business may be adversely affected.

All of our product candidates except Soliris are in early stages of development, and we do not expect our other product candidates to be commercially available for several years, if at all. Similarly, Soliris has not been approved for any indication other than for the treatment of patients with PNH, and we do not 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 materially harmed.

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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.

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

slow patient emornment, including for example due to the farity 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 of the product candidate being tested;
lack of sufficient funds;

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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.

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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 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 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.

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, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

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.

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## **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 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. Our drugs are expensive and time-consuming to test and develop. Without patent protection, competitors may copy our methods, or the chemical structure or other aspects of our drugs. Even if we obtain 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 in-licensed, may be found to infringe patents owned by or granted to others. In March 2007, we reported that two civil actions were filed against us relating to the commercialization of Soliris and the intellectual property rights of third parties. Oklahoma Medical Research Foundation, or OMRF, filed a civil action against us in Oklahoma alleging, among other things, breach of contract of an existing license agreement between OMRF and Alexion and Alexion s willful infringement of OMRF patents. During the first quarter of 2008, Alexion acquired all rights to the relevant patents for a total payment of \$10 million; and OMRF agreed to withdraw its civil action and release Alexion from all liabilities in connection with such license agreement and patents. PDL BioPharma, Inc., or PDL, filed a civil action against us in Delaware, alleging willful infringement of PDL patents. If it is finally determined that we infringe the PDL patents, we may be required to pay royalties to PDL on sales of Soliris. in January 2008, SB2, Inc. filed a civil action against us relating to the commercialization of Soliris and alleged infringement of SB2, Inc. s intellectual property rights. If it is finally determined that we infringe the SB2, Inc. patents, we may be required to pay royalties to SB2, Inc. on sales of Soliris. Although we do not believe that any valid patent of PDL or SB2, Inc. is necessary for the commercialization of Soliris, we cannot guarantee that we will be successful in defending against such actions. If we cannot successfully defend against these or any other future actions or conflicts, 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.

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 single chain 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 humanized single chain antibodies, recombinant human antibodies, or

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recombinant human single chain antibodies. In addition to the actions filed by PDL and SB2, Inc., 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:

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.

In addition to PDL and SB2, Inc., 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 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 have a material adverse effect on our business.

There can be no assurance that we would prevail in a patent infringement action, including the PDL and SB2, Inc. actions; 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.

## Risks Related to Our Common Stock

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

The trading price of our common stock has been volatile and may continue to be volatile in the future. Factors such as announcements of fluctuations in our or our competitors—operating results or clinical or scientific results, fluctuations in the trading prices or business prospects of our competitors and collaborators, changes in our prospects, particularly with respect to sales of Soliris, and market conditions for biopharmaceutical stocks in general could have a significant impact on the future trading prices of our common stock and our convertible senior notes. In particular, the trading price of the common stock of many biopharmaceutical companies, including ours, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of the companies whose stocks were affected. This is due to several factors, including general market conditions, the announcement of the results of our clinical trials or product development, the results of our efforts to obtain regulatory approval for our products and sales of Soliris. In particular, since August 1, 1999, the sales price of our common stock has ranged from a low of \$9.05 per share to a high of

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\$119.88 per share. While we cannot predict our future performance, if our stock price continues to fluctuate in a wide range, an investment in our common stock may result in considerable uncertainty for an investor.

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

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

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

Pursuant to our stockholder rights plan, each share of common stock has an associated preferred stock purchase right. The rights will not trade separately from the common stock until, and are exercisable only upon, the acquisition or the potential acquisition through tender offer by a person or group of 20% or more of the outstanding common stock. The rights are designed to make it more likely that all of our stockholders receive fair and equal treatment in the event of any proposed takeover of us and to guard against the use of partial tender offers or other coercive tactics to gain control of us.

These provisions could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices. These provisions could also limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and could adversely affect the price of our common stock.

Item 1B. UNRESOLVED STAFF COMMENTS.
None

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#### Item 2. PROPERTIES.

We lease our headquarters and research and development facilities in Cheshire, Connecticut. The lease, which had an initial term of ten years and six months, expiring in December 2010, was extended in June 2007 to expire in May 2017. At this site, we lease approximately 125,424 square feet of space.

Alexion Manufacturing, LLC owns a manufacturing facility in Smithfield, Rhode Island, which it purchased in July 2006. The facility is approximately 56,500 square feet, with approximately 25,000 square feet of manufacturing space and 31,500 square feet of clinical and office space.

We did not renew our lease for our New Haven, Connecticut facility, encompassing approximately 33,000 square feet of labs and offices, and the lease expired in October 2007. We relocated our pilot manufacturing plant, which may be used for producing compounds for some of our current and anticipated clinical trials, to Smithfield, Rhode Island.

We lease approximately 18,000 square feet of labs, office and unimproved storage space in San Diego, California. The lease has an initial term of ten years, expiring in August 2012. We ceased operations in California as of December 31, 2006 and entered into a sublease for the entire premises in September 2007.

Alexion Europe SAS rents approximately 350 square meters of office space in Paris, France. The agreement has automatic renewal features built in until the agreement is terminated by either party or December 2008, whichever is earlier.

Additionally, we lease office space in multiple countries in Europe to support our commercial activities. These agreements have automatic renewal features until the agreement is terminated by either party. The earliest agreement is set to expire in December 2008.

We believe that our administrative office space is adequate to meet our needs for the foreseeable future. We also believe that our research and development facilities and our manufacturing facility, together with third party manufacturing facilities, will be adequate for our on-going activities.

## Item 3. LEGAL PROCEEDINGS.

As previously reported in Alexion s filings with the SEC, Oklahoma Medical Research Foundation, or OMRF, PDL BioPharma, Inc., or PDL, and SB2, Inc., or SB2, each filed a civil action against Alexion in federal district court.

On March 15, 2007, OMRF filed a civil action against Alexion in the U.S. District Court for the Northern District of Oklahoma, alleging, among other things, allege (i) breach of contract by Alexion , (ii) willful infringement by Alexion of an OMRF patent, and (iii) fraud and constructive fraud under Oklahoma law. During the first quarter of 2008, Alexion agreed to acquire all rights to the relevant patents for a total payment of \$10 million; and OMRF withdrew its civil action and released Alexion from all liabilities in connection with such license agreement and patents.

On March 16, 2007, PDL filed a civil action against Alexion in the U.S. District Court for the District of Delaware. PDL claims willful infringement by Alexion of PDL patents due to sales of Soliris. PDL seeks

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unspecified damages, but no less than a reasonable royalty, plus attorney s fees. Alexion has denied PDL s claims. In addition, we filed counterclaims seeking declarations of non-infringement and invalidity of PDL patents U.S. no. 5,693,761, no. 5,693,762 and no. 6,180,370 B1.

On January 31, 2008, SB2 filed a civil action against Alexion in the U.S. District Court for the Northern District of California. SB2 claims willful infringement by Alexion of SB2 patents due to sales of Soliris. SB2 seeks unspecified monetary damages, equitable relief and attorneys fees. Alexion believes it has good and valid defenses to SB2's claims and intends to vigorously defend the case.

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

There were no matters submitted to a vote of security holders during the fourth quarter of 2007.

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

The executive officers and key employees of the Company and their respective ages and positions with the Company as of February 25, 2008 are as follows:

Name	Age	Position with Alexion
* Leonard Bell, M.D.	49	Chief Executive Officer, Secretary, Treasurer, Director
* David W. Keiser	56	President, Chief Operating Officer and Director
* Stephen P. Squinto, Ph.D.	51	Executive Vice President and Head of Research
* Patrice Coissac	59	Senior Vice President General Manager and President of Alexion Europe SAS
* Thomas I.H. Dubin, J.D.	45	Senior Vice President and General Counsel
David L. Hallal	41	Senior Vice President, United States Commercial Operations
Nancy C. Motola, Ph.D.	55	Senior Vice President, Regulatory Affairs and Quality
Russell P. Rother, Ph. D.	47	Senior Vice President, Research
* Vikas Sinha, M.B.A., C.A.	44	Senior Vice President and Chief Financial Officer
Eric Grinstead	50	Vice President, United States Access Services
M. Stacy Hooks, Ph.D.	40	Vice President, Manufacturing and Technical Services
Barry P. Luke, M.B.A.	49	Vice President, Finance, Assistant Secretary
Glenn Melrose	52	Vice President, Human Resources
Daniel N. Caron	44	Executive Director, Operations and Engineering

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

Leonard Bell, M.D. is the principal founder of Alexion, and has been a director of Alexion since February 1992 and the Company s President and Chief Executive Officer, Secretary and Treasurer from January 1992. In April 2002, the title of President was transferred to David Keiser. From 1991 to 1992, Dr. Bell was an Assistant Professor of Medicine and Pathology and co-Director of the program in Vascular Biology at the Yale University School of Medicine. From 1990 to 1992, Dr. Bell was an attending physician at the Yale-New Haven Hospital and an Assistant Professor in the Department of Internal Medicine at the Yale University School of Medicine. Dr. Bell was a recipient of the Physician Scientist Award from the National Institutes of Health and Grant-in-Aid from the American Heart Association as well as various honors and awards from academic and professional organizations. His work has resulted in more than 20 scientific publications and 9 patent applications. Dr. Bell was also a director of The Medicines Company from May 2000 until April 2005. He also served as a director of the Biotechnology Research and Development Corporation from 1993 to 1997. Dr. Bell received his A.B. from Brown University and M.D. from Yale University School of Medicine. Dr. Bell is currently an Adjunct Assistant Professor of Medicine and Pathology at Yale University School of Medicine.

David W. Keiser became President in addition to Chief Operating Officer, and joined the board as a director in April 2002. From July 1992 to April 2002, Mr. Keiser was Executive Vice President and Chief Operating Officer of Alexion. From 1990 to 1992, Mr. Keiser was Senior Director of Asia Pacific Operations for G.D. Searle & Company Limited, a manufacturer of pharmaceutical products. From 1986 to 1990, Mr. Keiser was successively Licensing Manager, Director of Product Licensing and Senior Director of Product Licensing for Searle. From 1984 to 1985, Mr. Keiser was New Business Opportunities Manager for Mundipharma AG, a manufacturer of pharmaceutical products, in Basel, Switzerland where he headed pharmaceutical licensing and

business development activities in Europe and the Far East. From 1978 to 1983, he was Area Manager for F. Hoffmann La Roche Ltd., a manufacturer of pharmaceutical products, in Basel, Switzerland. Mr. Keiser received his B.A. from Gettysburg College.

Stephen P. Squinto, Ph.D. is a founder of Alexion and has been Executive Vice President and Head of Research since August 2000. He held the positions of Senior Vice President and Chief Technical Officer from March 1998 to July 2000, Vice President of Research, Molecular Sciences, from August 1994 to March 1998, Senior Director of Molecular Sciences from July 1993 to July 1994, and Director of Molecular Development from 1992 to July 1993. From 1989 to 1992, Dr. Squinto held various positions at Regeneron Pharmaceuticals, Inc. most recently serving as Senior Scientist and Assistant Head of the Discovery Group. From 1986 to 1989, Dr. Squinto was an Assistant Professor of Biochemistry and Molecular Biology at Louisiana State University Medical Center. Dr. Squinto s work has led to over 70 scientific papers in the fields of gene regulation, growth factor biology and gene transfer. Dr. Squinto s work is primarily in the fields of regulation of eukaryotic gene expression, mammalian gene expression systems and growth receptor and signal transduction biology. Dr. Squinto served as a Director of the Biotechnology Research and Development Corporation, a biotechnology consortium, from 1997 to 2003. Dr. Squinto received his B.A. in Chemistry and Ph.D. in Biochemistry and Biophysics from Loyola University of Chicago.

Patrice Coissac, joined Alexion as Senior Vice President, General Manager and President of Alexion Europe SAS in November 2005. Mr. Coissac has a broad international background in the pharmaceutical industry. Most recently since mid 2004, he founded and ran his own consulting firm to serve the bio pharmaceutical companies in their strategic development. Previously he was President of Pharmacia SAS in France, a position he held from 1999 to mid 2003 when Pharmacia was acquired by Pfizer. While at Pharmacia, Mr. Coissac was responsible for the integration of Monsanto (Searle) with Pharmacia & Upjohn in France. During his tenure, sales grew almost three fold to 615 millions in 2002. Prior to joining Pharmacia, Mr. Coissac held several managerial positions at leading pharmaceutical companies including Head of Operations for Novartis, Belgium; and President of Boehringer Mannheim Therapeutics in France. Mr. Coissac also served as Senior Vice President, Marketing for global pharmaceutical operations at Corange International. And previously, he held several global marketing positions in Sandoz Pharmaceuticals: in Tokyo where he was posted during several years, in Switzerland in Sandoz World Headquarters and in France at the beginning of his career.

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

**David Hallal** has been Senior Vice President of US Commercial Operations since November 2007. He was Vice President, US Commercial Operations from June 2006 until November 2007. Mr. Hallal is responsible for all Commercial Functions in the U.S. Market, including marketing, sales, and reimbursement/access. Prior to Alexion, from April 2004 to June 2006, Mr. Hallal was Vice President of Sales at OSI Eyetech where he led the U.S. launch of the first-in-class anti-VEGF therapy, Macugen for age-related macular degeneration. From August 2002 to February 2004, Mr. Hallal was Senior Director of Sales for Biogen Idec's Immunology Sales Team,

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where he built a sales organization dedicated to the launch of the first-in-class biologic Amevive for psoriasis. For more than ten years starting in 1992, Mr. Hallal held various leadership positions at Amgen, focusing on the blockbuster brands Epogen, Neupogen, Neulasta and Aranesp in the hematology and oncology marketplace. More specifically from April 1999 to August 2002, he served as the Southeast Oncology Sales Director and Oncology Health Systems Sales Director. From 1998 to 1999, Mr. Hallal served as Amgen's Director of Oncology National Accounts. From 1992 to 1998, Mr. Hallal served in roles of escalating responsibility for the promotion of Epogen and Neupogen, including National Account Manager where he was responsible for forging relationships with many of the largest managed care organizations in the U.S. He holds a B.A. from the University of New Hampshire.

Nancy C. Motola, Ph.D., RAC has been the Senior Vice President, Regulatory Affairs and Quality since 2004. Dr. Motola was Vice President, Regulatory and Quality from 1998 to 2004. From 1991 to 1998, she served as Assistant, Associate and then Deputy Director, Regulatory Affairs for the Bayer Corporation Pharmaceuticals Division where she was responsible for regulatory aspects of product development and U.S. life-cycle management programs for cardiovascular, neuroscience, metabolic and oncology drugs. These programs included drugs targeting arthritis, cancer, cardiac disorders, stroke and cognitive dysfunction. Prior to Bayer, Dr. Motola held regulatory affairs positions of increasing responsibility at Abbott Laboratories from 1989 to 1991 and E.R. Squibb and Sons, Inc. from 1987 to 1989. From 1983 to 1987, she was Research Investigator, Chemical Process Technology at Squibb. Dr. Motola has been responsible for the filing of numerous Investigational New Drug Applications (INDs) and has filed New and Supplemental Drug Applications for marketing approval, resulting in marketed drugs. She also served as Chairperson of the Regulatory Sciences Section of the American Association of Pharmaceuticals Scientists (AAPS). Dr. Motola is Regulatory Affairs (RAC) certified and received her B.A. in Chemistry from Central Connecticut State University and M.S. and Ph.D. degrees in medicinal chemistry from the University of Rhode Island, College of Pharmacy.

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

Vikas Sinha, M.B.A., C.A. joined Alexion as Senior Vice President and Chief Financial Officer in September 2005. From June 1994 to August 2005, Mr. Sinha held various positions with Bayer AG in the United States, Japan, Germany, and Canada, most recently serving since February 2001 as Vice President and Chief Financial Officer of Bayer Pharmaceuticals Corporation, USA. Mr. Sinha has been responsible for financial and business risk management, strategic planning, contracting, customer services, information systems, and supply chain and site administration in North America. Mr. Sinha was also a member of the Pharmaceutical Management Committee for North America. Prior to his appointment in the United States, Mr. Sinha was Vice

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President and Chief Financial Officer of Bayer Yakuhin Ltd., in Japan and Manager, Mergers and Acquisitions with Bayer AG in Germany. He began his career at Bayer in Toronto as part of an executive development program in the healthcare division. Prior to Bayer, Mr. Sinha held several positions of increasing responsibilities with ANZ Bank and Citibank in South Asia. Mr. Sinha holds a Masters of Business Administration from the Asian Institute of Management which included an exchange program with the University of Western Ontario (Richard Ivey School of Business). He is also a qualified Chartered Accountant from the Institute of Chartered Accountants of India.

Eric Grinstead has been Vice President of US Commercial Operations since September 2007. These responsibilities include strategic and operational responsibility for the pricing, policy, health economics, distribution, national accounts, payor and channel segments, case management services and other access programs and functions in the United States. He was Executive Director for US Access Services at Alexion from September 2006 until September 2007. Prior to joining Alexion, Mr. Grinstead was Senior Director of Patient and Product Services at Genzyme Corporation, where he led Genzyme s distribution, collections, case management, customer service and national accounts efforts for Genzyme s LSD Division from January 2005 through Sept 2006. From July 1998 to January 2005, Mr. Grinstead held a number of commercial positions for Amgen including State Reimbursement and Strategic Alliances Manager and Marketing and Value-Access Associate Director for the Inflammatory and Renal Business Units. Mr. Grinstead worked for GlaxoSmithKline as a salesman, sales manager and state lobbyist before joining Amgen in 1998. Mr. Grinstead holds a B.A. in Religious Studies from Westmont University in Santa Barbara, CA.

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

**Barry P. Luke, M.B.A.** has been Vice President, Finance since September 1998 and Senior Director of Finance and Administration of Alexion from August 1995 to September 1998. Prior thereto he was Director of Finance and Accounting of the Company from May 1993 to August 1995. From 1989 to 1993, Mr. Luke was Chief Financial Officer, Secretary and Vice President-Finance and Administration at Comtex Scientific Corporation, a publicly held distributor of electronic news and business information. From 1985 to 1989, he was Controller and Treasurer of Softstrip, Inc., a manufacturer of computer peripherals and software. From 1980 to 1985, Mr. Luke was employed by General Electric Company where he held positions at GE s Corporate Audit Staff after completing GE s Financial Management Program. Mr. Luke received a B.A. in Economics from Yale University and an M.B.A. in management and marketing from the University of Connecticut.

Glenn Melrose joined Alexion as Vice President, Human Resources in July 2007 after serving in the same position at NPS Pharmaceuticals, Inc. from June 2005. He began his career as a scientist at the University of Maryland Cancer Center and Becton Dickinson before joining Amersham Diagnostics in 1988. At Amersham, he held various positions of increasing responsibility in sales and marketing, before rising to the position of Vice

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President, Human Resources, North America, ultimately leading the worldwide Human Resources function for Amersham Biosciences in 2003 and 2004. Mr. Melrose received a B.S. in Biology from Washington and Lee University and an M.S. in Experimental Biology from the University of Maryland.

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

#### **PART II**

# Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is quoted on The Nasdaq Stock Market, LLC under the symbol ALXN. The following table sets forth the range of high and low sales prices for our common stock on The Nasdaq Stock Market, LLC for the periods indicated since January 1, 2006.

Fiscal 2006	High	Low
First Quarter		
(January 1, 2006 to March 31, 2006)	\$ 38.40	\$ 20.06
Second Quarter		
(1. 11.4.2004 7. 20.2004)	****	<b></b>
(April 1, 2006 to June 30, 2006)	\$ 36.12	\$ 30.10
Third Quarter		
(July 1, 2006 to September 30, 2006)	\$ 38.68	\$ 31.46
Fourth Quarter	Ψ 30.00	Ψ 31.40
(October 1, 2006 to December 31, 2006)	\$ 45.40	\$ 34.84
Fiscal 2007		
First Quarter		
(January 1, 2007 to March 31, 2007)	\$ 43.78	\$ 35.77
Second Quarter		
(April 1, 2007 to June 30, 2007)	\$ 50.13	\$ 41.86
Third Quarter	ψ 50.15	Ψ 41.00
Time Variety		
(July 1, 2007 to September 30, 2007)	\$ 66.70	\$ 45.93
Fourth Quarter		
(October 1, 2007 to December 31, 2007)	\$ 79.80	\$ 66.83

As of February 25, 2008, we had 415 stockholders of record of our common stock and an estimated 5,000 beneficial owners. The closing sale price of our common stock on February 25, 2008 was \$60.95 per share.

In November 2006, we sold 3,450,000 shares of common stock in a public offering at \$43.00 per share, resulting in gross proceeds from the sale of approximately \$148.3 million. We incurred underwriting fees and commissions of approximately \$8.1 million as well as other costs, resulting in net proceeds of approximately \$140.2 million. We will utilize the proceeds from this offering to fund general corporate obligations.

## DIVIDEND POLICY

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

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## **EQUITY COMPENSATION PLAN INFORMATION**

Plan Category	Number of shares of common stock to be issued upon exercise of outstanding options (2)	Weighted- average exercise price of outstanding options	Weighted- average term to expiration of options outstanding	Number of shares of common stock remaining available for future issuance under equity compensation plans
Equity compensation plans approved by stockholders				
(1)	4,194,723	33.64	6.97	1,620,190

Equity compensation plans not approved by stockholders

- (1) Reflects number of shares of common stock to be issued upon exercise of outstanding options under all of our equity compensation plans, including our 2004 Incentive Plan. No shares of common stock are available for future issuance under any of our equity compensation plans, except the 2004 Incentive Plan.
- (2) Does not include 454,484 restricted shares outstanding that were issued under the 2004 Incentive Plan.
- (3) The outstanding options and restricted shares are not transferable for consideration and do not have dividend equivalent rights attached.

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#### THE COMPANY S STOCK PERFORMANCE

The following graph compares cumulative total return of the Company s Common Stock with the cumulative total return of (i) the NASDAQ Stock Market-United States, and (ii) the NASDAQ Biotechnology Index. The graph assumes (a) \$100 was invested on July 31, 2001 in each of the Company s Common Stock, the stocks comprising the NASDAQ Stock Market-United States and the stocks comprising the NASDAQ Biotechnology Index, and (b) the reinvestment of dividends.

## COMPARISON OF 65 MONTH CUMULATIVE TOTAL RETURN\*

Among Alexion Pharmaceuticals, Inc., The NASDAQ Composite Index

And The NASDAQ Biotechnology Index

Fiscal year ending December 31.

#### **CUMULATIVE TOTAL RETURN**

	7/02	7/03	7/04	7/05	12/05	12/06	12/07
Alexion Pharmaceuticals, Inc.	100.00	108.38	102.64	167.89	130.56	260.41	483.75
NASDAQ Composite	100.00	128.98	142.51	164.85	168.24	187.43	204.78
NASDAO Biotechnology	100.00	149.29	146.51	176.75	186.10	183.89	187.04

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<sup>\* \$100</sup> invested on 7/31/02 in stock or index-including reinvestment of dividends.

## Item 6. SELECTED CONSOLIDATED FINANCIAL DATA.

The selected financial data for the years ended December 31, 2007 and 2006, the five month period ended December 31, 2005 and the year ended July 31, 2005 and as of December 31, 2007 and 2006 is derived from, and should be read in conjunction with, the audited consolidated financial statements, including the notes thereto, and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Form 10-K. All other financial data in the table has been derived from the audited consolidated financial statements included in previous years Form 10-K filings, except for information for the five month period ended December 31, 2004 and as of December 31, 2004, which is derived from our unaudited financial statements. (amounts in thousands, except per share amounts)

	December 31, Endo		Five Mon Ended Dec 2005		Year E July : 2005	
Revenues:						
Net product sales	\$ 66,381	\$	\$	\$	\$	\$
Contract research revenue	5,660	1,558	664	245	1,064	4,609
Total revenues	72,041	1,558	664	245	1,064	4,609
Cost of sales	6,696					
Operating expenses:						
Research and development	68,961	83,225	48,238	31,914	91,388	59,840
Selling, general and administrative	96,142	55,418	12,763	6,160	18,951	15,219
Total operating expenses	165,103	138,643	61,001	38,074	110,339	75,059
	·	·	ŕ	ŕ	·	· ·
Operating loss	(99,758)	(137,085)	(60,337)	(37,829)	(109,275)	(70,450)
Other income and expense	6,723	5,198	1,931	2,407	(240)	(4,336)
Loss before income tax benefit	(93,035)	(131,887)	(58,406)	(35,422)	(109,515)	(74,786)
Income tax benefit	745	373	450	61	765	691
Net loss	\$ (92,290)	\$ (131,514)	\$ (57,956)	\$ (35,361)	\$ (108,750)	\$ (74,095)
1100 1000	Ψ ()2,2)0)	ψ (131,311)	Ψ (37,750)	ψ (33,301)	Ψ (100,750)	Ψ (7 1,022)
Basic and diluted net loss per common share	\$ (2.54)	\$ (4.15)	\$ (1.90)	\$ (1.28)	\$ (3.90)	\$ (3.43)
Dasic and unuted het loss per common share	$\varphi$ (2.34)	φ (4.13)	φ (1.90)	φ (1.20)	φ (3.90)	$\varphi = (3.43)$
	26.211	21.701	20.522	27.695	27.052	21 (22
Shares used in computing net loss per common share	36,311	31,701	30,523	27,685	27,852	21,622

## **Consolidated Balance Sheet Data:**

	As of December 31,				As of July 31,		
	2007	2006	2005	2004	2005	2004	
Cash, cash equivalents, and marketable securities	\$ 106,712	\$ 250,148	\$ 212,456	\$ 232,498	#\$ 195,404	\$ 266,501	
Trade accounts receivable	46,278						
Inventories	32,907	2,314					
Total current assets	205,354	236,776	217,551	235,883	201,162	276,333	
Property, plant and equipment	104,280	39,135					
Total assets	334,357	333,537	262,711	281,221	248,122	319,575	
Note payable						3,920	
Capital leases	771	350	217		224		
Mortgage loan	44,000	26,000					
Convertible subordinated notes	150,000	150,000	150,000	120,000	150,000	120,000	
Total stockholders equity	101,556	124,677	81,890	138,505	67,671	172,522	

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

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

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

#### Overview

We are a biopharmaceutical company engaged in the discovery, development and delivery of biologic therapeutic products aimed at treating patients with severe and life-threatening disease states, including hematologic and neurologic diseases, cancer and autoimmune disorders. From our inception in January 1992 through early 2007, we devoted substantially all of our resources to drug discovery, research, and product and clinical development.

In March 2007, the U.S. Food and Drug Administration, or FDA, granted approval for our lead product Soliris<sup>®</sup> (eculizumab) for the treatment of a rare, life-threatening blood disorder known as Paroxysmal Nocturnal Hemoglobinuria, or PNH. In June 2007, the European Commission, or E.C., also approved Soliris for the treatment of PNH.

Through December 31, 2007, our product sales have been solely attributable to sales of Soliris and have been generated from three sources: commercial sales in the United States (beginning in the second quarter of 2007), named-patient sales in certain European countries (beginning in the first quarter of 2007) and commercial sales in certain European countries (beginning in the fourth quarter of 2007).

We have incurred operating losses since our inception. We expect to incur operating losses and negative cash flow for additional periods due to costs associated with the commercialization of Soliris in the United States and Europe, pre-commercialization activities and anticipated commercialization activities in other territories, development of our manufacturing plant in Rhode Island, including engineering and validation runs, product research and development, preclinical studies and clinical testing, regulatory activities, commercial-scale manufacturing at our third party contractor and at our own manufacturing plant when that site is approved to manufacture Soliris, and other infrastructure support costs

Until we can generate sufficient levels of cash from our operations, we expect to continue to finance future cash needs primarily through the use of available cash, cash equivalents and short-term investments, availability under our credit agreement and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements.

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

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

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

Revenue recognition
Royalties
Inventories
Prepaid manufacturing
Research and development expenses
Stock-based compensation
Long-lived assets
Income Taxes Recognition

Net Product Sales

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

In the United States, our customers are primarily specialty distributors and specialty pharmacies who supply physician office clinics, hospital outpatient clinics, infusion clinics or home health care providers. In some cases, we also sell Soliris to government agencies. Soliris is generally shipped directly from our third party warehouse to the patients health-care provider, who is not typically our direct customer. Revenue is recorded on this transaction upon receipt of the product by the patients health-care provider, which is typically a hospital or physician s office.

Through December 31, 2007, we have recorded revenue on sales for individual patients through named-patient programs in certain European countries. The relevant authorities in those countries have agreed to reimburse for product sold on a named-patient basis where Soliris has not received formal approval for commercial sales. In Europe, we have entered into transitional agreements with a distributor to distribute Soliris on a named-patient basis in specified European countries.

We continue to engage with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required by each European country. We are more complete in those

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processes in certain countries such as Germany, and in earlier stages in other countries such as the United Kingdom. In European countries in which Soliris is currently commercially available and will be commercially available in the future, our customers are expected to be primarily hospitals, hospital buying groups, pharmacies and other health care providers, with the exception of the United Kingdom, in which our primary product sales will be through a distributor.

Sales within Europe are recorded upon receipt of product by the health-care provider.

To date, actual refunds and returns have been negligible. Because of the pricing of Soliris, the limited number of patients, the short period from sale of product to patient infusion and lack of return rights, Soliris customers generally carry limited inventory. Accordingly, we expect that sales related to Soliris will be closely tied to patient demand. We monitor inventory within our distribution channel to determine whether reserves are required related to inventory in our sales channels. To the extent that our actual experience differs from our estimates, we will revise these estimates resulting in an impact in the period in which the adjustment was made.

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

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

#### Contract Research Revenue

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

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

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

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

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#### **Royalties**

We record actual and estimated royalties to third parties related to the sale and commercial manufacture of Soliris. We estimate royalties potentially owed to third parties based on contractual arrangements with certain parties, as well as our assessment of possible royalty amounts owed to other third parties. These estimates may be influenced by the outcome of current litigation, the results of which are uncertain (see Note 9 of the Consolidated Financial Statements included in this Form 10-K). On a periodic basis and based on events such as changes in the status of litigation, we may reassess these estimates, resulting in adjustments to cost of sales.

#### **Inventories**

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

We capitalized inventory costs associated with Soliris prior to regulatory approval, but subsequent to the filing of the Biologics License Application, or BLA, when we determine that the inventory has probable future economic benefit. Inventory is not capitalized prior to completion of a Phase III clinical trial. A significant portion of product sold during the year ended December 31, 2007 was previously expensed prior to submission of our BLA, and therefore is not included in the cost of product revenues during this period. In the fourth quarter of 2007, we fully exhausted this supply of previously expensed inventory. Beginning in 2008, our cost of sales will reflect the full manufacturing cost of the inventory.

We analyze our inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of our product is subject to strict quality control, certain batches or units of product may, after a period of time, no longer meet quality specifications or may expire, at which point we would adjust our inventory values. Soliris currently has a maximum estimated life of 42 months and, based on our sales forecasts, we expect to fully realize the carrying value of the Soliris inventory.

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

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

#### **Prepaid Manufacturing Costs**

Cash advances paid by us to secure future manufacturing production at third-party contract manufacturers are recorded as prepaid manufacturing costs. These costs are recognized over the period of manufacturing production on a unit-of-production method. The cash advances are subject to forfeiture if we terminate the scheduled production.

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We evaluate the prepaid manufacturing costs against estimated net realizable value, or NRV. If estimated NRV were to be negative, all or a portion of the prepaid manufacturing cost may have to be recognized as an expense. Our calculation of NRV involves estimates of expected sales volumes and sales price of Soliris. If actual volumes and prices are substantially less than our estimates, write-downs of the prepaid manufacturing balance to cost of sales may be required. Based on our sales forecasts, we expect the carrying value of the prepaid manufacturing costs to be fully realized.

### **Research and Development Expenses**

Research and development expenses are comprised of costs incurred in performing research and development activities including salaries and benefits, preclinical, clinical trial and related clinical manufacturing costs, manufacturing development and scale-up costs, contract services and other outside contractor costs, research license fees, depreciation and amortization of lab facilities, and lab supplies. These costs are expensed when incurred.

Through March 31, 2007, we were involved in a collaboration research agreement with P&G in which we shared costs. We recorded those costs as research and development expenses as incurred. A portion of those costs were reimbursed by our collaborator and were recorded as a reduction of research and development expense.

We accrue costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations (CRO s), clinical study sites, laboratories, consultants, or other clinical trial vendors that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through close communication with the CRO s and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter for each individual trial. The estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in research and development expenses for the related period. For clinical study sites, which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. The estimates may differ from the actual amount subsequently invoiced, which may result in adjustment to research and development expense several months after the related services were performed.

## **Stock-Based Compensation**

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

Our estimates of employee stock option values rely on estimates of factors we input into the Black-Scholes model. The key factors involve an estimate of future uncertain events. Significant assumptions include the use of historical volatility to determine the expected stock price volatility. We also estimate expected term until exercise, forfeiture or cancellation, as well as the reduction in the expense from expected forfeitures. We currently use historical exercise and cancellation patterns as our best estimate of future estimated life. Actual

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volatility and lives of options may be significantly different from our estimates. If factors change and we employ different assumptions in the application of FAS 123(R), the compensation expense that we record in future periods may differ significantly from our prior recorded amounts.

## **Long-Lived Assets**

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

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

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

a significant decrease in market value of assets.

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

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

## **Income Taxes**

We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. We have recorded a full valuation allowance against our net deferred tax assets, the principal amount of which is the tax effect of federal net operating loss carryforwards of approximately \$732,653 at December 31, 2007. Future taxable income and ongoing prudent and feasible tax planning strategies have been considered in assessing the need for the valuation allowance. If we later determine that it is more likely than not that the deferred tax assets would be realized, the previously provided valuation allowance would be reversed. In order to realize our deferred tax assets we must be able to generate sufficient taxable income in the tax jurisdictions in which the deferred tax assets are located. This critical accounting assumption has been historically accurate, as we have not been able to utilize our net deferred tax assets, and we do not expect changes to this assumption until the ultimate realizability of the deferred tax assets becomes certain.

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# **Results of Operations**

The following table sets forth consolidated statements of operations data for the periods indicated. The information for the years ended December 31, 2007 and 2006 has been derived from the audited consolidated financial statements included elsewhere is this Form 10-K. The information for the year ended December 31, 2005 has been derived from our unaudited consolidated financial statements. (amounts in thousands, except per share data)

		Year Ended December 31,		
	2007	2006	2005	
Revenues:				
Net product sales	\$ 66,381	\$	\$	
Contract research revenue	5,660	1,458	1,482	
Other revenue		100		
Total revenues	72,041	1,558	1,482	
Cost of sales	6,696			
Research and development expenses:				
Clinical development	17,294	32,262	52,473	
Product development	11,944	4,794	23,430	
Discovery research	2,801	8,214	2,572	
Payroll and benefits	29,634	30,061	21,202	
Operating and occupancy	4,615	5,520	5,408	
Depreciation and amortization	2,673	2,374	2,670	
Total research and development expenses	68,961	83,225	107,755	
Selling, general and administrative	96,142	55,418	25,509	
Total operating expenses	165,103	138,643	133,264	
	,	,	ŕ	
Operating loss	(99,758)	(137,085)	(131,782)	
Other income (expense):				
Investment income	8,080	8,076	6,633	
Interest expense	(2,489)	(2,837)	(4,164)	
Foreign currency gain (loss)	1,132			
Loss on early extinguishment of debt			(3,185)	
Other		(41)		
Total other income (expense)	6,723	5,198	(716)	
	-,-	-,	(	
Income tax benefit	745	373	1,154	
moone an octon	715	313	1,154	
Net loss	\$ (92,290)	\$ (131,514)	\$ (131,344)	
TYCL TOSS	\$ (92,290)	φ (131,314)	φ (131,344)	
Racic and diluted not loss per common chara	¢ (2.54)	\$ (4.15)	\$ (4.20)	
Basic and diluted net loss per common share	\$ (2.54)	\$ (4.15)	\$ (4.30)	

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

#### December 31, 2006

(amounts in thousands, except per share data)

#### Revenues

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

As additional PNH patients request Soliris and obtain reimbursement, we expect that the number of patients taking Soliris will increase, resulting in an increase in product sales in the U.S. and Europe. We also expect product sales in Europe to increase as we progress with appropriate authorities on the operational, reimbursement, price approval and funding process in each European country.

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

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

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

## Cost of Sales

Cost of sales was \$6,696 for the year ended December 31, 2007. There were no cost of sales incurred for periods prior to December 31, 2006. Cost of sales includes actual and estimated royalty expenses associated with sales of Soliris, as well as other manufacturing costs. Changes in the estimates of royalties owed to certain third parties could have a material impact on our cost of sales in future periods. We expect that the purchase of patents from OMRF in February 2008 will have a favorable impact on our cost of sales.

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

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#### **Research and Development Expenses**

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

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

Increase of \$3,896 in product development expenses due to an increase of \$5,518 related to expenditures for drug development, quality assurance, scientific communications and regulatory affairs due to the regulatory approvals in both the United States (March 2007) and the European Union (June 2007). The increase was offset by a decrease in manufacturing costs of \$1,622 related to the capitalization of inventory costs beginning with filing of the BLA in September 2006. Prior to September 2006, we expensed all manufacturing costs, resulting in lower 2007 expenses compared to 2006.

Decrease of \$2,160 in discovery research was primarily due to the closure of AAT operations.

We expect our research and development expenses to increase in 2008 as a result of further clinical trials and research related to eculizumab development programs in asthma, myasthenia gravis and multifocal motor neuropathy, as well as the expected initiation of a clinical study of Anti-CD200 antibody in chronic lymphocytic leukemia. For additional information on these programs, please refer to Product and Development Programs in Item I of this Form 10-K.

#### Selling, General and Administrative Expenses

During the year ended December 31, 2007, we incurred selling, general and administrative expenses of \$96,142, an increase of \$41,263 or 75.2% versus the \$54,879 incurred during the year ended December 31, 2006. The increase was primarily due to the following:

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

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

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

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We expect our selling, general and administrative expenses to increase at a reduced rate in 2008, reflecting the completion of our product launch of Soliris in the United States and increased promotion, marketing and other infrastructure costs outside the United States.

#### Other Income (Expense)

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

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

#### **Income Taxes**

During the year ended December 31, 2007, we recorded an income tax benefit of \$745, compared to \$373 for the year ended December 31, 2006. The increase in the tax benefit was attributable to an increase in the estimated cash exchange of a state incremental research and development tax credit. We expect a reduced tax benefit in 2008 due to a reduction in state research and development credits and the incurrence of state tax liabilities.

We will continue to monitor our deferred tax assets through 2008 to determine whether necessary adjustments may be required related to our valuation allowance.

#### Comparison of the Year Ended December 31, 2006 to the Year Ended

#### December 31, 2005

(amounts in thousands, except per share data)

#### Revenues

We earned contract research revenues of approximately \$1,458 and \$1,482 for the years ended December 31, 2006 and 2005, respectively. Revenue reflects the amortization of deferred revenue resulting from cash received from P&G under our collaboration for the development and commercialization of pexelizumab, U.S. government funded research grant revenue related to our research programs, and a nonrefundable fee for exclusive access to our xenotransplantation technologies, a program that was terminated in October 2003.

## **Research and Development Expenses**

During the year ended December 31, 2006, we incurred research and development expenses of \$83,225, a decrease of \$24,530, or 22.8%, versus the \$107,755 incurred during the year ended December 31, 2005. The decrease was primarily due to and offset by the following:

a significant decrease in clinical development and manufacturing expenses costs, \$20,211 and \$18,636, respectively, related to the termination of the pexelizumab programs.

substantial increases in payroll and benefits costs of \$8,859, which were primarily impacted by the adoption of SFAS 123(R) and the resulting expensing of employee stock options grants

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increased headcount to support our research and drug development activities, and

research and discovery expenses increased by approximately \$5,642, primarily related to development activities related to our PNH programs.

#### Selling, General and Administrative Expenses

During the year ended December 31, 2006, we incurred selling, general and administrative expenses of \$54,879, an increase of \$29,370, or 115.1% versus the \$25,509 incurred during the year ended December 31, 2005. The increase was primarily due to the following:

increased pre-commercial activities associated with Soliris in the U.S. as well as in Europe,

increased headcount in support of our operations, and

increased expenses related to the closure of Alexion Antibody Technologies, Inc.

#### Other Income (Expenses)

During the year ended December 31, 2006, we recognized \$8,076 of investment income, representing an increase \$1,443, or 21.8%, versus the \$6,633 recognized during the year ended December 31, 2005. The increase was a reflection of higher market interest rates and higher cash, cash equivalent and marketable securities balances.

Interest expense decreased to \$2,799 from \$4,164, for the years ended December 31, 2006 and 2005, respectively. The decrease resulted from the lower coupon rate on the \$150,000 principal amount of 1.375% convertible senior notes, following the redemption of our \$120,000 principal amount of 5.75% convertible subordinated notes, in March 2005.

A state tax benefit of \$373 and \$1,154 was recognized for the years ended December 31, 2006 and 2005, respectively, resulting from our estimated exchange of our December 31, 2006 and 2005 incremental research and development tax credits.

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

As of December 31, 2007, our consolidated cash, cash equivalents, marketable securities and restricted cash totaled \$106,712, a decrease of \$143,436, from \$250,148 at December 31, 2006. The reduction in cash held was primarily due to our ongoing expenditures for commercialization efforts related to Soliris in the United States and the European Union, expenditures on our Rhode Island manufacturing facility, inventory purchases, and our continuing product research and development efforts. Until required for use in the business, we invest our cash reserves in money market funds and high quality commercial, corporate and U.S. Government notes in accordance with our investment policy.

As of December 31, 2007, \$958 of cash was restricted to be used for the construction and other costs related to our Rhode Island manufacturing facility.

At December 31, 2007, our working capital was \$167,645, compared to \$208,954 at December 31, 2006.

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We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. We do indemnify certain third parties against liabilities they may incur in connection with the manufacturing, development, or sale of Soliris or any of our other drug candidates.

We have incurred operating losses since our inception. As of December 31, 2007, we had an accumulated deficit of \$729,279. We expect to incur operating losses and negative cash flows for additional future periods due to costs associated with the launch and commercialization of Soliris in the United States, pre-commercialization activities and anticipated commercialization activities outside of the United States, development of our manufacturing plant in Rhode Island, including engineering and validation runs, product research and development, preclinical studies and clinical testing, regulatory activities, commercial-scale manufacturing at our third party contractor and at our own manufacturing plant when that site is qualified to manufacture Soliris, and other infrastructure support costs.

Until we can generate sufficient levels of cash from our operations, we expect to continue to finance future cash needs primarily through cash, cash equivalents and short-term investments, availability under our credit agreement, and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements. The requirement to obtain additional cash from debt or equity financing will be highly dependent on our sales, and related cash collections, of Soliris in the United States and European Union.

#### Cash Flows from Operating Activities

Net cash used in operating activities was \$140,373 for the year ended December 31, 2007 versus \$109,914 for the year ended December 31, 2006, an increase of \$30,459, or 27.7%. The increase in cash used compared to the same period in the previous year is primarily due to increased commercialization activities as compared to the same period in 2006. The components of cash used in operating activities for the year ended December 31, 2007 are as follows:

Net loss of \$70,514, net of non-cash items, including depreciation and amortization of \$4,927, stock-based compensation of \$22,025 and the recognition of the remaining \$5,343 of deferred revenue related to the termination of P&G agreement

Net cash outflow due to changes in operating assets of \$80,578, primarily attributable to increases in inventories and accounts receivable. Due to the payment terms granted to our U.S. and European Union customers, a significant portion of our product sales to date have not yet been collected. These increases were offset by an increase in our accrued expenses for compensation and actual and estimated royalties.

In 2008, changes in cash from operations will be highly dependent on sales levels, and related cash collections, from sales of Soliris. In addition, we expect that cash outflows related to the changes in operating assets will continue to increase related to sales and resulting accounts receivable increases and for purchases of additional inventory from our supply agreement with Lonza.

### Cash Flows from Investing Activities

Net cash provided by investing activities was \$3,458 for the year ended December 31, 2007 versus \$53,907 provided by investing activities for the year ended December 31, 2006. For the year ended December 31, 2007, the net cash used for investing activities consisted of the following:

\$39,306 cash inflow from the net sale of marketable securities, which was used to fund our operations

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\$68,484 of additions to property, plant and equipment, of which \$62,575 was attributable to the construction of our Rhode Island manufacturing facility, with the remaining attributable to spending on information technology and facility capital costs

\$32,636 of restricted cash used for costs incurred in connection with the construction and certain operating escrow balances of our Rhode Island manufacturing facility pursuant to the terms of our mortgage loan.

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

Through December 31, 2007, we have capitalized \$91,231 related to the facility, which includes all costs associated with construction, renovation and upgrades, engineering runs and capitalized interest. Through December 31, 2007, costs incurred in seeking regulatory approval, including engineering runs, was \$21,999, and capitalized interest was \$4,328.

# Cash Flows from Financing Activities

Net cash provided by financing activities was \$65,562 and \$179,324 for the year ended December 31, 2007 and 2006, respectively, consisting primarily of proceeds from the issuance of common stock related to the exercise of stock options of \$47,005 and \$153,827, respectively and proceeds from the mortgage loan agreement with iStar of \$18,000 and \$26,000, respectively.

### **Contractual Obligations**

Our contractual obligations include our \$150,000 1.375% Convertible Senior Notes due February 2012, or 1.375% Notes, our \$44,000 mortgage loan due August 2017 with a fixed annual interest rate of 9.12%, our annual payments of approximately \$4,500 for operating and capital leases, principally for facilities and equipment, and an open letter of credit of \$200 which serves as a security deposit on our facility in Cheshire, Connecticut. We also have contractual obligations related to our third party manufacturer and to other third parties.

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The following table summarizes our contractual obligations at December 31, 2007 and the effect such obligations and commercial commitments are expecting to have on our liquidity and cash flow in future fiscal years. These do not include milestones and assume non-termination of agreements. These obligations, commitments and supporting arrangements represent payments based on current operating forecasts, which are subject to change:

	Total	Less than 1 Year	2-3 Years	4-5 Years	More than 5 Years
Contractual obligations:					
Convertible notes payable	150,000			150,000	
Mortgage loan	44,020		4,890	11,740	27,390
Interest expense	33,800	6,200	12,200	9,300	6,100
Capital and operating leases	28,100	5,300	6,900	6,000	9,900
Total contractual obligations	255,920	11,500	23,990	177,040	43,390
Commercial commitments:					
Clinical and manufacturing development	32,860	2,860	11,250	15,000	3,750
Licenses	2,500	700	900	600	300
Total commercial commitments	35,360	3,560	12,150	15,600	4,050
	291,280	15,060	36,140	192,640	47,440

In addition to the above, we acquired from OMRF in February 2008 certain patents related to complement-inhibition technology from Oklahoma Medical Research Foundation, or OMRF. We will pay \$10,000, plus interest, to OMRF for the rights to the patents, of which \$7,500 will be remitted in 2008 and the remaining \$2,500 in the first half of 2009. No further amounts, including royalties, will be owed to OMRF in respect of sales of Soliris or other use of the OMRF patents.

# Convertible Notes Payable

We hold \$150,000 principal amount of 1.375% Convertible Senior Notes due February 1, 2012, or the 1.375% Notes. We pay interest on these notes on a semi-annual basis on February 1 and August 1 of each year, beginning August 1, 2005. However, no principal payments are due until February 2012, except under certain circumstances such as liquidation, merger or business combination. The convertible notes payable do not have covenants related to our financial performance.

The 1.375% Notes are convertible into our common stock at an initial conversion rate of 31.7914 shares of common stock (equivalent to a conversion price of approximately \$31.46 per share) per \$1 principal amount of the 1.375% Notes, subject to adjustment, at any time prior to the close of business on the final maturity date of the notes. We do not have the right to redeem any of the 1.375% Notes prior to maturity.

As of December 31, 2007, the market value of our \$150,000, 1.375% Convertible Notes due February 1, 2012, based on quoted market prices, was estimated at \$375,000. The \$157,875 increase from December 31, 2006 is largely attributable to the increase in the price of our common stock during the period.

### Mortgage Loan

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

As a condition of the loan, we are required to maintain restricted cash accounts. These accounts must be used specifically for the purchase and construction of the manufacturing facility and maintain certain operating escrow balances. The lender has a first priority security interest and the right to approve all disbursements from the accounts holding restricted cash. Under the agreement, we are required to maintain a balance in the restricted cash accounts sufficient to complete the project. During 2007, a substantial portion of these disbursements were made, resulting in a restricted cash balance of \$958.

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

# Working Capital Loan

In February 2008, we entered into a Credit Agreement with Bank of America, N.A. to provide for an available \$25,000 revolving credit facility, that can be used for working capital requirements and other general corporate purposes. The loan is collateralized by substantially all of Alexion Pharmaceuticals, Inc.'s assets, including the pledge of the equity interests of certain direct subsidiaries, but excluding intellectual property, assets of foreign subsidiaries and assets related to our manufacturing facility in Smithfield, RI. The borrowing base is limited to 80% of eligible domestic receivables, as defined. As of February 25, 2008, we have not borrowed under the revolving credit facility.

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

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

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### Capital Leases

We currently lease office equipment under capital lease agreements expiring in 2010. The assets and liabilities under capital lease agreements are recorded at the lower of the present value of the minimum lease payments or the fair value of the asset. The assets are amortized over the lower of their related lease terms or their estimated useful lives. The average interest rates on the above capital leases is 9.5% and is imputed based on the lower of our incremental borrowing rate at the inception of each lease.

### **Operating Leases**

Our operating leases are principally for facilities and equipment. We lease our headquarters and research and development facility in Cheshire, Connecticut. The lease, which had an initial term of ten years and six months, expiring in December 2010, was extended in August 2006 and revised again in June 2007. The lease is set to expire in May 2017. At this site, we lease a total of 125,424 square feet of space.

In January 2003, we entered into a lease agreement for our pilot manufacturing plant and associated labs and offices in New Haven, Connecticut. The lease expired in October 2007. Pilot manufacturing operations have been transferred to our manufacturing facility located in Smithfield, Rhode Island. We lease additional research space in San Diego, California. In connection with the closure of Alexion Antibody Technologies in 2006, we accrued the fair value of future payments under the lease (see Note 6 of the Consolidated Financial Statements included in this Form 10-K). In September 2007, the Company signed a sub-lease for the AAT facility, which provides for sub-lease payments through the term of the lease, or 2012. We believe our research and development facilities and pilot manufacturing facility, together with third party manufacturing facilities, will be adequate for our current ongoing activities.

### **Commercial Commitments**

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

### Lonza Agreement

We have a supply agreement with Lonza Sales AG relating to the manufacture of Soliris, which requires payments to Lonza at the inception of the contract and as product is manufactured. We are required to prepay certain amounts 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.

In June 2007, we amended our supply agreement to provide for additional purchase commitments of Soliris of \$30,000 to \$35,000 through 2013. Such commitments may only be cancelled in limited circumstances.

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

## Additional Commercial Commitments

Additional payments, related to our commercial commitments, such as licenses, aggregating up to approximately \$1,745, would be required if we elect to continue development under our current preclinical development programs and if specified development milestones are reached (including achievement of commercialization). These amounts are not included in the above table.

#### Income Taxes

At December 31, 2007, we have available for Federal tax reporting purposes, net operating loss carry forwards of approximately \$732,653, which expire from 2008 through 2027. We also have federal and state research and development credit carry forwards of approximately \$25,088, which expire from 2008 through 2027.

The Tax Reform Act of 1986 contains certain provisions that can limit a taxpayer's ability to utilize net operating loss and tax credit carry forwards in any given year resulting from cumulative changes in ownership interests in excess of 50 percent over a three-year period. We have determined that these limiting provisions were triggered. However, such limitation is not expected to result in the loss of the Federal net operating loss and research and development credit carry forwards. As a result, the net operating losses and tax credits are expected to significantly reduce cash payable for Federal income taxes in the United States for the foreseeable future.

### Recently Issued Accounting Standards

In December 2007, Statement of Financial Accounting Standards No. 141(R), *Business Combinations*, or SFAS 141(R), was issued. This standard will require an acquiring company to measure all assets acquired and liabilities assumed, including contingent consideration and all contractual contingencies, at fair value as of the acquisition date. In addition, the acquiring company is required to capitalize IPR&D and either amortize it over the life of the product, or write off if the project is abandoned or impaired. The Standard is effective for transactions occurring on or after January 1, 2009.

In February 2007, Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including and Amendment of FASB Statement No. 115*, or SFAS 159, was issued. This standard permits us to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements. This standard is effective January 1, 2008 for the Company.

In September 2006, Statement of Financial Accounting Standards No. 157, *Fair Value Measurement*, or SFAS 157, was issued. This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, or GAAP, and expands disclosure about fair value measurements. This standard is effective January 1, 2008 for the Company.

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We do not expect these Standards to have a material impact on our financial statements

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

(amounts in thousands, except per share data)

### **Interest Rate Risk**

As of December 31, 2007, we held approximately 90% of our cash and investments, including restricted cash, in financial instruments, primarily money market funds, with original maturity dates of three months or less. The remaining 10% is held in financial instruments with original maturity dates of equal to or greater than one year and less than two years. These financial instruments are subject to interest rate risk and will decline in value if interest rates increase. However, we expect to hold time-based investments, such as corporate bonds, through maturity. We estimate that a change of 100 basis points in interest rates would result in an increase or decrease of approximately \$11 in the fair value of our cash and investments, which had a weighted average duration of approximately 1 month at December 31, 2007.

Our outstanding long-term liabilities as of December 31, 2006 included our \$150,000, 1.375% Convertible Senior Notes due February 1, 2012. As the notes bear interest at a fixed rate, our results of operations would not be impacted by interest rate changes. As of December 31, 2006, the market value of our \$150,000 1.375% convertible senior notes due February 1, 2012, based on quoted market prices, was estimated at \$217,125.

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

During the first quarter of 2008, we entered into Credit Agreement with Bank of America and may borrow up to \$25,000. We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.75% to 2.25% depending on Alexion's liquidity (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect and (B) the Federal Funds Rate then in effect plus 0.50%, plus 0% to 0.25% depending on Alexion's liquidity (as calculated in accordance with the agreement). As of February 25, 2008, we have not borrowed any amounts related to this facility.

Our exposure to market risk for changes in interest rates relates to our revolving credit facility. An effective increase or decrease of 10% in interest rates would not have a material effect on our results of operations or cash flows.

We do not believe that there is any material market risk exposure with respect to derivative or other financial instruments that would require disclosure under this item.

#### Foreign Exchange Market Risk

As a result of our European operations, we may face exposure to adverse movements in foreign currency exchange rates, primarily to the Euro. The current exposures arise primarily from monetary instruments, primarily accounts receivable and intercompany receivables and payables denominated in foreign currencies. In

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the future, we may elect to limit this exposure through hedging programs. As of December 31, 2007, we estimate that the potential loss in fair value of our foreign currency exposure that would result from a hypothetical 10% adverse change in exchange rates to be \$1,265.

In addition to our balance sheet risk, we have revenues and costs denominated in currencies other than the U.S. Dollar. Accordingly, future results may be impacted by changes in foreign exchange rates.

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

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

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE
None.

# Item 9A. CONTROLS AND PROCEDURES Disclosure Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act,) as of December 31, 2007. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2007, our disclosure controls and procedures were effective to provide reasonable assurance that information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure, and ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

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

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

Management utilized the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, to conduct an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2007. Based on the assessment, management has concluded that, as of December 31, 2007, our internal control over financial reporting is effective.

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The effectiveness of our internal control over financial reporting as of December 31, 2007 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

# Changes in Internal Control over Financial Reporting.

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

We have expanded and improved our internal control structure to meet the requirements of a worldwide commercial entity, including the addition of appropriate processes related to revenue recognition, inventory and international operations. Other than these changes, there has been no change in our internal control over financial reporting that occurred during the year ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9A (T). CONTROLS AND PROCEDURES.

Not applicable

**Item 9B.** *OTHER INFORMATION* None.

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#### PART III

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

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

# SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

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

#### CODE OF ETHICS

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

# Item 11. EXECUTIVE COMPENSATION.

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

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

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

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

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

#### PART IV

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

The information required by this Item will be set forth in our definitive Proxy Statement under the caption Independent Registered Public Accounting Firm , to be filed within 120 days after the end of the year ended December 31, 2007 covered by this Annual Report on Form 10-K, and is incorporated herein by reference to our Proxy Statement.

# Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

### (1) Financial Statements

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

### (2) Financial Statement Schedules

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

- (3) Exhibits:
- 3.1 Certificate of Incorporation, as amended.(1)
- 3.2 Bylaws, as amended.(2)
- 4.1 Specimen Common Stock Certificate.(3)
- 4.2 Form of Amended and Restated Senior Debt Indenture dated as of May 7, 2004 between Alexion Pharmaceuticals, Inc. and U.S. Bank National Association, as trustee. (4)
- 4.3 Form of Amended and Restated Subordinated Debt Indenture dated as of May 7, 2004 between Alexion Pharmaceuticals, Inc. and U.S. Bank National Association, as trustee. (4)
- 4.4 Rights Agreement between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer & Trust Company, Rights Agent, dated as of February 14, 1997. (5)
- 4.5 Amendment No. 1 to Rights Agreement, dated as of September 18, 2000, between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer and Trust Company. (6)
- 4.6 Amendment No. 2 to Rights Agreement, dated as of December 12, 2001, between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer and Trust Company, which includes as Exhibit B the form of Right Certificate. (7)
- 4.7 Amendment No. 3 to Rights Agreement, dated as of November 16, 2004, between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer and Trust Company. (8)
- 4.8 Amendment No. 4 to Rights Agreement, dated February 23, 2007, between Alexion Pharmaceuticals, Inc. and Continental Stock Transfer and Trust Company. (9)

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4.9	Indenture between Alexion Pharmaceuticals, Inc. and U.S. Bank National Association relating to Alexion Pharmaceuticals, Inc.'s 1.375% Convertible Senior Notes due 2012. (10)
4.10	Registration Rights Agreement between Alexion Pharmaceuticals, Inc., Morgan Stanley & Co. Incorporated, Bear, Stearns & Co. Inc., SG Cowen & Co., LLC and J.P. Morgan Securities Inc. (10)
10.1	Employment Agreement, dated as of February 14, 2006, between the Company and Dr. Leonard Bell.(11)
10.2	Employment Agreement, dated as of February 14, 2006, between the Company and David W. Keiser.(11)
10.3	Employment Agreement, dated as of February 14, 2006, between the Company and Dr. Stephen P. Squinto.(11)
10.4	Employment Agreement, dated as of February 14, 2006, between the Company and Vikas Sinha.(11)
10.5	Employment Agreement, dated November 7, 2005, between the Company and Patrice Coissac.(12)
10.6	Amendment to Employment Agreement, dated July 25, 2007, between the Company and Patrice Coissac.
10.7	Amendment to Employment Agreement, dated January 14, 2008, between the Company and Patrice Coissac.
10.8	Form of Employment Agreement (Senior Vice Presidents). (11)
10.9	Severance Letter Agreement, dated as of November 7, 2005, by and between Alexion Europe SAS and Patrice Coissac. (12)
10.10	Administrative, Research and Development Facility Lease, dated May 9, 2000, between the Company and WE Knotter L.L.C.(13)
10.11	Company s 1992 Stock Option Plan, as amended.(14)
10.12	Company s 2000 Stock Option Plan, as amended.(2)
10.13	Company s 1992 Outside Directors Stock Option Plan, as amended.(15)
10.14	Company s Amended and Restated 2004 Incentive Plan, as amended.
10.15	License Agreement dated March 27, 1996 between the Company and Medical Research Council.(15)+
10.16	Research and Development Facility lease, dated February 1, 2002, between the Company and PMSI SRF L.L.C.(16)
10.17	Large-Scale Product Supply Agreement, dated December 18, 2002, between the Company and Lonza Biologics plc., as amended.(14)+
10.18	Form of Stock Option Agreement for Directors. (17)
10.19	Form of Stock Option Agreement for Executive Officers (Form A). (18)
10.20	Form of Stock Option Agreement for Executive Officers (Form B). (18)
10.21	Form of Restricted Stock Award Agreement for Executive Officers (Form A). (19)

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10.22	Form of a Stock Option Agreement for named executive officer(s) of Alexion Europe SAS. (12)
10.23	Form of a Restricted Stock Agreement for named executive officer(s) of Alexion Europe SAS. (12)
10.24	Purchase and Sale Agreement by and between The Dow Chemical Company and Alexion Manufacturing LLC, dated as of April 13, 2006, as amended. (20)
10.25	Loan and Security Agreement between Alexion Manufacturing LLC and iStar Financial Inc., dated as of July 11, 2006. (20)
10.26	Completion, Payment, and Performance Guarantee by Alexion Pharmaceuticals, Inc. in favor of iStar Financial Inc., dated as of July 11, 2006. (20)
10.27	Construction Mortgage Deed, Assignment of Leases and Rents, Security Agreement and Fixture Filing, dating as of July 11, 2006 by Alexion Manufacturing LLC in favor of iStar Financial Inc. (21)
10.28	Environmental Indemnity Agreement by and among Alexion Manufacturing LLC, Alexion Pharmaceuticals, Inc. in favor of iStar Financial Inc., dated as of July 11, 2006. (20)
10.29	First Amendment to Loan Agreement and Other Loan Documents, between Alexion Manufacturing LLC and iStar Financial Inc., dated July 18, 2007. (21)
10.30	Promissory Note, dated July 18, 2007 issued by Alexion Manufacturing LLC. (21)
10.31	First Amendment to Construction Mortgage Deed, Assignment of Leases and Rents, Security Agreement and Fixture Filing, by Alexion Manufacturing LLC in favor of iStar Financial Inc., dated July 18, 2007. (21)
12.1	Statement Regarding Computation of Ratio of Earnings to Fixed Charges.(1)
21.1	Subsidiaries of Alexion Pharmaceuticals, Inc.
23.1	Consent of PricewaterhouseCoopers LLP.
31.1	Certificate of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002.
31.2	Certificate of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
32.1	Certificate of Chief Executive Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.
32.2	Certificate of Chief Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.

- (1) Incorporated by reference to our Registration Statement on Form S-3 (Reg. No. 333-128085), filed on September 2, 2005.
- (2) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2004.
- (3) Incorporated by reference to our Registration Statement on Form S-1 (Reg. No. 333-00202).
- (4) Incorporated by reference to Amendment No. 1 to Form S-3 (Reg. No. 333-114449), filed on May 10, 2004.
- (5) Incorporated by reference to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on February 21, 1997.

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- (6) Incorporated by reference to Amendment No. 1 to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on October 6, 2000.
- (7) Incorporated by reference to Amendment No. 2 to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on February 12, 2002
- (8) Incorporated by reference to Amendment No. 3 to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on November 17, 2004.

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- (9) Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2007, filed on February 23, 2007.
- (10) Incorporated by reference to our report on Form 8-K, filed on January 25, 2005.
- (11) Incorporated by reference to our Report on Form 8-K filed on February 16, 2006.
- (12) Incorporated by reference to our report on Form 8-K, filed on November 14, 2005.
- (13) Incorporated by reference to our Registration Statement on Form S-3 (Reg. No. 333-36738) filed on May 10, 2000.
- (14) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2003.
- (15) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended July 31, 1996.
- (16) Incorporated by reference to our quarterly report on form 10-Q for the quarter ended January 31, 2002.
- (17) Incorporated by reference to our report on Form 8-K, filed on December 16, 2004.
- (18) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2005.
- (19) Incorporated by reference to our report on Form 8-K, filed on March 14, 2005.
- (20) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2006.
- (21) Incorporated by reference to our report on Form 8-K, filed on July 23, 2007.
- + Confidential treatment was granted for portions of such document.

### Item 15(b) Exhibits

See (a) (3) above.

### Item 15(c) Financial Statement Schedules

See (a) (2) above.

### **SIGNATURES**

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

ALEXION PHARMACEUTICALS, INC.

By: /s/ Leonard Bell

Leonard Bell, M.D.

Chief Executive Officer, Secretary and Treasurer

Dated: February 29, 2008

By: /s/ David W. Keiser

David W. Keiser

President and Chief Operating Officer

Dated February 29, 2008

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

/s/ Leonard Bell		February 29, 2008
Leonard Bell, M.D.	Chief Executive Officer, Secretary, Treasurer and Director (principal executive officer)	
/s/ David W. Keiser	President, Chief Operating Officer and Director	February 29, 2008
David W. Keiser		
/s/ Vikas Sinha	Senior Vice President and Chief Financial Officer (principal financial officer)	February 29, 2008
Vikas Sinha, M.B.A., C.A.		
/s/ Scott Phillips	Corporate Controller and Chief Accounting Officer (principal accounting officer)	February 29, 2008
Scott Phillips		
/s/ Max Link	Chairman of the Board of Directors	February 29, 2008
Max Link, Ph.D.		
/s/ Larry L. Mathis	Director	February 29, 2008
Larry L. Mathis		

/s/ Joseph A. Madri Director February 29, 2008

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

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/s/ R. Douglas Norby

/s/ ALVIN S. PARVEN Director February 29, 2008

Alvin S. Parven

/s/ Ruedi E. Waeger, Ph.D.

February 29, 2008

February 29, 2008

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# Alexion Pharmaceuticals, Inc.

# **Contents**

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

# and Year Ended July 31, 2005

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# Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders

of Alexion Pharmaceuticals, Inc.:

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Alexion Pharmaceuticals, Inc. and its subsidiaries at December 31, 2007 and December 31, 2006, and the results of their operations and their cash flows for the years ended December 31, 2007 and December 31, 2006 and the five month period ended December 31, 2005 and the year ended July 31, 2005 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it accounts for uncertain tax positions in 2007 and the manner in which it accounts for share-based compensation in 2005.

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

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

/s/ PricewaterhouseCoopers LLP

Hartford, Connecticut

February 28, 2008

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# Alexion Pharmaceuticals, Inc.

# **Consolidated Balance Sheets**

# (amounts in thousands, except per share amounts)

	Decem 2007	ber 31, 2006
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 95,321	\$ 166,826
Marketable securities	10,433	49,728
Trade accounts receivable	46,278	
Inventories	32,907	2,314
Prepaid manufacturing costs	13,775	13,935
Prepaid expenses and other current assets	6,640	3,973
Total current assets	205,354	236,776
Property, plant and equipment, net	104,280	39,135
Goodwill, net	19,954	19,954
Restricted cash	958	33,594
Other assets	3,811	4,078
Total assets	\$ 334,357	\$ 333,537
Liabilities and Stockholders Equity		
CURRENT LIABILITIES:	ф. 0.072	Ф. 10.020
Accounts payable	\$ 9,072	\$ 10,939
Accrued expenses	28,324	16,228
Deferred revenue	41	588
Current portion of capital lease obligations	272	67
Total current liabilities	37,709	27,822
Capital lease obligations, less current portion	499	283
Deferred revenue, less current portion		4,755
Mortgage loan	44,000	26,000
Convertible notes	150,000	150,000
Other liabilities	593	
Total liabilities	232,801	208,860
COMMITMENTS AND CONTINGENCIES (Notes 2, 8 and 9)		
STOCKHOLDERS EQUITY:		
Preferred stock, \$.0001 par value; 5,000 shares authorized, no shares issued or outstanding		
Common stock, \$.0001 par value; 145,000 shares authorized; 37,873 and 35,568 shares issued at		
December 31, 2007 and 2006, respectively	4	4
Additional paid-in capital	833,534	763,691
Treasury stock, at cost, 57 shares	(1,260)	(1,260)
Accumulated other comprehensive loss	(1,443)	(177)
Accumulated deficit	(729,279)	(637,581)
Total stockholders equity	101,556	124,677

Total liabilities and stockholders equity

\$ 334,357

\$ 333,537

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

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# Alexion Pharmaceuticals, Inc.

# **Consolidated Statements of Operations**

# (amounts in thousands, except per share amounts)

	Year l Decem	Ended ber 31,	Five Month Period Ended	Year Ended
	2007	2006	December 31, 2005	July 31, 2005
Revenues:				
Net product sales	\$ 66,381	\$	\$	\$
Contract research revenues	5,660	1,558	664	1,064
Total revenues	72,041	1,558	664	1,064
Cost of sales	6,696			
Operating expenses:				
Research and development	68,961	83,225	48,238	91,388
Selling, general and administrative	96,142	55,418	12,763	18,951
Total operating expenses	165,103	138,643	61,001	110,339
Operating loss	(99,758)	(137,085)	(60,337)	(109,275)
Other income and expense:				
Investment income	8,080	8,076	3,123	5,266
Interest expense	(2,489)	(2,837)	(1,192)	(6,125)
Gain from extinguishment of note payable				3,804
Loss on early extinguishment of debt				(3,185)
Foreign currency gain	1,132			
Other		(41)		
Loss before income tax benefit	(93,035)	(131,887)	(58,406)	(109,515)
Income tax benefit	745	373	450	765
Net loss	\$ (92,290)	\$ (131,514)	\$ (57,956)	\$ (108,750)
Net loss per share basic and diluted	\$ (2.54)	\$ (4.15)	\$ (1.90)	\$ (3.90)
Shares used in computing basic and diluted net loss per common share	36,311	31,701	30,523	27,852

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

# Alexion Pharmaceuticals, Inc.

# 

# (amounts in thousands)

	Comm Stoc		Additional Paid-In		ry Stock Cost	Oth Compre Inco	hensiv	e Deferred Stock-Based	Accumulated	Total Stockholders	prehensive Income
			Capital		Amoun			Compensation		Equity	(Loss)
Balances, July 31, 2004	27,557	3	512,827	37	(600	)	(347)		(339,361)	172,522	
Net change in unrealized gains on marketable securities							(219)			(219)	(219)
Issuance of common stock from exercise of options	563		3,743							3,743	
Issuance of restricted common stock	107		2,150					(2,150)			
Amortization of deferred stock-based compensation	10,		2,100					212		212	
Noncash compensation expense			163					212		163	
related to grant of stock options Net loss			103						(108,750)	(108,750)	(108,750)
Balances, July 31, 2005	28,227	\$ 3	\$ 518,883	37	\$ (600	) \$	(566)	\$ (1,938)	\$ (448,111)	\$ 67,671	\$ (108,969)
Foreign currency translation	-,		, , , , , , , , , , , , , , , , , , , ,		, (	, ·	(8)	, ( ), /		(8)	(8)
Net change in unrealized gains on marketable securities							259			259	259
Issuance of common stock, net of issuance costs of \$2,145	2.500		64,517							64.517	
Issuance of common stock from exercise of options	233		3,474							3,474	
Issuance of restricted common			3,474							3,474	
stock Exchange of common shares for	20										
treasury Reversal of deferred				13	(381	)				(381)	
stock-based compensation (Note			(4.020)					4.020			
11)			(1,938)					1,938			
Share-based compensation expense			4,314							4,314	
Net loss			·						(57,956)	(57,956)	(57,956)
Balances, December 31, 2005	30,980	\$ 3	\$ 589,250	50	\$ (981	) \$	(315)	\$	\$ (506,067)	\$ 81,890	\$ (57,705)

# Alexion Pharmaceuticals, Inc.

# Consolidated Statements of Changes in Stockholders Equity and Comprehensive Loss Continued

# (amounts in thousands)

	Com	ock	Additional Paid-In	at	ry Stock Cost			Stock-Based				nprehensive Income
B 1	Shares	Amount	t Capital	Shares	Amount			Compensatio	n Defici	t	Equity	(Loss)
Foreign currency translation							(120)				(120)	(120)
Net change in unrealized gains on marketable securities							258				258	258
Issuance of common stock, net of												
issuance costs of \$8,121	3,450	1	140,282								140,283	
Issuance of common stock from												
exercise of options	925		13,544								13,544	
Issuance of restricted common												
stock	213											
Exchange of common shares for treasury				7	(279)	)					(279)	
Share-based compensation												
expense			20,615								20,615	
Net loss									(131,	514)	(131,514)	(131,514)
Balances, December 31, 2006	35,568	\$ 4	\$ 763,691	57	\$ (1,260)	) \$	(177)	\$	\$ (637,	581)	\$ 124,677	\$ (131,376)
Adoption of FASB Interpretation No. 48										592	592	
Opening balance at January 1, 2007, as adjusted	35,568	\$ 4	\$ 763,691	57	\$ (1,260)	) \$	(177)	\$	\$ (636,	989)	\$ 125,269	
Foreign currency translation							(1,316)				(1,316)	(1,316)
Net change in unrealized gains on							, , , ,				, , , ,	, i
marketable securities							50				50	50
Issuance of common stock from												
exercise of options	2,096		47,005								47,005	
Issuance of restricted common												
stock	209											
Recognition of equity impact on												
R&D tax credit			813								813	
Share-based compensation												
expense			22,025								22,025	
Net loss									(92,	290)	(92,290)	(92,290)
Balances, December 31, 2007	37,873	4	833,534	57	(1,260)	)	(1,443)		(729,	279)	101,556	(93,556)

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

# Alexion Pharmaceuticals, Inc.

# **Consolidated Statements of Cash Flows**

# (amounts in thousands)

Cash flows from operating activities:   Net loss   Separating activities:   Separating activit			Year Ended December 31,		Ionth Period Ended	Ye	ar Ended	
Net loss		2007	2006	· · · · · · · · · · · · · · · · · · ·		J	July 31, 2005	
Adjustments to reconcile net loss to net cash used by operating activities:  Non-cash exit costs  (375) 539  (3,86)  Gain from extinguishment of note payable  Loss on disposal of property, plant & equipment  Depreciation and amortization  Share-based compensation expense  22,025 20,615 4,314 33  Write-off of deferred financing costs  Changes in operating assets and liabilities:  Accounts receivable  Inventories  (49,545)  Inventories  (600) 942 663 4,00  Prepaid expenses and other assets  Receivable accrued expenses  11,478 2,673 676 9,17  Deferred revenue and research and development costs  (5,343) (767) (298) (1,74  Net cash used in operating activities:  Purchase of marketable securities  (48,719) (734,567) (419,086) (508,8)  Proceeds from muturity or sale of marketable securities  Purchase of marketable securities  (68,825) (31,856) (4444) (2,9)  Decrease (Increase) in restricted cash  Net cash provided by (used in) investing activities  (28,10)  Cash flows from financing activities  (29,10)  Cash flows from financing activities  3,077 53,907 (20,559) 1,66								
Non-cash exit costs   Gain from extinguishment of note payable   Gain from extinguishment of note payable   Cash flows from investing activities   Gain from extinguishment of note payable   Gash flows from financing octivities   Gash flows from financing activities   Gash flows from finan	- 101 - 101	\$ (92,290)	\$ (131,514)	\$	(57,956)	\$	(108,750)	
Cash flows from investing activities   Cash flows from financing activities   Cash flows from	, ,							
Loss on disposal of property, plant & equipment   542   141		(375)	539					
Depreciation and amortization							(3,804)	
Share-based compensation expense         22,025         20,615         4,314         37           Write-off of deferred financing costs         1,2           Changes in operating assets and liabilities:           Accounts receivable         (49,545)           Inventories         (30,593)         (2,314)           Prepaid expenses and other assets         (600)         942         663         4,00           Prepaid manufacturing costs         160         (3,935)         600         (1,10           Accounts payable & accrued expenses         11,478         2,673         676         9,17           Deferred revenue and research and development costs         (5,343)         (767)         (298)         (1,74           Net cash used in operating activities         (139,614)         (109,914)         (50,308)         (96,73           Cash flows from investing activities:         (48,719)         (734,567)         (419,086)         (508,8           Proceeds from maturity or sale of marketable securities         87,985         853,924         398,971         513,42           Purchase of property, plant and equipment         (68,825)         (31,856)         (444)         (2,98           Decrease (Increase) in restricted cash         3,077         53,907         (20,559)					1.600		2 000	
Write-off of deferred financing costs         Changes in operating assets and liabilities:         Accounts receivable       (49,545)         Inventories       (30,593)       (2,314)         Prepaid expenses and other assets       (600)       942       663       4,07         Prepaid manufacturing costs       160       (3,935)       600       (1,16         Accounts payable & accrued expenses       11,478       2,673       676       9,17         Deferred revenue and research and development costs       (5,343)       (767)       (298)       (1,74         Net cash used in operating activities       (139,614)       (109,914)       (50,308)       (96,75         Cash flows from investing activities:       (48,719)       (734,567)       (419,086)       (508,81)         Proceeds from maturity or sale of marketable securities       87,985       853,924       398,971       513,47         Purchase of property, plant and equipment       (68,825)       (31,856)       (444)       (2,98)         Decrease (Increase) in restricted cash       3,077       53,907       (20,559)       1,62         Cash flows from financing activities:       3,077       53,907       (20,559)       1,62          Cash flows from financing activities:	1						3,808	
Changes in operating assets and liabilities:  Accounts receivable Inventories (30,593) (2,314) Prepaid expenses and other assets (600) 942 663 4,07 Prepaid manufacturing costs (600) 942 663 4,07 Prepaid manufacturing costs (600) 942 663 4,07 Prepaid manufacturing costs (160) (3,935) 600 (1,10 Accounts payable & accrued expenses (11,478 2,673 676 9,17 Deferred revenue and research and development costs (5,343) (767) (298) (1,76  Net cash used in operating activities  (139,614) (109,914) (50,308) (96,75  Cash flows from investing activities:  Purchase of marketable securities (48,719) (734,567) (419,086) (508,81 Proceeds from maturity or sale of marketable securities (48,719) (734,567) (419,086) (508,81 Proceeds from maturity or sale of marketable securities (68,825) (31,856) (444) (2,98 Decrease (Increase) in restricted cash (32,636 (33,594)  Net cash provided by (used in) investing activities (30,779 53,907 (20,559) 1,62  Cash flows from financing activities:		22,025	20,615		4,314		375	
Accounts receivable (49,545) Inventories (30,593) (2,314) Prepaid expenses and other assets (600) 942 663 4,07 Prepaid manufacturing costs 160 (3,935) 600 (1,16 Accounts payable & accrued expenses 111,478 2,673 676 9,17 Deferred revenue and research and development costs (5,343) (767) (298) (1,74  Net cash used in operating activities (139,614) (109,914) (50,308) (96,75)  Cash flows from investing activities:  Purchase of marketable securities (48,719) (734,567) (419,086) (508,81) Proceeds from maturity or sale of marketable securities 87,985 853,924 398,971 513,42  Purchase of property, plant and equipment (68,825) (31,856) (444) (2,981) Decrease (Increase) in restricted cash 32,636 (33,594)  Net cash provided by (used in) investing activities 3,077 53,907 (20,559) 1,620  Cash flows from financing activities:							1,212	
Inventories   (30,593)   (2,314)		(40.545)						
Prepaid expenses and other assets         (600)         942         663         4,07           Prepaid manufacturing costs         160         (3,935)         600         (1,16           Accounts payable & accrued expenses         11,478         2,673         676         9,17           Deferred revenue and research and development costs         (5,343)         (767)         (298)         (1,74           Net cash used in operating activities         (139,614)         (109,914)         (50,308)         (96,75           Cash flows from investing activities:         Purchase of marketable securities         (48,719)         (734,567)         (419,086)         (508,85           Proceeds from maturity or sale of marketable securities         87,985         853,924         398,971         513,45           Purchase of property, plant and equipment         (68,825)         (31,856)         (444)         (2,98)           Decrease (Increase) in restricted cash         32,636         (33,594)           Net cash provided by (used in) investing activities         3,077         53,907         (20,559)         1,62           Cash flows from financing activities:         1,62         1,62         1,62         1,62         1,62         1,62         1,62         1,62         1,62         1,62         1,62		( / /	(2.214)					
Prepaid manufacturing costs         160         (3,935)         600         (1,10           Accounts payable & accrued expenses         11,478         2,673         676         9,17           Deferred revenue and research and development costs         (5,343)         (767)         (298)         (1,74           Net cash used in operating activities         (139,614)         (109,914)         (50,308)         (96,75)           Cash flows from investing activities:         (48,719)         (734,567)         (419,086)         (508,81)           Proceeds from maturity or sale of marketable securities         87,985         853,924         398,971         513,42           Purchase of property, plant and equipment         (68,825)         (31,856)         (444)         (2,98           Decrease (Increase) in restricted cash         32,636         (33,594)         (33,594)         (20,559)         1,62           Cash flows from financing activities:         3,077         53,907         (20,559)         1,62					662		4.077	
Accounts payable & accrued expenses 11,478 2,673 676 9,17  Deferred revenue and research and development costs (5,343) (767) (298) (1,74  Net cash used in operating activities (139,614) (109,914) (50,308) (96,75)  Cash flows from investing activities:  Purchase of marketable securities (48,719) (734,567) (419,086) (508,81)  Proceeds from maturity or sale of marketable securities 87,985 853,924 398,971 513,47  Purchase of property, plant and equipment (68,825) (31,856) (444) (2,98)  Decrease (Increase) in restricted cash 32,636 (33,594)  Net cash provided by (used in) investing activities 3,077 53,907 (20,559) 1,629  Cash flows from financing activities:								
Deferred revenue and research and development costs         (5,343)         (767)         (298)         (1,74)           Net cash used in operating activities         (139,614)         (109,914)         (50,308)         (96,75)           Cash flows from investing activities:         Purchase of marketable securities         (48,719)         (734,567)         (419,086)         (508,81)           Proceeds from maturity or sale of marketable securities         87,985         853,924         398,971         513,42           Purchase of property, plant and equipment         (68,825)         (31,856)         (444)         (2,98)           Decrease (Increase) in restricted cash         32,636         (33,594)         (33,594)         (20,559)         1,62           Cash flows from financing activities:         3,077         53,907         (20,559)         1,62								
Net cash used in operating activities       (139,614)       (109,914)       (50,308)       (96,75)         Cash flows from investing activities:       Purchase of marketable securities       (48,719)       (734,567)       (419,086)       (508,81)         Proceeds from maturity or sale of marketable securities       87,985       853,924       398,971       513,42         Purchase of property, plant and equipment       (68,825)       (31,856)       (444)       (2,98)         Decrease (Increase) in restricted cash       32,636       (33,594)         Net cash provided by (used in) investing activities       3,077       53,907       (20,559)       1,62         Cash flows from financing activities:			· ·					
Cash flows from investing activities:           Purchase of marketable securities         (48,719)         (734,567)         (419,086)         (508,81)           Proceeds from maturity or sale of marketable securities         87,985         853,924         398,971         513,42           Purchase of property, plant and equipment         (68,825)         (31,856)         (444)         (2,98           Decrease (Increase) in restricted cash         32,636         (33,594)           Net cash provided by (used in) investing activities         3,077         53,907         (20,559)         1,62           Cash flows from financing activities:         1,62 <t< td=""><td>Deferred revenue and research and development costs</td><td>(5,343)</td><td>(/6/)</td><td></td><td>(298)</td><td></td><td>(1,748)</td></t<>	Deferred revenue and research and development costs	(5,343)	(/6/)		(298)		(1,748)	
Purchase of marketable securities         (48,719)         (734,567)         (419,086)         (508,81)           Proceeds from maturity or sale of marketable securities         87,985         853,924         398,971         513,42           Purchase of property, plant and equipment         (68,825)         (31,856)         (444)         (2,982)           Decrease (Increase) in restricted cash         32,636         (33,594)           Net cash provided by (used in) investing activities         3,077         53,907         (20,559)         1,622           Cash flows from financing activities:	Net cash used in operating activities	(139,614)	(109,914)		(50,308)		(96,757)	
Purchase of marketable securities         (48,719)         (734,567)         (419,086)         (508,81)           Proceeds from maturity or sale of marketable securities         87,985         853,924         398,971         513,42           Purchase of property, plant and equipment         (68,825)         (31,856)         (444)         (2,982)           Decrease (Increase) in restricted cash         32,636         (33,594)           Net cash provided by (used in) investing activities         3,077         53,907         (20,559)         1,622           Cash flows from financing activities:								
Proceeds from maturity or sale of marketable securities 87,985 853,924 398,971 513,42  Purchase of property, plant and equipment (68,825) (31,856) (444) (2,982)  Decrease (Increase) in restricted cash 32,636 (33,594)  Net cash provided by (used in) investing activities 3,077 53,907 (20,559) 1,622  Cash flows from financing activities:	8	(40.740)	(504.555)		(440.000)		(500.040)	
Purchase of property, plant and equipment (68,825) (31,856) (444) (2,982) Decrease (Increase) in restricted cash 32,636 (33,594)  Net cash provided by (used in) investing activities 3,077 53,907 (20,559) 1,622  Cash flows from financing activities:							(508,818)	
Decrease (Increase) in restricted cash  32,636 (33,594)  Net cash provided by (used in) investing activities  3,077 53,907 (20,559) 1,62  Cash flows from financing activities:								
Net cash provided by (used in) investing activities 3,077 53,907 (20,559) 1,62  Cash flows from financing activities:					(444)		(2,980)	
Cash flows from financing activities:	Decrease (Increase) in restricted cash	32,636	(33,594)					
	Net cash provided by (used in) investing activities	3,077	53,907		(20,559)		1,625	
Proceeds from convertible debt offering 150.00	Cash flows from financing activities:							
	Proceeds from convertible debt offering						150,000	
Convertible debt issuance costs (4,7:	Convertible debt issuance costs						(4,758)	
Redemption of convertible notes (120,00	Redemption of convertible notes						(120,000)	
		(161)	(224)		(57)		(126)	
Proceeds from mortgage loan 18,000 26,000		18,000	26,000					
Exchange of treasury shares (279) (381)								
Net proceeds from issuance of common stock 47,005 153,827 67,991 3,74	Net proceeds from issuance of common stock	47,005	153,827		67,991		3,743	
Net cash provided by financing activities 64,844 179,324 67,553 28,85	Net cash provided by financing activities	64,844	179,324		67,553		28,859	
Effect of exchange rate changes on cash 188 (120) (8)	Effect of exchange rate changes on cash	188	(120)		(8)			
		(54.505)					(66,273)	
							113,224	
Cash and cash equivalents at end of period \$ 95,321 \$ 166,826 \$ 43,629 \$ 46,95	Cash and cash equivalents at end of period	\$ 95,321	\$ 166,826	\$	43,629	\$	46,951	
Supplemental disclosures								
		\$ 6,146					7,966	
Cash paid for income taxes \$ 24 \$ \$	Cash paid for income taxes	\$ 24	\$	\$		\$		

See Notes 8 and 11 for investing and financing non-cash disclosures

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

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### Alexion Pharmaceuticals, Inc.

#### **Notes to Consolidated Financial Statements**

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

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

Alexion Pharmaceuticals, Inc. (Alexion, we, our, us, the Company) is a biopharmaceutical company engaged in the discovery, development delivery of biologic therapeutic products aimed at treating patients with severe and life-threatening disease states, including hematologic and neurologic diseases, cancer and autoimmune disorders. From our inception in January 1992 through early 2007, we devoted substantially all of our resources to drug discovery, research, and product and clinical development.

In March 2007, the U.S. Food and Drug Administration, or FDA, granted approval for our lead product Soliris® (eculizumab) for the treatment of a rare, life-threatening blood disorder known as Paroxysmal Nocturnal Hemoglobinuria, or PNH. In June 2007, the European Commission, or E.C., also approved Soliris for the treatment of PNH.

Through December 31, 2007, our product sales have been solely attributable to sales of Soliris and have been generated from three sources: commercial sales in the United States (beginning in the second quarter of 2007), pre-approval, or named-patient, sales in certain European countries (beginning in the first quarter of 2007) and commercial sales in certain European countries (beginning in the fourth quarter of 2007).

We have incurred operating losses since our inception. As of December 31, 2007, we had an accumulated deficit of \$729,279. We expect to incur operating losses and negative cash flow for additional future periods due to costs associated with the commercialization of Soliris in the United States and Europe, pre-commercialization activities and anticipated commercialization activities in other territories, development of our manufacturing plant in Rhode Island, including engineering and validation runs, product research and development, pre-clinical studies and clinical testing, regulatory activities, commercial-scale manufacturing at our third party contractor and at our own manufacturing plant when that site is approved to manufacture Soliris, and other infrastructure support costs.

Until we can generate sufficient levels of cash from our operations, we expect to continue to finance future cash needs primarily through the use of available cash, cash equivalents and short-term investments, and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements.

# **Basis of Presentation and Principles of Consolidation**

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

# **Dividend Policy**

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

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### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

#### **Use of Estimates**

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

#### **Foreign Currency Translation**

The financial statements of our subsidiaries with functional currencies other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for stockholders—equity and weighted average exchange rates for operating results. Translation gains and losses are included in accumulated other comprehensive income in stockholders—equity. Foreign currency transaction gains and losses are included in the results of operations in other income (expense).

# **Segment Reporting**

SFAS No. 131, Disclosure about Segments of an Enterprise and Related Information, establishes annual and interim reporting standards for an enterprise's operating segments and related disclosures about its products, services, geographic areas and major customers. We operate in a single segment, the discovery, development and commercialization of biopharmaceutical products (see Note 14 for geographic information).

# Cash and Cash Equivalents

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

# **Restricted Cash**

Under the terms of our mortgage loan (see Note 7), we maintain a restricted cash balance equal to the amount required under our mortgage loan agreement. At December 31, 2007 and 2006, \$958 and \$33,594, respectively, of cash is restricted for that purpose.

# **Fair Value of Financial Instruments**

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term maturities. Our marketable securities, all of which are available-for-sale, are carried at fair value based on quoted market prices. Our convertible notes and mortgage loan are carried at historical cost (see Note 7 for fair value disclosures).

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## Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

#### Marketable Securities

We invest our excess cash balances in marketable securities of highly rated financial institutions and investment-grade debt instruments. We limit the amount of investment exposure as to institution, maturity and investment type. We classify our marketable securities as available-for-sale and, accordingly, record such securities at fair value. Unrealized gains or losses, deemed temporary, are included in accumulated other comprehensive loss as a separate component of stockholders' equity. If any adjustment to fair value reflects a decline in the value of the security, we consider all available evidence to evaluate the extent to which the decline is other than temporary and mark the security to market through a charge to our statement of operations.

#### **Accounts Receivable**

We make judgements as to our ability to collect outstanding receivables and will provide allowances for the portion of receivables if and when collection becomes doubtful. We record allowances to reduce accounts receivable to amounts expected to be collected.

For the year ended December 31, 2007, three individual customers each accounted for 39%, 26% and 12% of the accounts receivable balance. For the year ended December 31, 2007, three individual customers each accounted for 40%, 25% and 11% of net product sales.

# Inventories

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

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

	Decen	ıber 31,
	2007	2006
Raw Materials	\$ 4,985	\$
Work-In-Process	17,677	
Finished Goods	10,245	2,314
	\$ 32,907	\$ 2,314

# Capitalization of Inventory Costs

We capitalize inventory produced for commercial sale, including the capitalization of inventory costs prior to regulatory approval but subsequent to the filing of a Biologics License Application, or BLA, when the Company has determined that the inventory has probable future economic benefit. Inventory is not capitalized

### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

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

Inventory Write-Offs

We analyze our inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of our product is subject to strict quality control, certain batches or units of product may, after a period of time, no longer meet quality specifications or may expire, at which point we would adjust our inventory values. Soliris currently has a maximum estimated life of 42 months and, based on our sales forecasts, we expect the carrying value of the Soliris inventory and prepaid manufacturing costs to be fully realized.

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

### **Prepaid Manufacturing Costs**

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

#### **Property, Plant and Equipment**

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

Laboratory equipment five to seven years

Furniture and office equipment three to five years

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

### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

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

## Long-Lived Assets

We evaluate our long-lived assets, which are primarily comprised of property, plant and equipment, for impairment whenever events or changes in circumstances indicate the carrying value of an asset or group of assets is not recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to future undiscounted net cash flows expected to be generated by the assets group. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. The Company did not recognize any impairment loss for long-lived assets during the year ended December 31, 2007. See Note 6 for information related to exit activities in the year ended December 31, 2006.

# Goodwill

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

# **Revenue Recognition**

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

Net Product Sales

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

### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

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. Soliris is generally shipped directly from our third party warehouse to the patients health-care provider, who is not typically our direct customer. Revenue is recorded upon receipt of the product by the patients health-care provider, which is typically a hospital or physician s office.

Through December 31, 2007, we have recorded revenue on sales for individual patients through named-patient programs in certain European countries. The relevant authorities in those countries have agreed to reimburse for product sold on a named-patient basis where Soliris has not received formal approval for commercial sales. In Europe, we have entered into transitional agreements with a distributor to distribute Soliris on a named-patient basis in specified European countries.

We continue to engage with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required by each European country. We are more complete in those processes in certain countries such as Germany and in earlier stages in other countries such as the United Kingdom. In European countries in which Soliris is currently commercially available and will be commercially available in the future, our customers are expected to be primarily hospitals, hospital buying groups, pharmacies and other health care providers, with the exception of the United Kingdom, in which our primary product sales will be through a distributor.

Sales within Europe are recorded upon receipt of product by the health-care provider.

To date, actual refunds and returns have been negligible. 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 return rights, Soliris customers generally carry limited inventory. We monitor inventory within our distribution channel to determine whether reserves are required based on inventory in our sales channel.

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

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

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### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

### Contract Research Revenue

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

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

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

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

Effective March 30, 2007, we and Procter & Gamble Pharmaceuticals, or P&G, agreed to terminate our 1999 collaboration agreement for the development and commercialization of pexelizumab (See Note 2). As the agreement has been terminated, and no further obligations remain, the remaining portion of the \$10,000 non-refundable up-front license fee, or \$5,343, was recognized as revenue during the three months ended March 31, 2007.

# Royalties

Our cost of sales for the year ended December 31, 2007 consists of actual and estimated royalties to third parties related to the sale and commercial manufacture of Soliris. We estimate royalties potentially owed to third parties based on contractual arrangements with certain parties, as well as our assessment of possible royalty amounts owed to other third parties. These estimates may be influenced by changes in the status of current litigation (See Note 9), the results of which are uncertain. On a periodic basis and based on events such as the outcome of litigation, we may reassess these estimates, resulting in adjustments to cost of sales.

### **Research and Development Expenses**

Research and development expenses are comprised of costs incurred in performing research and development activities including salaries and benefits, pre-clinical, clinical trial and related clinical manufacturing costs, manufacturing development and scale-up costs, contract services and other outside

## Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

contractor costs, research license fees, depreciation and amortization of lab facilities, and lab supplies. These costs are expensed as incurred. We accrue costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the vendors that perform the services.

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

#### **Stock-Based Compensation**

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

We adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment , or SFAS 123(R), effective August 1, 2005. SFAS 123(R) requires compensation costs relating to stock-based payment transactions to be recognized in the financial statements using a fair-value measurement method.

Prior to August 1, 2005, we accounted for the 2004 Incentive Plan and preceding plans under the intrinsic value method described in Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, (APB No. 25) and related Interpretations as permitted by Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation. (SFAS 123). When applying the intrinsic value method, we generally did not record stock-based compensation cost because the exercise price of our stock options equalled the market price of the underlying stock on the date of grant.

### Earnings (Loss) per Share (EPS)

Basic EPS is computed by dividing net loss by the weighted average number of shares of common stock outstanding. For purposes of calculating diluted EPS, net loss is adjusted for the after-tax amount of interest and deferred financing costs associated with the convertible debt, and the denominator reflects the potential dilution, using the treasury stock method, that could occur if options or other contracts to issue common stock were exercised or converted into common stock. Due to our net loss, convertible debt, unvested restricted stock, and stock options granted under the stock option plan but not yet exercised are anti-dilutive and therefore not considered for the diluted EPS calculations.

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### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

Potentially dilutive securities include:

		December 31,			
	2007	2006	2005	2005	
Options to purchase common stock	4,194,723	5,372,463	5,092,085	4,729,793	
Unvested restricted stock	454,484	324,289	133,500	105,500	
Common stock issuable under convertible debt	4,768,710	4,768,710	4,768,710	4,768,710	
	9,417,917	10,465,462	9,994,295	9,604,003	

There is no difference between basic and diluted net loss per common share, as the effect of other potential common share equivalents is anti-dilutive for the periods presented.

### **Income Taxes**

The provision for income taxes includes federal, state, local and foreign taxes. Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences of temporary differences between the financial statement carrying amounts and their respective tax basis at the statutory tax rates that will be in effect when the differences are expected to recovered or settled. A valuation allowance for the net deferred tax assets is recorded to the extent we cannot determine that the ultimate realization of net deferred tax assets is more likely than not.

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

We adopted the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 48, Accounting for Uncertainty in Income Taxes, (FIN 48) on January 1, 2007. As a result of this adoption, we recognized a benefit of \$591 to the January 1, 2007 accumulated deficit balance.

# **Comprehensive Income (Loss)**

SFAS No. 130, Reporting Comprehensive Income, requires us to display comprehensive income (loss) and its components as part of our financial statements. Comprehensive income (loss) is comprised of net income

## Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

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(loss) and other comprehensive income (loss). Other comprehensive income (loss) includes changes in equity that are excluded from net income (loss), such as translation adjustments and unrealized holding gains and losses on available-for-sale marketable securities. All of these changes in equity are reflected net of tax, as appropriate.

# **Recently Issued Accounting Standards**

In December 2007, Statement of Financial Accounting Standards No. 141(R), *Business Combinations*, or SFAS 141(R), was issued. This standard will require an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, the acquiring company is required to capitalize in-process research and development and either amortize it over the life of the product, or write-off the costs if the project is abandoned or impaired. The Standard is effective for transactions occurring on or after January 1, 2009.

In February 2007, Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including and Amendment of FASB Statement No. 115*, or SFAS 159, was issued. This standard permits us to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements. This standard is effective January 1, 2008 for the Company.

In September 2006, Statement of Financial Accounting Standards No. 157, *Fair Value Measurement*, or SFAS 157, was issued. This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, or GAAP, and expands disclosure about fair value measurements. This standard is effective January 1, 2008 for the Company.

We do not expect these standards to have a material impact on our financial statements.

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

In January 1999, we and Procter & Gamble Pharmaceuticals, or P&G, entered into an exclusive collaboration to develop and commercialize pexelizumab. We granted P&G an exclusive license to our intellectual property related to pexelizumab, with the right to sublicense. In December 2001, we and P&G entered into an agreement pursuant to which the January 1999 collaboration was revised. We and P&G agreed to share concurrently 50% of the ongoing U.S. pre-production and development manufacturing costs for pexelizumab as well as any acute myocardial infarction or coronary artery bypass graft Phase III clinical trial costs. We were recognizing a nonrefundable up-front license fee of \$10,000 related to the P&G collaboration as revenue over 17 years beginning in 1999.

#### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

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

#### License and Research and Development Agreements

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

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

Clinical and manufacturing development agreements generally provide for us to fund manufacturing development and on-going clinical trials. Clinical trial and development agreements include contract services and outside contractor services including contracted clinical site services related to patient enrolment for our clinical trials. Manufacturing development agreements include clinical manufacturing and manufacturing development and scale-up. We have executed a large-scale product supply agreement with Lonza Sales AG for the long-term commercial manufacture of Soliris (see Note 9).

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

The minimum fixed payments (assuming non-termination of the above agreements) as of December 31, 2007, for each of the next five years are as follows:

		Clinical and
		Manufacturing
	License	Development
Years Ending December 31,	Agreements	Agreements
2008	\$ 707	\$ 2,860
2009	552	3,750
2010	322	7,500
2011	300	7,500
2012	300	7,500

#### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

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#### 3. Marketable Securities

The following table summarizes our marketable securities:

	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
December 31, 2007				
Federal agency obligations	\$ 8,711	\$ 3	\$	\$ 8,714
Corporate bonds	1,722		(3)	1,719
Total	\$ 10,433	\$ 3	\$ (3)	\$ 10,433
December 31, 2006				
Federal agency obligations	\$ 19,907	\$ 2	\$ (30)	\$ 19,879
Corporate bonds	13,117	4	(17)	13,104
Certificates of deposit	11,820		(5)	11,815
Commercial paper	4,932		(2)	4,930
Total	\$ 49,776	\$ 6	\$ (54)	\$ 49,728

Realized gains of approximately \$101 were recorded during the year ended July 31, 2005. No realized gains were recorded for the year ended December 31, 2007 and 2006, and the five month period ended December 31, 2005. No realized losses were recorded for the year ended December 31, 2007 and 2006, five month period ended December 31, 2005 and the year ended July 31, 2005, respectively. We utilize the specific identification method in computing realized gains and losses. At December 31, 2007, our marketable securities had a maximum maturity of approximately nine months with an average of approximately two months. The weighted average interest rate associated with marketable debt securities was 4.7 percent, 5.3 percent, 4.4 percent and 3.7 percent at December 31, 2007 and 2006 and 2005 and July 31, 2005, respectively.

At December 31, 2007, all marketable securities had a maturity of less than one year.

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

#### Alexion Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

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The following tables show the gross unrealized losses and fair value of our investments with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position at:

#### December 31, 2007

	Less than	12 Months		12 Mont	hs or More	T	otal	
Description of Securities	Fair Value	Unrealiz Losses		Fair Value	Unrealized Losses	Fair Value	Unrealiz Losses	
Federal agency obligations	\$	\$		\$	\$	\$	\$	
Corporate bonds	1,719	(	(3)			1,719		(3)
	\$ 1,719	\$	(3)	\$	\$	\$ 1,719	\$	(3)

#### December 31, 2006

	Less than		nths ealized	12 Month		lore ealized	To	tal Unr	ealized
Description of Securities	Fair Value	Lo	osses	Fair Value	Lo	osses	Fair Value	Lo	osses
Federal agency obligations	\$ 8,194	\$	(10)	\$ 8,143	\$	(20)	\$ 16,337	\$	(30)
Corporate bonds	7,006		(6)	2,012		(11)	9,018		(17)
Certificates of deposit	9,779		(5)				9,779		(5)
Commercial paper	4,931		(2)				4,931		(2)
	\$ 29,910	\$	(23)	\$ 10,155	\$	(31)	\$ 40,065	\$	(54)

For the investments in all categories shown in the above table, the unrealized losses were caused primarily by increases in market interest rates.

## 4. Other Assets

Prepaid expenses and other current assets consist of the following:

	ember 31, 2007	Dec	December 31, 2006	
State tax receivable	\$ 2,330	\$	1,448	

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VAT Receivable Other	1,039 3,271	2,525
	\$ 6.640	\$ 3,973

#### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

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Other non-current assets consist of the following:

	Dec	December 31, 2007		ember 31, 2006
Deferred financing costs, net	\$	2,768	\$	3,446
Leasehold deposits		1,043		632
	\$	3,811	\$	4,078

In July 2007, we amended our existing license agreement with the University of Iowa Research Foundation, or UIRF, to buy out the royalty payable to UIRF with respect to sales of Soliris for the treatment of PNH. Under the terms of the amended license agreement, we agreed to pay UIRF \$1,000 in exchange for elimination of the royalty payable on net sales of Soliris for the treatment of PNH. Such payment was made in July 2007 and has been recorded as a prepaid royalty. The amount will be amortized to cost of sales over the estimated useful life. The payment does not affect any other product marketed by Alexion under the license, and net sales of any other product covered by the UIRF license agreement shall be subject to royalties.

#### 5. Property, Plant and Equipment

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

Asset	December 31, 2007		December 3	
Land	\$	692	\$	692
Buildings and improvements		9,266		10,163
Laboratory equipment		10,742		10,735
Furniture and office equipment		8,645		4,453
Construction-in-progress		91,305		28,827
		120,650		54,870
Less: Accumulated depreciation and amortization		(16,370)		(15,735)
	\$	104,280	\$	39,135

Depreciation and amortization of property, plant and equipment was approximately \$4,243, \$3,028, \$1,359 and \$2,996 for the year ended December 31, 2007 and 2006, five month period ended December 31, 2005 and for the years ended July 31, 2005, respectively.

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

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#### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

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

Through December 31, 2007, we have capitalized \$91,231 related to the facility, which includes all costs associated with construction, renovation and upgrades, labor, materials and overhead for engineering runs and capitalized interest. Through December 31, 2007, non-construction validation costs incurred in seeking regulatory approval, including engineering runs, was \$21,999, and capitalized interest has \$4,328. See Note 7 for a description of the terms of the related mortgage payable.

#### 6. Accrued Expenses

Accrued expenses consist of the following:

	nber 31, 007	December 3 2006		
Payroll and employee benefits	\$ 10,610	\$	4,465	
Royalties	4,724			
Clinical expense	3,437		4,379	
VAT Payable	1,415			
Rebates	1,006			
Other	7,132		7,384	
	\$ 28,324	\$	16,228	

## **Exit Activities**

In December 2006, we initiated an integration plan with our subsidiary, Alexion Antibody Technologies, Inc., to consolidate certain functions and operations, including the termination of all Alexion Antibody personnel, closure of Alexion Antibody facilities, and impairment of equipment in that facility. These costs have been recognized as liabilities and are included in selling, general and administrative expenses for the year ended December 31, 2006. The following table summarizes the liabilities established for exit activities as of December 31, 2006 and subsequent cash payments and revision of estimates made during year ended December 31, 2007:

	Employee Related Benefits	Facility Lease Costs	Other Exit Activities	Total Exit Activities
Recorded on exit date	\$ 5,401	\$ 1,379	\$ 539	7,319
Revision of estimate				
Payments and other settlements	(43)			(43)
Balance at December 31, 2006	\$ 5,358	\$ 1,379	\$ 539	\$ 7,276

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Revision of estimate	21		(144)		(123)
Payments and other settlements	(5,379)	(616)	(395)	(	(6,390)
Balance at December 31, 2007	\$	\$ 763	\$	\$	763

#### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

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Employee benefits consist of expenses for severance compensation as well as accelerated vesting of share-based grants. Facility lease costs are associated with the lease on our San Diego, California facility as described in Note 6 and other exit activities consist of impairment charges on equipment. The Company remains obligated for lease payments through 2012. In September 2007, the Company signed a sub-lease for the AAT facility, which provides for sub-lease payments through the term of the lease, or 2012. The accrual for restructuring activities reflects the present value of lease obligations, reduced by estimated sub-lease income. As of December 31, 2007, all remaining costs associated with employee related benefits and other exit activities have been paid or settled.

#### 7. Debt Convertible Notes

In January 2005 we sold \$150,000 principal amount of 1.375% Convertible Senior Notes due February 1, 2012 (the 1.375% Notes) in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 1.375% per annum on the principal amount from January 25, 2005, payable semi-annually in arrears in cash on February 1 and August 1 of each year, beginning August 1, 2005. The 1.375% Notes is convertible into our common stock at an initial conversion rate of 31.7914 shares of common stock (equivalent to a conversion price of approximately \$31.46 per share) per \$1 principal amount of the 1.375% Notes, subject to adjustment, at any time prior to the close of business on the final maturity date of the notes. We do not have the right to redeem any of the 1.375% Notes prior to maturity. The convertible notes payable do not require compliance with covenants related to our financial performance.

The net proceeds of approximately \$145,200 from this offering were used to redeem our entire outstanding \$120,000 principal amount of 5.75% Convertible Subordinated Notes due March 2007 ( 5.75% Notes ) and for general corporate purposes. On March 15, 2005, we redeemed all of the 5.75% Notes outstanding at the redemption price of 101.643% for each \$1 principal amount of 5.75% Notes. We paid a redemption premium related to these notes of approximately \$2,000 during the year ended July 31, 2005. The difference between the amount paid, including the redemption premium, and the carrying value of the notes, including the remaining deferred financing costs, was recognized as a \$3,185 loss from early extinguishment of convertible notes.

We capitalized deferred financing costs related to this offering of approximately \$4,800 which are amortized as a component of interest expense over the seven-year term of the notes.

Amortization expense associated with deferred financing costs for the year ended December 31, 2007 and 2006, five month period ended December 31, 2005 and the year ended July 31, 2005 was approximately \$677, \$0, \$282 and \$686, respectively.

As of December 31, 2007, the market value of our \$150,000, 1.375% Convertible Notes due February 1, 2012, based on quoted market prices, was estimated at \$375,000.

#### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

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The Convertible Senior Notes require certain designated events which could occur such as a liquidation or change in control in which consideration which is not at least 90% common stock that is listed on a U.S. national exchange or market. If the holder elects to convert its 1.375% Notes upon the occurrence of a designated event, the holder will be entitled to receive an additional number of shares of common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option, are set according to a table within the offering document, and are capped (in no event will the shares issuable upon conversion of a note exceed 42.9100 per \$1 principal amount).

#### Mortgage Loan

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

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

The fair value of mortgage loan approximates the carrying amount at December 31, 2007, as the interest rate on the loan represents the approximate rates available to the Company for loans with similar terms.

#### 8. Leases Capital Leases

We lease office equipment under capital lease agreements expiring in 2010. The assets and liabilities under capital lease are recorded at the lower of the present value of the minimum lease payments or the fair value of the asset. The assets are amortized over the lower of their related lease terms or their estimated useful lives. Amortization of assets under capital lease is included in depreciation expense. As of December 31, 2007, the cost of equipment under capital lease is \$940 and accumulated amortization is \$234. The weighted-average interest rate on the capital leases is approximately 9.5%.

#### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

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Minimum future lease payments under capital lease as of December 31, 2007 are:

Year	
2008	\$ 336
2009	336
2010	214
2011	
	886
Less: Amount representing interest	(115)
Present value of minimum lease payments	\$ 771

## **Operating Leases**

As of December 31, 2007, we lease our headquarters and primary research and development facilities in Cheshire, Connecticut. The lease commenced in August 2000, was extended in August 2006 and revised again in June 2007. The lease is set to expire in May 2017. Monthly fixed rent started at approximately \$162, increasing to approximately \$193 over the term of this lease.

In January 2003, we entered into a lease agreement for our pilot manufacturing plant and associated labs and offices in New Haven, Connecticut. The lease expired in October 2007. Pilot manufacturing operations have been transferred to our manufacturing facility located in Smithfield, Rhode Island.

We lease additional research space in San Diego, California, starting at a monthly fixed rent of approximately \$35 and increasing to approximately \$55. In connection with the closure of Alexion Antibody Technologies (AAT) in 2006, we accrued the fair value of future payments under the lease (see Note 6). In September 2007, the Company signed a sub-lease for the AAT facility, which provides for sub-lease payments through the term of the lease, or 2012.

We rent office space in various European cities, at a monthly rent of approximately \$121, certain of which are renewable monthly. The rental agreements begin to expire in December 2008. Many of these agreements have built-in renewal features.

Aggregate lease expense for our facilities was \$4,021, \$2,592, \$1,094 and \$2,296 for the years ended December 31, 2007 and 2006, five month period ended December 31, 2005 and the year ended July 31, 2005, respectively. Lease expense is being recorded on a straight-line basis over the applicable lease terms.

#### Alexion Pharmaceuticals, Inc.

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

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Aggregate future minimum annual rental payments for the next five years and thereafter under non-cancellable operating leases (including facilities and equipment) as of December 31, 2007 are:

2008	\$ 4,935
2009	3,144
2010	3,160
2011	3,200
2012	2,768
Thereafter	9,934

# 9. Commitments and Contingencies Legal Proceedings

On March 16, 2007, PDL BioPharma, Inc., or PDL, filed a civil action against Alexion in the U.S. District Court for the District of Delaware. PDL claims willful infringement by Alexion of PDL patents due to sales of Soliris. PDL seeks unspecified damages, but no less than a reasonable royalty, plus attorney s fees. Alexion has denied PDL's claims. In addition, we filed counterclaims seeking declarations of non-infringement and invalidity of certain U.S. patents held by PDL. Alexion believes it has good and valid defenses to PDL's claims and intends to vigorously defend the case and pursue its counterclaims.

On February 4, 2008, SB2, Inc. filed a civil action against Alexion in the United States District Court for the Northern District of California. SB2, Inc. claims willfull infringement by Alexion of SB2, Inc. patents due to sales of Soliris. SB2, Inc. seeks unspecified monetary damages, equitable relief and attorneys fees. Alexion believes it has good and valid defenses to SB2's claims and intends to vigorously defend the case and pursue its counterclaims.

The results of such civil actions cannot be predicted with certainty due to their early stages. However, depending on the outcome of these legal matters, the operating results of the Company could be materially impacted through adjustments to cost of sales (see Notes 2, 6 and 15 for additional information related to royalties).

#### **Product Supply**

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

#### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

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#### 10. Income Taxes

We currently record a full valuation allowance against our deferred tax assets as we have determined it is not more-likely-than-not that the benefit from these assets will be realized. Accordingly, we do not record a tax benefit related to our significant net operating losses and other deferred tax assets. We record the benefit of certain research and development tax credits which are subject to a cash exchange with the State of Connecticut. In addition, we record current tax expense related to certain state income taxes.

At December 31, 2007, we have available for federal tax reporting purposes, net operating loss carry forwards of approximately \$732,653 which expire from 2008 through 2027. We also have federal and state research and development credit carry forwards of approximately \$25,088, which expire from 2008 through 2027. The exercise of non-qualified stock options gives rise to compensation that is included in the taxable income of the applicable employees and deducted by us for federal and state income tax purposes. As a result of the exercise of non-qualified stock options, we have net operating loss carry forwards of approximately \$99,972 attributable to excess tax benefits from stock compensation deductions which can be used to offset future taxable income, if any. If and when realized, the related tax benefits of these net operating losses carry forwards will be credited directly to paid-in capital.

The Tax Reform Act of 1986 contains certain provisions that can limit a taxpayer's ability to utilize net operating loss and tax credit carry forwards in any given year resulting from cumulative changes in ownership interests in excess of 50 percent over a three-year period. We have determined that these limiting provisions were triggered. However, such limitation is not expected to result in the loss of the federal net operating loss and research and development credit.

As a result of the implementation of FIN 48, we recognized a benefit of \$591 to the January 1, 2007 accumulated deficit balance. In addition, we also decreased our fully reserved deferred tax assets by \$6,671 as a consequence of implementing FIN 48. The total amount of unrecognized tax benefits as of January 1, 2007, including the cumulative effect of the adoption of FIN 48, is \$6,671. We did not record any changes to our unrecognized tax benefits during 2007. None of the amount, if recognized, would affect the effective tax rate due to our full valuation allowance against deferred tax assets. While we believe we have adequately provided for all tax positions, amounts asserted by tax authorities could differ from our estimate. We are not aware of any events that could occur within the next 12 months that could cause a significant change in our unrecognized tax benefits.

The State of Connecticut provides companies with the ability to exchange certain research and development tax credit carry forwards for cash in exchange for foregoing the carry forward of the research and development credits. The program provides for such exchange of the research and development credits at a rate of 65 percent of the annual incremental and non-incremental research and development credits, as defined. For the year ended December 31, 2007, we plan to file claims to exchange research and tax development credits and, therefore, recognized a state tax benefit of \$686. The state tax benefit excludes our estimated capital-based taxes which was recorded as an operating expense.

## Alexion Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

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The components of deferred income tax assets are as follows:

	Year Ended December 31, 2007	Year Ended December 31, 2006
Deferred income tax assets:		
Domestic net operating loss carryforwards	\$ 245,454	\$ 218,169
Foreign net operating loss carryforwards	3,849	2,580
Tax credit carryforwards	25,088	21,891
Deferred revenues		2,096
Stock compensation	5,917	4,974
Other	2,104	1,743
Total deferred tax assets	282,412	251,453
Less: valuation allowance	(282,412)	(251,453)
	\$	\$

The reconciliation of the statutory federal income tax rate to our effective income tax rate is as follows:

	Year Ended December 31,		<b>Five Month Period</b>	Year Ended	
	2007	2006	Ended December 31, 2005	July 31, 2005	
Federal statutory rate	-35%	-34%	-34%	-34%	
International rate differential	7%	0%	0%	0%	
Permanent difference	1%	0%	0%	0%	
State tax benefit, net of federal tax effect	0%	-5%	-5%	-5%	
Research and development credits	-7%	-5%	-4%	-5%	
Increase in deferred tax valuation allowance	34%	43%	42%	43%	
Effective rate	-1%	-1%	-1%	-1%	

# 11. Stock Options and Restricted Stock Stock Options

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At December 31, 2007, we have one stock option plan, the 2004 Incentive Plan ( 2004 Plan ). Under the 2004 Plan, common stock, as well as incentive and non-qualified stock options, may be granted for up to a maximum of 5,068,519 shares to our directors, officers, key employees and consultants. The amount of shares authorized for granting includes 2,500,000 initially authorized under the plan, 593,519 shares transferred from the 2000 Plan and an additional 1,975,000 shares authorized by our shareholders in 2006 and 2007. Stock options granted under all Plans have a maximum contractual term of ten years from the date of grant, have an exercise price not less than the fair value of the stock on the grant date and generally vest over four years.

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#### Alexion Pharmaceuticals, Inc.

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

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and Year Ended July 31, 2005

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

We selected the modified prospective method as prescribed in SFAS 123(R) and, therefore, prior periods were not restated. Under the modified prospective application, SFAS 123(R) was applied to new grant awards after August 1, 2005, and the unvested portion of previously granted awards that remain outstanding as of August 1, 2005. In addition, the unrecognized expense of awards not yet vested at the date of adoption, determined under the original provisions of SFAS 123, shall be recognized in the periods after the date of adoption. For the years ended December 31, 2007 and 2006, and the five month period ended December 31, 2005, we recognized total stock compensation expense of \$16,438, \$17,601 and \$4,054 for stock options and \$3,736, \$3,014 and \$260 for restricted stock, respectively. During the year ended December 31, 2007, we capitalized \$1,526 and \$325 towards the Rhode Island manufacturing facility and inventory, respectively.

Deductions resulting from the exercise of stock options were not used to reduce current taxes payable, and therefore a windfall tax benefit was not recognized during the period. The balance of deferred stock-based compensation at July 31, 2005 related to the restricted stock grants noted above was approximately \$1,938. Upon the adoption of SFAS 123R, we eliminated the deferred stock-based compensation account of \$1,938 through corresponding adjustments to additional paid-in-capital.

The weighted average fair value at the date of grant for options granted during the years ended December 31, 2007 and 2006, five month period ended December 31, 2005 and the year ended July 31, 2005 is \$22.94, \$19.87, \$17.21 and \$14.27 per option, respectively.

Options exercisable at December 31, 2007 had an aggregate intrinsic value of \$94,947 and a weighted average remaining contractual life of 5.25 years. The aggregate intrinsic value of options exercised during the year ended December 31, 2007 was \$68,942. The fair market value of options vested during the year ended December 31, 2007 was \$41,083.

As of December 31, 2007, there was \$37,014 of total unrecognized compensation expense related to non-vested share-based compensation arrangements granted under the Plan. The expense is expected to be recognized over a weighted-average period of 1.34 years.

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## Alexion Pharmaceuticals, Inc.

## Notes to Consolidated Financial Statements (Continued)

## For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

## and Year Ended July 31, 2005

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

A summary of the status of our stock option plans at December 31, 2007 and 2006, and changes during the years then ended is presented in the table and narrative below:

	Number of shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2005	5,092,085	\$ 24.16		
Granted	1,462,450	29.72		
Exercised	(925,372)	14.69		
Forfeited and cancelled	(256,700)	23.37		
Outstanding at December 31, 2006	5,372,463	\$ 26.69	6.19	\$ 143,266,717
Granted	1,217,500	45.16		
Exercised	(2,096,152)	22.44		
Forfeited and cancelled	(299,088)	33.70		
Outstanding at December 31, 2007	4,194,723	\$ 33.64	6.97	\$ 174,053,644
Vested and unvested expected to vest at December 31, 2007	4,046,823	\$ 33.52	6.90	\$ 168,437,059
Exercisable at December 31, 2007	2,111,629	\$ 30.28	5.25	\$ 94,946,813

The following table presents weighted average price and life information about significant option groups outstanding at December 31, 2007:

		Options Outstanding Weighted-Average		Options	Exercisable
Range of Exercise Prices	Number Outstanding	Remaining Contractual Life (Yrs)	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
\$00.00 to 10.79	234,939	2.6	\$ 9.81	234,939	\$ 9.81
\$10.80 to 21.58	1,126,336	6.3	19.28	789,217	19.00
\$21.59 to 32.36	593,293	6.9	25.47	385,031	24.81
\$32.37 to 43.15	1,175,016	8.5	36.58	268,896	34.72
\$43.15 to 53.94	613,739	9.3	46.48	68,646	45.28
\$53.95 to 75.51	382,900	4.2	65.02	296,400	64.27
\$75.52 to 107.88	68,500	2.3	81.64	68,500	81.64

2,111,629

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4,194,723

#### Alexion Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

The fair value of options at the date of grant was estimated using the Black-Scholes model with the following weighted average assumptions:

			Five Month		
	Year Ended	Year Ended	Period Ended	Year Ended	
	December 31, 2007	December 31, 2006	December 31, 2005	July 31, 2005	
Expected life in years	4.28	6.25	6.25	7.5	
Interest rate	3.10%	4.70%	4.30%	4.10%	
Volatility	43%	68%	68%	78%	

Dividend yield

The expected stock price volatility rates are based on historical volatilities of our common stock. The risk-free interest rates are based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. The average expected life represents the weighted average period of time that options granted are expected to be outstanding. For the year ended December 31, 2006 and 2005, the five month period ended December 31, 2005 and the year ended July 31, 2005, the average expected life was determined using the simplified approach as permitted by Staff Accounting Bulletin No. 107, or SAB 107. For the year ended December 31, 2007, we estimated the expected life of stock options based on historical experience of exercises, cancellations and forfeitures of our stock options.

#### **Restricted Stock**

A summary of the status of our non-vested restricted stock and changes during the periods then ended are:

	Year Ended	Year Ended	
	December 31, 2007	December 31, 2006	
Nonvested restricted stock, beginning of the period	324,289	133,500	
Shares issued	267,055	227,559	
Shares cancelled	(58,086)	(14,770)	
Shares exercised	(78,774)	(22,000)	
Nonvested restricted stock, end of the period	454,484	324,289	
Weighted average grant date fair value	\$ 34.77	\$ 32.95	

Restricted stock that generally vests over four years from grant date has been issued to certain key employees. Compensation expense related to restricted stock for the year ended December 31, 2007 and 2006, five month period ended December 31, 2005 and the year ended July 31, 2005 was approximately \$4,051, \$3,014, \$260 and \$238, respectively.

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#### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

# 12. Common and Preferred Stock

In November 2006, we sold 3,450,000 shares of common stock in a public offering at \$43.00 per share, resulting in gross proceeds from the sale of \$148,350. We incurred underwriting fees and commissions of \$8,121, as well as other costs, resulting in net proceeds of \$140,229.

During the year ended December 31, 2006, we increased our holdings of common stock in treasury by 6,919 shares in lieu of withholding taxes on the exercise of restricted stock. The shares were exchanged at fair market value for \$279 in total. During the five month period ended December 31, 2005, we increased our holdings of common stock in treasury by 13,713 through stock-based exercise of employee options. The shares were exchanged at fair market value for \$381 in total.

In August 2005, we sold 2,500,000 shares of common stock in a public offering at \$26.75 per share, resulting in gross proceeds from the sale of \$66,875. We incurred underwriting fees and commissions of \$2,145, as well as other costs, resulting in net proceeds of \$64,530.

#### Preferred Stock

In February 1997, our Board of Directors declared a dividend of one preferred stock purchase right for each outstanding share of Common Stock (including all future issuances of Common Stock). Under certain conditions, each right may be exercised to purchase one one-hundredth of a share of a new series of preferred stock at an exercise price of \$75.00 (see below), subject to adjustment. The rights may be exercised only after a public announcement that a party acquired 20 percent or more of our Common Stock or after commencement or public announcement to make a tender offer for 20 percent or more of our Common Stock. The rights, which do not have voting rights, expire on March 6, 2007, and may be redeemed by us at a price of \$0.01 per right at any time prior to their expiration or the acquisition of 20 percent or more of our stock. The preferred stock purchasable upon exercise of the rights will have a minimum preferential dividend of \$10.00 per year, but will be entitled to receive, in the aggregate, a dividend of 100 times the dividend declared on a share of Common Stock. In the event of liquidation, the holders of the shares of preferred stock will be entitled to receive a minimum liquidation payment of \$100 per share, but will be entitled to receive an aggregate liquidation payment equal to 100 times the payment to be made per share of Common Stock.

On September 18, 2000, our Board of Directors amended the purchase price under the preferred stock purchase rights. Such purchase price, for each one one-hundredth of a share of preferred stock to be issued upon the exercise of each preferred stock purchase right was increased from \$75.00 to \$725.00. Except for the increase in the purchase price, the terms and conditions of the rights remain unchanged.

#### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

In the event that we are acquired in a merger, other business combination transaction, or 50 percent or more of our assets, cash flow, or earning power are sold, proper provision shall be made so that each holder of a right shall have the right to receive, upon exercise thereof at the then current exercise price, that number of shares of Common Stock of the surviving company which at the time of such transaction would have a market value of two times the exercise price of the right.

#### 13. 401(k) Plan

We have a qualified 401(k) plan covering all eligible employees. Under the plan, employees may contribute up to the statutory allowable amount for any calendar year. We make matching contributions at a rate of \$1.00 for each dollar contributed up to the first 3 percent and \$0.50 for each dollar contributed of the next 2 percent of compensation. For the years ended December 31, 2007 and 2006, five month period ended December 31, 2005 and the year ended July 31, 2005, we made matching contributions of approximately \$1,535, \$406, \$202 and \$390, respectively.

#### 14. Segment Information

In accordance with SFAS 131, Disclosures about Segments of an Enterprise and Related Information, we present segment information in a manner consistent with the method we use to report this information to our management. We have determined we operate in a single segment.

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

	Year Ended I	December 31,	Five Month Period Ended December 31,	Year Ended July 31,
Revenues:	2007	2006	2005	2005
United States	\$ 51,856	\$ 1,558	\$ 664	\$ 1,064
Europe	20,185			
	\$ 72,041	\$ 1,558	\$ 664	\$ 1,064

	Decembe	er 31, 2007
Long-lived assets:	2007	2006
United States	\$ 126,457	\$ 62,534
Europe	545	
	\$ 127,002	\$ 62,534

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#### Alexion Pharmaceuticals, Inc.

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

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

#### 15. Subsequent Events

In February 2008, we agreed to purchase certain patents related to complement-inhibition technology from Oklahoma Medical Research Foundation, or OMRF. We will pay \$10,000 to OMRF for the rights to the patents, of which \$7,500 will be remitted in 2008 and the remaining \$2,500 in the first half of 2009. No further amounts, including royalties, will be owed to OMRF in respect of sales of Soliris or other use of the OMRF patents. Accordingly, the previously announced claims filed by OMRF and counterclaims filed by Alexion in the U.S. District Court for the Northern District of Oklahoma will be dismissed.

In February, SB2, Inc. filed a civil action against Alexion. See Note 9 for information regarding litigation with SB2, Inc.

In February 2008, we entered into a credit agreement with Bank of America, N.A. The agreement provides for an available \$25,000 revolving credit facility that can be used for working capital requirements and other general corporate purposes. The loan is collateralized by substantially all of 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. The borrowing base is limited to 80% of eligible domestic receivables, as defined. The revolving credit facility requires that we comply with quarterly financial covenants related to liquidity and profitability ratios, as well as revenue. 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 defined, 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 defined. 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.

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## Alexion Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

For the Years Ended December 31, 2007 and 2006, Five Month Period Ended December 31, 2005,

and Year Ended July 31, 2005

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

## 16. Quarterly Financial Information (unaudited)

The following is condensed quarterly financial information for the years ended December 31, 2007 and 2006:

		Quarter Ended			
	March 31	June 30	September 30	December 31	
2007:					
Revenue	\$ 6,317	\$ 9,756	\$ 22,110	\$ 33,858	
Operating expenses	41,057	37,983	41,850	44,213	
Operating loss	(34,825)	(29,294)	(21,894)	(13,746)	
Net loss applicable to common shareholders	(32,693)	(27,184)	(20,084)	(12,330)	
Net loss per common share, basic and diluted	(0.92)	(0.75)	(0.55)	(0.33)	

		Quarter Ended				
	March 31	June 30	September 30	December 31		
2006:						
Revenue	\$ 768	\$ 340	\$ 262	\$ 188		
Operating expenses	29,359	34,884	33,325	41,075		
Operating loss	(28,591)	(34,544)	(33,063)	(40,887)		
Net loss applicable to common shareholders	(27,226)	(33,166)	(31,872)	(39,250)		
Net loss per common share, basic and diluted	(0.88)	(1.06)	(1.02)	(1.19)		

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