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

FORM 10-K

x **Annual report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934**
For the fiscal year ended December 31, 2014

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, par value $0.0001
Name of each exchange on which registered:	**The NASDAQ Stock Market LLC**
Securities registered pursuant to Section 12(g) of the Act:	**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 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 whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. Check One:

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

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

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, 2014, was $30,706,252,188.[(1)]

The number of shares of Common Stock outstanding as of February 3, 2015 was 202,148,509.

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 6, 2015, are incorporated by reference into Part III of this report.

(1) Excludes 1,378,571 shares of common stock held by directors and executive officers at June 30, 2014. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

Alexion Pharmaceuticals, Inc.

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PART I

Unless the context requires otherwise, references in this report to "Alexion", the “Company”, "we", "our" or "us" refer to Alexion Pharmaceuticals, Inc. and its subsidiaries.

Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management's beliefs, and certain assumptions made by our management, and may include, but are not limited to, statements regarding the potential benefits and commercial potential of Soliris® (eculizumab) for its approved indications and any expanded uses, timing and effect of sales of Soliris in various markets worldwide, pricing for Soliris, level of insurance coverage and reimbursement for Soliris, level of future Soliris sales and collections, timing regarding development and regulatory approvals for additional indications or in additional territories for Soliris, the medical and commercial potential of additional indications for Soliris, failure to satisfactorily address the issues raised by the U.S. Food and Drug Administration (FDA) in the March 2013 Warning Letter and Form 483 issued by the FDA in August 2014, costs, expenses and capital requirements, cash outflows, cash from operations, status of reimbursement, price approval and funding processes in various countries worldwide, progress in developing commercial infrastructure and interest about Soliris and our drug candidates in the patient, physician and payer communities, the safety and efficacy of Soliris and our product candidates, estimates of the potential markets and estimated commercialization dates for Soliris and our drug candidates around the world, sales and marketing plans, any changes in the current or anticipated market demand or medical need for Soliris or our drug candidates, status of our ongoing clinical trials for eculizumab, asfotase alfa and our other product candidates, commencement dates for new clinical trials, clinical trial results, evaluation of our clinical trial results by regulatory agencies, the adequacy of our pharmacovigilance and drug safety reporting processes, prospects for regulatory approval of asfotase alfa and our other product candidates, need for additional research and testing, the uncertainties involved in the drug development process and manufacturing, performance and reliance on third party service providers, our future research and development activities, plans for acquired programs, our ability to develop and commercialize products with our collaborators, assessment of competitors and potential competitors, the outcome of challenges and opposition proceedings to our intellectual property, assertion or potential assertion by third parties that the manufacture, use or sale of Soliris infringes their intellectual property, estimates of the capacity of manufacturing and other service facilities to support Soliris and our product candidates, potential costs resulting from product liability or other third party claims, the sufficiency of our existing capital resources and projected cash needs, the possibility that expected tax benefits will not be realized, assessment of impact of recent accounting pronouncements, declines in sovereign credit ratings or sovereign defaults in countries where we sell Soliris, delay of collection or reduction in reimbursement due to adverse economic conditions or changes in government and private insurer regulations and approaches to reimbursement, the short and long term effects of other government healthcare measures, and the effect of shifting foreign exchange rates. Words such as “anticipates,” “expects,” “intends,” “plans,” “believes,” “seeks,” “estimates,” variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this report under the section entitled “Risk Factors”. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in this and other reports or documents we file from time to time with the Securities and Exchange Commission.

Item 1. ***BUSINESS.***
(dollars and shares in thousands)

Overview

We are a biopharmaceutical company focused on serving patients with severe and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Our marketed product Soliris is the first and only therapeutic approved for patients with either of two severe and ultra-rare disorders resulting from chronic uncontrolled activation of the complement component of the immune system: paroxysmal nocturnal hemoglobinuria (PNH), a life-threatening and ultra-rare genetic blood disorder, and atypical hemolytic uremic syndrome (aHUS), a life-threatening and ultra-rare genetic disease. We are also evaluating additional potential indications for Soliris in severe and devastating diseases in which we believe that uncontrolled complement activation is the underlying mechanism, and we are progressing in various

stages of development with additional biotechnology product candidates as treatments for patients with severe and life-threatening ultra-rare disorders. We were incorporated in 1992 and began commercial sale of Soliris in 2007.

Soliris is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation associated with chronic disorders in several therapeutic areas, including hematology, nephrology, transplant rejection and neurology. Soliris is a humanized monoclonal antibody that effectively blocks terminal complement activity at the doses currently prescribed. The initial indication for which we received approval for Soliris is PNH. PNH is a debilitating and life-threatening, ultra-rare genetic blood disorder defined by chronic uncontrolled complement activation leading to the destruction of red blood cells (hemolysis). The chronic hemolysis in patients with PNH may be associated with life-threatening thromboses, recurrent pain, kidney disease, disabling fatigue, impaired quality of life, severe anemia, pulmonary hypertension, shortness of breath and intermittent episodes of dark-colored urine (hemoglobinuria).

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

In September and November 2011, Soliris was approved by the FDA and EC, respectively, for the treatment of pediatric and adult patients with aHUS in the United States and Europe. In September 2013, the MHLW approved Soliris for the treatment of pediatric and adult patients with aHUS in Japan. aHUS is a severe and life-threatening genetic ultra-rare disease characterized by chronic uncontrolled complement activation and thrombotic microangiopathy (TMA), the formation of blood clots in small blood vessels throughout the body, causing a reduction in platelet count (thrombocytopenia) and life-threatening damage to the kidney, brain, heart and other vital organs. In addition, the FDA and EC have granted Soliris orphan drug designation for the treatment of patients with aHUS.

Products and Development Programs

The human immune system defends the body from attack or invasion by infectious agents or pathogens. This defense 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 certain stimuli, the immune system triggers a series of enzymatic and biochemical reactions called the complement cascade that results in a pro-inflammatory, pro-thrombotic and cytolytic (cell lysis) response. This set of responses is one of the immune system's weapons against foreign pathogens or otherwise diseased tissue. Given this role of the complement cascade, it must be tightly regulated so that damage to healthy cells, tissues and organs does not occur. However, in certain settings, the complement cascade is subject to uncontrolled excessive or inappropriate activation, or as well an individual may be deficient in naturally occurring complement inhibitors (regulatory proteins). Any of these circumstances may result in acute and chronic inflammatory conditions and damage to healthy tissues and organs.

We focus our product development programs on life-transforming therapeutics for severe and life-threatening ultra-rare diseases for which we believe current treatments are either non-existent or inadequate. Eculizumab is a humanized antibody known as a C5 terminal complement inhibitor (C5 Inhibitor), which is designed to selectively block the cleavage of C5 and hence the production of the pro-inflammatory, pro-thrombotic and cytolytic proteins of the terminal complement cascade. In addition to PNH and aHUS, for which the use of eculizumab has been approved in the United States, Europe, Japan, and other countries, we believe that C5 Inhibitors may be useful in the treatment of a variety of other serious diseases and conditions resulting from uncontrolled complement activation.

Marketed Products

Our marketed products include the following:

Product	Development Area	Description	Development Stage
Soliris (eculizumab)	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Commercial
		PNH Registry	Phase IV
	Hematology/Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)	Commercial
		aHUS Registry	Phase IV

Paroxysmal Nocturnal Hemoglobinuria (PNH)

Soliris is the first and only therapy approved for the treatment of patients with PNH, a debilitating and life-threatening ultra-rare blood disorder in which an acquired genetic deficiency causes uncontrolled complement activation which leads to life-threatening complications. We continue to work with researchers to expand the base of knowledge in PNH and the utility of Soliris to treat patients with PNH. In 2013, the EC extended the Soliris label to include pediatric patients with PNH. The Committee for Medicinal Products for Human Use (CHMP) recommends that the renewal be granted with unlimited validity. Additionally, we are sponsoring a multinational registry to gather information regarding the natural history of patients with PNH and the longer term outcomes during Soliris treatment.

Atypical Hemolytic Uremic Syndrome (aHUS)

aHUS is a chronic and life-threatening ultra-rare genetic disease in which uncontrolled complement activation causes blood clots in small blood vessels throughout the body, or TMA, leading to kidney failure, stroke, heart attack and death. Soliris is the first and only therapy approved for the treatment of pediatric and adult patients with aHUS. Pursuant to a post marketing requirement imposed by the FDA, we have now completed enrollment in a prospective open-label trial in adults with aHUS and, separately, enrollment has been completed in a prospective trial of pediatric patients with aHUS. In May 2014, based on data from these trials, the FDA approved conversion of Soliris accelerated approval in aHUS to regular approval for the treatment of adult and pediatric patients with aHUS to inhibit complement-mediated TMA.

Clinical Development Program

Our programs, including investigator sponsored clinical programs, include the following:

Product	Development Area	Description	Development Stage
Soliris (eculizumab)	Transplant	Delayed Kidney Transplant Graft Function	Phase III
		Antibody Mediated Rejection (AMR) Presensitized Renal Transplant - Living Donor	Phase II
		Antibody Mediated Rejection (AMR) Presensitized Renal Transplant - Deceased Donor	Phase II
		Treatment of Antibody Mediated Rejection (AMR) Following Renal Transplantation*	Phase II
	Neurology	Neuromyelitis Optica (NMO)	Phase III
		Myasthenia Gravis (MG)	Phase III
Asfotase alfa	Metabolic Disorders	Hypophosphatasia (HPP)	Phase II
cPMP (ALXN 1101)	Metabolic Disorders	MoCD Type A	Phase II
ALXN 1007	Inflammatory Disorders	GI Graft versus Host Disease	Phase II
		Anti-phospholipid Syndrome	Phase II
ALXN 1210	Next Generation		Phase I
ALXN 5500	Next Generation		Phase I

* Investigator Initiated Trial

Soliris (eculizumab)

Transplant

Delayed Kidney Transplant Graft Function

Delayed graft function (DGF) is the term used to describe the failure of a kidney or other organs to function immediately after transplantation due to ischemia-reperfusion and immunological injury. Enrollment has been completed in this Phase III registration trial study of eculizumab in patients at elevated risk for DGF following kidney transplant. Eculizumab has been granted orphan drug designation for DGF by the FDA and, in the first quarter of 2014, the EC granted orphan drug designation to eculizumab for prevention of DGF after solid organ transplantation. In August 2014, we announced the initiation of dosing in a single, multinational, placebo-controlled DGF registration trial based on positive discussions with regulators in the U.S. and EU.

Antibody Mediated Rejection (AMR) in Presensitized Kidney Transplant Patients

AMR is the term used to describe a type of transplant rejection that occurs when the recipient has antibodies to the donor organ. Enrollment in a multi-national, multi-site controlled clinical trial of eculizumab in presensitized kidney transplant patients at elevated risk for AMR who received kidneys from deceased organ donors was completed in March 2013. The study was re-opened in October 2013 to enroll additional patients at the request of participating investigators. Enrollment and dosing in this expanded trial has been completed and patient follow-up in the trial is continuing. In September 2013, researchers presented positive preliminary data from the eculizumab deceased-donor AMR kidney transplant study at the European Society of Organ Transplant in Vienna, Austria.

Enrollment in a multi-national, multi-site randomized controlled clinical trial of eculizumab in presensitized kidney transplant patients at elevated risk for AMR who received kidneys from living donors has been completed and patient follow-up in the trial is ongoing. In January 2015, we reported results from a randomized, open-label, multicenter Phase II clinical trial to determine the safety and efficacy of eculizumab in the prevention of AMR in living-donor kidney transplant recipients requiring desensitization. The primary composite endpoint of the trial did not reach statistical significance. Data analyses are

ongoing and based on discussions with regulators, we are developing plans to commence a clinical trial with eculizumab as a treatment for patients with AMR.

In April 2014, the EC granted orphan drug designation to eculizumab for the prevention of graft rejection following solid organ transplantation.

Neurology

Neuromyelitis Optica (NMO)

NMO is a severe and ultra-rare autoimmune disease of the central nervous system (CNS) that primarily affects the optic nerves and spinal cord. In an investigator-initiated Phase II clinical trial of eculizumab in severe and relapsing NMO, eculizumab reduced the median number of NMO attacks at 12 months with a high degree of statistical significance. In the first half of 2014, we commenced a Phase III pivotal trial to evaluate eculizumab as as treatment for patients with relapsing NMO. The FDA , EC, and MHLW have each granted orphan designation for eculizumab as a treatment for patients with NMO.

Myasthenia Gravis (MG)

MG is an ultra-rare autoimmune syndrome characterized by complement activation leading to the failure of neuromuscular transmission. Data from a Phase II trial evaluating the safety and efficacy of eculizumab in patients with refractory generalized MG indicated improvement in clinical measures. In the second quarter of 2014, we commenced a Phase III pivotal trial to evaluate eculizumab as a treatment for patients with refractory generalized MG. In addition, the FDA, EC and MHLW have granted orphan drug designation for eculizumab as a treatment for patients with MG.

Asfotase Alfa

Hypophosphatasia (HPP)

HPP is an ultra-rare, genetic, and life-threatening metabolic disease characterized by impaired phosphate and calcium regulation, leading to progressive damage to multiple vital organs including destruction and deformity of bones, profound muscle weakness, seizures, impaired renal function, and respiratory failure.

Asfotase alfa, a targeted enzyme replacement therapy in Phase II clinical trials for patients with HPP, is designed to directly address the morbidities and mortality of HPP by targeting alkaline phosphatase directly to the deficient tissue. In this way, asfotase alfa is designed to normalize the genetically defective metabolic process and prevent or reverse its severe and life-threatening complications in patients with HPP. Studies with asfotase alfa in HPP patients indicate that the treatment significantly decreases the levels of targeted metabolic substrates. In 2013, asfotase alfa received Breakthrough Therapy Designation from the FDA. In September 2014, the MHLW granted orphan drug designation to asfotase alfa for the treatment of patients with HPP.

Interim results from a separate multinational Phase II open-label study of infants and children with HPP were presented at the European Society of Pediatric Endocrinology meeting held in September 2013. Results of 15 enrolled and treated patients representing a range of HPP characteristics were summarized, showing that the primary efficacy endpoint was achieved with a high degree of clinical and statistical significance and several key secondary endpoints were also achieved. The study continues to enroll and dose patients.

We have completed two natural history studies in infantile-onset patients with HPP and juveniles with HPP. We have completed our initial analysis for the studies. We have commenced and completed a rolling submission of our U.S. Biologics License Application (BLA) for asfotase alfa, which allows completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. In July 2014, we announced that the European Medicines Agency (EMA) informed us that it had validated our Marketing Authorization Application (MAA) for asfotase alfa for the treatment of HPP. We believe the analysis of our clinical data supports our regulatory filings in the U.S., EU, and Japan.

In September 2014, results of several HPP trials were presented at the 2014 Annual Meeting of the American Society of Bone and Mineral Research (ASBMR). Results of these trials indicate that in HPP patients at high risk of death, overall survival rates significantly greater in asfotase alfa patients compared with survival in historical control patients. In addition, patients receiving asfotase alfa significantly improved ventilator-free survival.

cPMP (ALXN 1101)

Molybdenum Cofactor Deficiency (MoCD) Disease Type A (MoCD Type A)

MoCD Type A is an ultra-rare metabolic disorder characterized by severe and rapidly progressive neurologic damage and death in newborns. MoCD Type A results from a genetic deficiency in cyclic Pyranopterin Monophosphate (cPMP), a molecule that enables production of certain enzymes, the absence of which allows neurotoxic sulfite to accumulate in the brain. To date, there is no approved therapy available for MoCD Type A. There has been some early clinical experience with the cPMP replacement therapy in a small number of children with MoCD Type A, and we have initiated a natural history study in patients with MoCD Type A. In October 2013, cPMP received Breakthrough Therapy Designation from the FDA for the treatment of patients with MoCD Type A. Evaluation of our synthetic cPMP replacement therapy in a Phase I healthy volunteer study is complete. As a result, we have initiated a multi-center, multinational, open-label clinical trial of synthetic cPMP in patients with MoCD Type A being treated with recombinant cPMP.

ALXN 1007

ALXN 1007 is a novel humanized antibody designed to target rare and severe inflammatory disorders and is a product of our proprietary antibody discovery technologies. We have completed enrollment in both a Phase I single-dose, dose escalating safety and pharmacology study in healthy volunteers, as well as in a multi-dose, dose escalating safety and pharmacology study in healthy volunteers. As a result of meetings with the FDA, we commenced dosing in the second quarter of 2014 a Phase II proof-of-concept study in patients with anti-phospholipid syndrome (APS). APS is an ultra-rare autoimmune, hypercoagulable state caused by antiphospholipid antibodies. A second proof-of-concept study in patients with another ultra-rare disorder, gastrointestinal graft versus host disease (GI-GVHD) was initiated in September 2014. Patients with GI-GVHD following bone marrow or hematopoietic stem cell transplant experience engrafted hematopoietic cells that attack host gastrointestinal tissues in the first 100 days post-transplant causing damage to the GI tract, liver and skin.

Manufacturing

We currently rely on two manufacturing facilities, Alexion's Rhode Island manufacturing facility (ARIMF) and one facility operated by Lonza Group AG and its affiliates (Lonza), to produce commercial and clinical bulk quantities of Soliris, and we rely on a facility operated by Lonza for clinical quantities of asfotase alfa. We produce our clinical and preclinical quantities of our other product candidates at ARIMF. We have entered into an agreement with Lonza to manufacture commercial and clinical supplies of Soliris and asfotase alfa at an additional site. We also depend on a limited number of third party providers for other services with respect to our clinical and commercial requirements, including manufacturing services, product finishing, packaging, filling and labeling.

We have various agreements with Lonza through 2026, with remaining total non-cancellable commitments of approximately $383,500 through 2018. Our agreements with Lonza also include potential payments totaling up to $5,000 that will become payable if and when certain milestones are achieved. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at ARIMF and a payment with respect to sales of Soliris manufactured at Lonza facilities.

In March 2013, we received a Warning Letter (Warning Letter)from the FDA regarding compliance with current Good Manufacturing Practices (cGMP) at ARIMF. The Warning Letter followed an FDA inspection which concluded in August 2012. At the conclusion of that inspection, the FDA issued a Form 483 Inspectional Observations, to which we responded in August 2012 and provided additional information to the FDA in September and December 2012. The observations relate to commercial and clinical manufacture of Soliris at ARIMF. We responded to the Warning Letter in a letter to the FDA dated in April 2013. At the conclusion of another inspection of ARIMF in August 2014, the FDA issued a Form 483 with three inspectional observations, none of which were designated as a repeat observation to the Warning Letter. The observations are inspectional and do not represent a final FDA determination of compliance. We continue to manufacture products, including Soliris, at ARIMF. While the resolution of the issues raised in this Warning Letter is difficult to predict, we do not currently believe a loss related to this matter is probable or that the potential magnitude of such loss or range of loss, if any, can be reasonably estimated. To the extent that circumstances related to this matter change, the impact could have a material adverse effect on our financial operations.

The EMA inspected ARIMF in January 2013 and issued a cGMP certificate in May 2013.

Unrelated to the Warning Letter, we initiated voluntary recalls and replacements of certain lots of Soliris in 2013 and 2014 due to the presence of visible particles detected in a limited number of vials in these lots. These recalls did not interrupt

the supply of Soliris to patients. Following investigation, we believe that we have identified the fill/finish process step at our third party provider that resulted in the presence of the visible particles and we have implemented the changes necessary to modify the process step. During the fourth quarter of 2013, we recorded expense of $14,277 in costs of sales resulting from the disposal of inventory in 2014. Expenses associated with recalls were not material in 2014.

In April 2014, we purchased a fill/finish facility in Athlone, Ireland. Following refurbishment of the facility, and after successful completion of the appropriate validation processes and regulatory approvals, the facility will become our first company-owned fill/finish and packaging facility for Soliris and other clinical and commercial products. Our plans for future expansion in Ireland also include the construction of office and laboratory facilities on property in Dublin, Ireland, which we purchased in April 2014.

Sales and Marketing

We have established a commercial organization to support current and future sales of Soliris in the United States, Europe, Japan, Asia Pacific countries, and other territories. Our sales force for Soliris is small compared to that of other drugs with similar revenues; however, we believe that a relatively smaller sales force is appropriate to effectively market Soliris due to the incidence and prevalence of PNH and aHUS. If we receive regulatory approval in new territories or for new products or indications, we may expand our own commercial organizations in such territories and market and sell Soliris through our own sales force in these territories. However, we evaluate each jurisdiction on a country-by-country basis, and, in certain territories, we promote Soliris in collaboration with marketing partners or rely on relationships with one or more companies with established distribution systems and direct sales forces in certain countries.

Customers

Our customers are primarily comprised of distributors, pharmacies, hospitals, hospital buying groups, and other health care providers. In some cases, we may also sell Soliris to governments and government agencies.

During 2014, sales to our largest customer accounted for 18% of our Soliris net product sales. During 2013, sales to our largest customer accounted for 20% of our Soliris net product sales.

Because of factors such as the pricing of Soliris, the limited number of patients, the short period from product sale to patient infusion and the lack of contractual return rights, Soliris customers often carry limited inventory. We also monitor inventory within our sales channels to determine whether deferrals are appropriate based on factors such as inventory levels compared to demand, contractual terms and financial strength of distributors.

Please also see "Management’s Discussion and Analysis – Net Product Sales," and Note 17 of the Consolidated Financial Statements included in this Annual Report on Form 10-K, for financial information about geographic areas.

Intellectual Property Rights and Market Exclusivity

Patents and other intellectual property rights are important to our business. We own or license a number of patents in the U.S. and foreign countries that cover our products and investigational compounds; also we file and prosecute patent applications covering new technologies and inventions that are meaningful to our business. In addition to patents, we rely on trade secrets, know-how, trademarks, regulatory exclusivity and other forms of intellectual property. Our intellectual property rights have material value and we act to protect them.

In the biopharmaceutical industry, two forms of intellectual property generally determine the period of a product’s market exclusivity: patent rights and regulatory forms of exclusivity. It is during the period of market exclusivity that an innovative product generally realizes most of its commercial value.

Patents provide the owner with a right to exclude others from practicing an invention. Patents may cover the active ingredients, uses, formulations, doses, administrations, delivery mechanisms, manufacturing processes and other aspects of a product. The period of patent protection for any given product may depend on the expiration date of various patents and may differ from country to country according to the type of patents, the scope of coverage and the remedies for infringement available in a country.

Most of our products and investigational compounds are protected by patents with varying terms that depend on the type of patent and its filing date. However, a significant portion of a product's patent life can elapse during the time it takes to develop and obtain regulatory approval of the product. As compensation, certain developed countries will extend a patent’s term, subject to a number of factors and caps.

With respect to Soliris, we own an issued U.S. patent that covers the product and will expire in 2021, taking into account patent term extension. We also own a corresponding issued European patent that covers Soliris and will expire in 2015, though in certain European countries where we filed for supplementary protection certificates we expect exclusivity to extend into 2020. In Japan and other countries where we own patents covering Soliris the patents will expire between 2015 and 2020. We also own U.S. and foreign patents and patent applications that protect our investigational compounds and product candidates. At present, it is not known whether any such investigational compound or product candidate will be approved for human use and sale.

Regulatory forms of exclusivity are another source of valuable rights that can contribute toward market exclusivity for an innovative biopharmaceutical product such as Soliris. Many developed countries provide such non-patent incentives to develop medicines. In the U.S., Europe and Japan, for instance, regulatory intellectual property rights provide incentives to develop medicines for rare diseases, or orphan drugs, and medicines for pediatric patients. Those countries and others also provide data protection for a period of time after the approval of a new drug, during which regulatory agencies may not rely on the innovator's data to approve a biosimilar or generic copy. Regulatory forms of exclusivity can work in conjunction with patents to strengthen market exclusivity, and in countries where patent protection has expired or does not exist, regulatory forms of exclusivity can extend a product's market exclusivity period.

With respect to Soliris, we rely on regulatory forms of exclusivity such as data protection and orphan drug protection to support the product's market exclusivity. Specific aspects of the laws governing regulatory exclusivity vary by country, but most forms of regulatory exclusivity do not prevent competitive products from gaining regulatory approval on the basis of the competitor's own safety and efficacy data, even when the competitive product is a biosimilar or generic copy. In certain countries, however, orphan drugs can obtain a period of exclusivity during which no competitive product containing the same drug may be approved for the same orphan indication.

Our success will depend in part on our ability to obtain and maintain patent and regulatory protections for our products and investigational compounds, to preserve our trade secrets and other proprietary rights, to operate without infringing the proprietary rights of third parties, and to prevent third parties from circumventing our rights. Due to the time and expense of bringing new products through development and regulatory approval to the marketplace, there is particular importance in obtaining patent and trade secret protection for significant new technologies, products and processes. As of December 31, 2014, we owned or in-licensed patents and patent applications that relate to C5 inhibitors, high throughput screening, biologic manufacturing processes, vectors, cancer, recombinant antibodies, bone delivery conjugates, nucleic acid-based therapies, natriuretic peptides, human molybdenum cofactor deficiency, targeted complement inhibitors, and other technologies.

Significant legal questions exist concerning the extent and scope of patent protection for biopharmaceutical products and processes in the United States and elsewhere. Accordingly, there is no certainty that patent applications owned or licensed by us will issue as patents, or that our issued patents will afford meaningful protection against competitors. Once issued, patents are subject to challenge through both administrative and judicial proceedings in the U.S. and other countries. Such proceedings include re-examinations, inter partes reviews, post-grant reviews and interference proceedings before the U.S. Patent and Trademark Office, as well as opposition proceedings before the European Patent Office. Litigation may be required to enforce, defend or obtain our patent and other intellectual property rights. Any administrative proceeding or litigation could require a significant commitment of our resources and, depending on outcome, could adversely affect the scope, validity or enforceability of certain of our patent or other proprietary rights.

In regard to third party intellectual property, we have in the past received, and may in the future receive, notices claiming infringement of their patents. We are aware of other patents owned by third parties that the owners might claim to be infringed by the development and commercialization of Soliris or some of our investigational compounds. We have obtained licenses to some of those patents and may obtain licenses to others. In other instances, we have determined in our judgment that:

- our products and investigational compounds do not infringe the patents;
- the patents are not valid or enforceable; or
- we have identified and are testing various alternatives that should not infringe the patents and which should permit continued development and commercialization of our products and investigational compounds.

If a 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 products. 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.

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

The market exclusivity of our products may be impacted by competitive products that are either innovative or biosimilar or generic copies. In our industry, the potential for biosimilar challenges has been an increasing risk to product market exclusivity. U.S. law enacted in 2010 created a new approval pathway for biosimilar versions of innovative biological products. Prior to that time, innovative biologics had essentially unlimited regulatory exclusivity. Under the new pathway, the FDA may approve products that are similar to (but not generic copies of) innovative biologics on the basis of less extensive data than is required by a full biologic license application. After an innovator has marketed its product for four years, other manufacturers may apply for approval of a biosimilar version of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not actually approve a biosimilar version until 12 years after the innovative product received its approval. The law also provides a mechanism for innovators to enforce their patents that protect their products and for biosimilar applicants to challenge the patents. Such litigation may begin as early as four years after the innovative biological product is first approved by the FDA. Pathways for biosimilar products also exist in many other markets also, including Europe and Japan.

We estimate the market exclusivity period for our products solely for business planning purposes. The actual length of market exclusivity for any product is impossible to predict with certainty due to the complex interaction between patent and regulatory factors and the inherent uncertainties of litigation.

License and Collaboration Agreements

In January 2015, we entered into a license agreement with a third party to obtain certain intellectual property rights and technology related to specific therapeutic compounds. The agreement provides an exclusive research, development and commercial license for products to be developed using such compounds. Pursuant to the terms of the agreement, we made an upfront payment of $50,000 during the first quarter 2015. We could be required to pay up to an additional $213,000 in development and regulatory milestones related to a product developed under the agreement for a single disease indication. An additional $437,000 in milestone payments could be due if certain development and regulatory milestones are achieved for additional disease indications. The agreement also provides for royalty payments and potential milestone payments of up to $180,000 on commercial sales of products developed under the agreement.

In December 2014, we entered into an agreement with X-Chem Pharmaceuticals (X-Chem) that allows us to identify novel drug candidates from X-Chem's proprietary drug discovery engine. Alexion will have the exclusive worldwide rights to develop and commercialize up to three targets arising from the collaboration. Due to the early stage of these assets, we recorded expense for an upfront payment of $8,000. In addition, for each drug target, to a maximum of three targets, we could be required to make additional payments upon the achievement of specified research, development and regulatory milestones up to $75,000, as well as royalties on commercial sales.

In January 2014, we entered into an agreement with Moderna Therapeutics, Inc. (Moderna) that provides the option to purchase drug products for clinical development and commercialization of Moderna's messenger RNA (mRNA) therapeutics to treat rare diseases. Due to the early stage of these assets, we recorded expense for an upfront payment of $100,000 in 2014. We will also be responsible for funding research activities under the program. In addition, for each drug target, up to a maximum of ten targets, would could be required to make an option exercise payment of $15,000 and to pay up to an additional $120,000 with respect to a rare disease product and $400,000 with respect to a non-rare disease product in development and sales milestones if the specific milestones are met over time as well as royalties on commercial sales.

In July 2013, we entered into a license and collaboration agreement with Ensemble Therapeutics Corporation for the identification, development and commercialization of therapeutic candidates based on specific drug targets. Due to the early stage of these assets, we recorded expense for an upfront payment of $11,500 during the third quarter of 2013. We will also be responsible for funding research activities under the program. In addition, for each drug target, up to a maximum of four targets, we could be required to pay up to an additional $90,750 in development milestones as the specific milestones are met over time. The agreement also provides for royalty payments on commercial sales of each product developed under the agreement.

In January 2013, we entered into a license agreement for a technology, which provides an exclusive research license and an option for an exclusive commercial license for specific targets and products to be developed. Due to the early stage of this asset, we recorded expense for an upfront payment of $3,000 during the first quarter of 2013. We will also be required to pay annual maintenance fees during the term of the arrangement. In addition, for each target, up to a maximum of six targets we develop, we could be required to pay up to an additional $70,500 in license fees, development and sales milestones as the specific milestones are met over time.

In October 2012, we entered into a settlement and non-exclusive license agreement with a third party. Under the terms of the agreement, we made an upfront payment and will pay royalties on sales of Soliris through 2018 in accordance with the terms of the agreement.

In March 1996, we entered into a license agreement with the Medical Research Council (MRC) whereby MRC granted to us worldwide non-exclusive rights to certain patents related to the humanization and production of monoclonal antibodies. The license agreement requires us to pay MRC royalties on a quarterly basis with respect to sales of Soliris in the United States and Canada, as well as foreign sales of Soliris for product manufactured and vialed in the U.S. The royalty is payable until the expiration of the last patent covered by the license agreement, which is expected to be in 2015, except that royalties for sales in Canada will continue until January 2017. MRC may terminate the license if we file for bankruptcy or become insolvent, or if we fail to perform our obligations under the agreement and such failure is not remedied within three months after delivery of notice. Under the agreement, we agreed to (a) make royalty payments with respect to sales of licensed products, (b) promote the sale of Soliris of good marketable quality, and (c) use reasonable endeavors to meet market demand for licensed products.

Government Regulation

Drug Development and Approval in the U.S.

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 United States, the European Union and other territories. In the United States, pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. Soliris is regulated by the FDA as a biologic. Biologics require the submission of a Biologics License Application (BLA) and approval by the 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 process for obtaining regulatory approval to market a biologic is expensive, often takes many years, and can vary substantially based on the type, complexity, and novelty of the product candidates involved. The steps required before a biologic may be approved for marketing of an indication in the United States generally include:

(1) preclinical laboratory tests and animal tests;

(2) submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may commence;

(3) adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended use;

(4) submission to the FDA of a BLA or supplemental BLA;

(5) FDA pre-approval inspection of the manufacturing sites identified in the BLA; and

(6) FDA review and approval of the BLA or supplemental BLA. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological animal studies to assess the potential safety and efficacy of the product candidate. Preclinical safety tests intended for submission to FDA must be conducted in compliance with FDA's Good Laboratory Practice (GLP) regulations and the United States Department of Agriculture's Animal Welfare Act. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND which must become effective before human clinical trials may be commenced. The investigational new drug (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. FDA may stop the clinical trials by placing them on "clinical hold" because of concerns about the safety of the product being tested, or for other reasons.

Clinical trials involve the administration of the investigational product to healthy volunteers or to patients, under the supervision of qualified principal investigators. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and Good Clinical Practice (GCP) requirements, which establish standards for conducting, recording data from, and reporting the results of clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted in accordance with protocols that detail the objectives of the study, the criteria for determining subject eligibility, the dosing plan, patient monitoring requirements, timely reporting of adverse events, and other elements necessary to ensure patient safety, and any efficacy criteria to be evaluated. Each protocol must be submitted to FDA as part of the IND; further, each clinical study at each clinical site must be reviewed and approved by an independent institutional review board, prior to the recruitment of subjects. The institutional review board's role is to protect the rights and welfare of human subjects involved in clinical studies by evaluating, among other things, the potential risks and benefits to subjects, processes for obtaining informed consent, monitoring of data to ensure subject safety, and provisions to protect the subjects' privacy. Foreign studies conducted under an IND application must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of a BLA if the study was conducted in accordance with GCP and FDA is able to validate the data.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap and different trials may be initiated with the same drug candidate within the same phase of development in similar or differing patient populations. Phase I studies may be conducted in a limited number of patients, but are usually conducted in healthy volunteer subjects. The drug is usually tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmaco-dynamics and pharmaco-kinetics. Phase II usually involves studies in a larger, but still limited patient population to evaluate preliminarily the efficacy of the drug candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible short-term adverse effects and safety risks.

Phase III trials are undertaken to gather additional information to evaluate the product's overall risk-benefit profile, and to provide a basis for physician labeling. Phase III trials evaluate clinical efficacy of a specific endpoint and 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, sponsor or institutional review board 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.

We must register each controlled clinical trial, other than Phase I trials, on a website administered by National Institutes of Health (NIH) (http://clinicaltrials.gov). Registration must occur not later than 21 days after the first patient is enrolled, and the submission must include descriptive information (e.g., a summary in lay terms of the study design, type and desired outcome), recruitment information (e.g., target number of participants and whether healthy volunteers are accepted), location and contact information, and other administrative data (e.g., FDA identification numbers). Within one year of a trial's completion, information about the trial including characteristics of the patient sample, primary and secondary outcomes, trial results written in lay and technical terms, and the full trial protocol must be submitted to the FDA. The results information is posted to the website unless the drug has not yet been approved, in which case the FDA posts the information shortly after approval. A BLA, BLA supplement, and certain other submissions to the FDA require certification of compliance with the FDAAA clinical trials database requirements. There are proposals to expand these registration requirements to additional studies.

The results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA as part of a BLA requesting approval to market the product candidate for a proposed indication. Under the Prescription Drug User Fee Act, as amended, the fees payable to the FDA for reviewing a BLA, as well as annual fees for commercial manufacturing establishments and for approved products, can be substantial. The BLA review fee alone can exceed $2,000 subject to certain limited deferrals, waivers and reductions that may be available. Each BLA submitted to the FDA for approval is typically reviewed for administrative completeness and reviewability within 60 days following submission of the application. If the FDA finds the BLA sufficiently complete, the FDA will "file" the BLA, thus triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. FDA performance goals provide for action on an application

within 12 months of submission. The FDA, however, may not approve a drug within these established goals and its review goals are subject to change from time to time because the review process is often significantly extended by FDA requests for additional information or clarification. As part of its review, the FDA may refer the BLA to an advisory committee composed of outside experts for evaluation and a recommendation as to whether the application should be approved. Although the FDA is not bound by the recommendation of an advisory committee, the agency usually has followed such recommendations.

Further, the outcome of the review, even if generally favorable, may not be an actual approval but instead a “complete response letter” communicating the FDA's decision not to approve the application, outlining the deficiencies in the BLA, and identifying what information and/or data (including additional pre-clinical or clinical data) is required before the application can be approved. Even if such additional information and data are submitted, the FDA may decide that the BLA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we do.

Before approving a BLA, the FDA typically will inspect the facilities at which the product is manufactured and will not approve the product unless 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. FDA also may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a Risk Evaluation Mitigation Strategies (REMS), or otherwise limit the scope of any approval. A REMS may include various elements, ranging from a medication guide to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. 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 may be required. In addition, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

In 2010, the Biologics Price Competition and Innovation Act (BPCI) was enacted, creating a statutory pathway for licensure, or approval, of biological products that are biosimilar to, and possibly interchangeable with, reference biological products licensed under the Public Health Service Act. Under the BPCI, innovator manufacturers of original reference biological products are granted 12 years of exclusive use before biosimilar versions of such products can be licensed for marketing in the United States. This means that the FDA may not approve an application for a biosimilar version of a reference biological product until 12 years after the date of approval of the reference biological product (with a potential six-month extension of exclusivity if certain pediatric studies are conducted and the results reported to FDA), although a biosimilar application may be submitted four years after the date of licensure of the reference biological product. Additionally, the BPCI establishes procedures by which the biosimilar applicant must provide information about its application and product to the reference product sponsor, and by which information about potentially relevant patents is shared and litigation over patents may proceed in advance of approval. The BPCI also provides a period of exclusivity for the first biosimilar to be determined by the FDA to be interchangeable with the reference product.

The objectives of the BPCI are conceptually similar to those of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the "Hatch-Waxman Act", which established abbreviated pathways for the approval of small molecule drug products. The FDA is currently in the process of establishing the procedures and standards it will apply in implementing the abbreviated approval pathway for biological products created by the BPCI. We anticipate that contours of the BPCI will be defined as the statute is implemented over a period of years. This likely will be accomplished by a variety of means, including FDA issuance of guidance documents, proposed regulations, and decisions in the course of considering specific applications. FDA has released guidance documents interpreting the BPCI in each of the last three years. These guidance documents, among other things, elaborate on the definition of a biosimilar as a biological product that is highly similar to an already approved biological product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biosimilar and the approved biological product in terms of the safety, purity, and potency. Under this proposed approval pathway, biological products are approved based on demonstrating they are biosimilar to, or interchangeable with, a biological product that is already approved by the FDA, which is called a reference product. The approval of a biologic product biosimilar to one of our products could have a material impact on our business because it may be significantly less costly to bring to market and may be priced significantly lower than our products.

Both before and after the FDA approves a product, the manufacturer and the holder or holders of the BLA for the product are subject to comprehensive regulatory oversight. If ongoing regulatory requirements are not satisfied or if safety problems occur after the product reaches the market, the FDA may at any time withdraw its product approval or take actions that would

suspend marketing. For example, quality control and manufacturing procedures must conform, on an ongoing basis, to cGMP requirements, and the FDA periodically subjects manufacturing facilities to unannounced inspections to assess compliance with cGMP. Failure to comply with applicable cGMP requirements and other conditions of product approval may lead the FDA to seek sanctions, including fines, recalls, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Accordingly, manufacturers must continue to spend time, money and effort to maintain cGMP compliance.

The FDA and other federal regulatory agencies also closely regulate the promotion of drugs and biologics through, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs and biologics for "off-label" uses - that is, uses not approved by the FDA and therefore not described in the product's labeling - because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug or biologic for off-label use, but may engage in non-promotional, balanced communication regarding off-label use under certain conditions. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. Noncompliance could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug or biologic products.

Orphan Drug Designation in the United States, the European Union and Other Foreign Jurisdictions

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs and biological products intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a BLA or supplemental BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for that drug or biologic for the indication for which it has such designation, the product is entitled to an orphan exclusivity period, in which the FDA may not approve any other applications to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as where the sponsor of different version of the product is able to demonstrate that its product is clinically superior to the approved orphan drug product. This exclusivity does not prevent a competitor from obtaining approval to market a different product that treats the same disease or condition or the same product to treat a different disease or condition. The FDA can revoke a product's orphan drug exclusivity under certain circumstances, including when the holder of the approved orphan drug application is unable to assure the availability of sufficient quantities of the drug to meet patient needs. A sponsor of a product application that has received an orphan drug designation is also granted tax incentives for clinical research undertaken to support the application. In addition, the FDA will typically coordinate with the sponsor on research study design for an orphan drug and may exercise its discretion to grant marketing approval on the basis of more limited product safety and efficacy data than would ordinarily be required.

Medicinal products: (a) that are used to treat life-threatening or chronically debilitating conditions; (b) that affect no more than five in 10,000 people in the European Union; (c) that, for economic reasons, would be unlikely to be developed without incentives; and (d) where no satisfactory method of diagnosis, prevention or treatment of the condition concerned exists, or, if such a method exists, the medicinal product must be of significant benefit to those affected by the condition, may be granted an orphan designation in the European Union. The application for orphan designation is submitted to the EMA before an application is made for marketing authorization. Once authorized, orphan medicinal products are entitled to ten years of market exclusivity. During this ten year period, with a limited number of exceptions, neither the competent authorities of the European Union member states, the EMA, or the European Commission are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the

basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity.

Soliris has received orphan drug designation for the treatment of PNH and aHUS in the United States, the European Union, and in several other territories, for the prevention of delayed graft function in renal transplant patients in the United States, for the treatment of patients with myasthenia gravis in the United States, Japan, and the European Union, and for prevention of graft rejection and delayed graft rejection following solid organ transplantation in the European Union. Orphan drug designation provides certain regulatory and filing fee advantages, including market exclusivity, except in limited circumstances, for several years after approval. In 2008, asfotase alfa received orphan drug designation for the treatment of patients with hypophosphatasia in the United States and the European Union, and in Japan in November 2014.

Breakthrough Designation in the United States

With the passage of the Food and Drug Administration Safety Act (FDASIA) of 2012, Congress created the Breakthrough Therapy designation program. FDA may grant Breakthrough Therapy status to a drug intended for the treatment of a serious condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint over existing therapies. The Breakthrough Therapy designation, which may be requested by a sponsor when filing or amending an IND, is intended to facilitate and expedite the development and FDA review of a product candidate. Specifically, the Breakthrough Therapy designation may entitle the sponsor to more frequent meetings with FDA during drug development, intensive guidance on clinical trial design, and expedited FDA review by a cross-disciplinary team comprised of senior managers. The designation does not guarantee a faster development or review time as compared to other drugs, however, nor does it assure that the drug will obtain ultimate marketing approval by the FDA. Once granted, the FDA may withdraw this designation at any time. We have received Breakthrough Therapy designations for asfotase alfa, intended to treat hypophosphatasia in perinatal-, infant-, and juvenile-onset patients, and cyclic Pyranopterin Monophosphate, intended to treat Molybdenum Cofactor Deficiency Type A. Because the Breakthrough Therapy designation program is relatively new, it is difficult for us to predict the impact that these designations will have on the development and FDA review of our products.

Foreign Regulation of Drug Development and Approval

In addition to regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing approval, and post-marketing regulation 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. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The approval process varies from country to country, can involve additional testing beyond that required by FDA, and may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country.

Under the European Union regulatory system, we may submit applications for marketing authorizations either under a centralized, decentralized, or mutual recognition marketing authorization procedure. The centralized procedure provides for the grant of a single marketing authorization for a medicinal product by the European Commission on the basis of an opinion by the EMA. A centralized marketing authorization is valid for all European Union member states and three of the four EFTA States (Iceland, Liechtenstein and Norway). The decentralized procedure and the mutual recognition procedure apply between European Union member states. The decentralized marketing authorization procedure involves the submission of an application for marketing authorization to the competent authority of all European Union member states in which the product is to be marketed. One national competent authority, selected by the applicant, assesses the application for marketing authorization. The competent authorities of the other European Union member states are subsequently required to grant marketing authorization for their territory on the basis of this assessment, except where grounds of potential serious risk to public health require this authorization to be refused. The mutual recognition procedure provides for mutual recognition of marketing authorizations delivered by the national competent authorities of European Union member states by the approval authorities of other European Union member states. The holder of a national marketing authorization may submit an application to the competent authority of a European Union member state requesting that this authority recognize the marketing authorization delivered by the competent authority of another European Union member state.

Similarly to the U.S., both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual European Union member states both before and after grant of the manufacturing and marketing authorizations. This includes European Union cGMP rules,

which govern quality control of the manufacturing process and require documentation policies and procedures. We and our third party manufacturers are required to ensure that all of our processes, methods, and equipment are compliant with cGMP.

Failure by us or by any of our third party partners, including suppliers, manufacturers, and distributors to comply with European Union laws and the related national laws of individual European Union member states governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of marketing authorization, may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal, or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing, or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The European Union has had an established regulatory pathway for biosimilars since 2005 and has approved several biosimilar products. The approval of a biosimilar of one of our products marketed in the European Union could have a material impact on our business. The biosimilar may be significantly less costly to bring to market and may be priced significantly lower than our products.

Pharmaceutical Pricing and Reimbursement

Sales of pharmaceutical products depend in significant part on the extent of coverage and reimbursement from government programs, including Medicare and Medicaid in the United States, and other third party payers. Third party payers are sensitive to the cost of drugs and are increasingly seeking to implement cost containment measures to control, restrict access to, or influence the purchase of drugs, biologicals, and other health care products and services. Governments may regulate reimbursement, pricing, and coverage of products in order to control costs or to affect levels of use of certain products. Private health insurance plans may restrict coverage of some products, such as by using payer formularies under which only selected drugs are covered, variable co-payments that make drugs that are not preferred by the payer more expensive for patients, and by employing utilization management controls, such as requirements for prior authorization or prior failure on another type of treatment. Payers may especially impose these obstacles to coverage for higher-priced drugs such as Soliris. Consequently, Soliris may be subject to payer-driven restrictions, rendering patients responsible for a higher percentage of the total cost of drugs in the outpatient setting. This can lower the demand for our products if the increased patient cost-sharing obligations are more than they can afford.

Medicare is a U.S. federal government insurance program that covers individuals aged 65 years or older, as well as individuals of any age with certain disabilities, and individuals with End-Stage Renal Disease. The primary Medicare programs that may affect reimbursement for Soliris are Medicare Part B, which covers physician services and outpatient care, and Medicare Part D, which provides a voluntary outpatient prescription drug benefit. Medicare Part B provides limited coverage of certain outpatient drugs and biologicals that are reasonable and necessary for diagnosis or treatment of an illness or injury. Under Part B, reimbursement for most drugs is based on a fixed percentage above the applicable product's average sales price (ASP). Manufacturers calculate ASP based on a statutory formula and must report ASP information to the Centers for Medicare and Medicaid Services (CMS), the federal agency that administers Medicare and the Medicaid Drug Rebate Program, on a quarterly basis. For 2015, the reimbursement rate for drugs and biologicals in both the hospital outpatient department setting and the physician office setting is ASP + 4.3%. The rate for the physician clinic setting is set by statute, but CMS has the authority to adjust the rate for the hospital outpatient setting on an annual basis. This reimbursement rate may decrease in the future. In both settings, the amount of reimbursement is updated quarterly based on the manufacturer's submission of new ASP information.

Medicare Part D coverage is available through private plans, and the list of prescription drugs covered by Part D plans varies by plan. However, drug lists maintained by individual plans are required by statute to cover certain therapeutic categories and classes of drugs or biologicals and to have at least two drugs in each unique therapeutic category or class, with certain exceptions.

Medicare Part A covers inpatient hospital benefits. Hospitals typically receive a single payment for an inpatient stay depending on the Medicare Severity Diagnosis Related Group (MS-DRG) to which the inpatient stay is assigned. The MS-DRG for a hospital inpatient stay varies based on the patient's condition. Hospitals generally do not receive separate payment for drugs and biologicals administered to patients during an inpatient hospital stay. As a result, hospitals may not have a financial incentive to utilize Soliris for inpatients.

Beginning April 1, 2013, the Budget Control Act of 2011, Pub. L. No. 112-25, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240, required Medicare payments for all items and services, including drugs and biologicals, to

be reduced by 2% under the sequestration (i.e., automatic spending reductions). This 2% reduction was extended to 2023 by the Bipartisan Budget Act of 2013, Pub. L. No. 113-67. This 2% reduction in Medicare payments affects all Parts of the Medicare program and could impact sales of Soliris.

Medicaid is a government health insurance program for low-income children, families, pregnant women, and people with disabilities. It is jointly funded by the federal and state governments, and it is administered by individual states within parameters established by the federal government. Coverage and reimbursement for drugs and biologicals thus varies by state. Drugs and biologicals may be covered under the medical or pharmacy benefit. State Medicaid programs may impose utilization management controls, such as prior authorization, step therapy, or quantity limits on drugs and biologicals. Medicaid also includes the Drug Rebate Program, under which we are required to pay a rebate to each state Medicaid program for quantities of Soliris that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for Soliris under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS. These data include the average manufacturer price and the best price for Soliris. As further described below under "U.S. Healthcare Reform and Other U.S. Healthcare Laws," the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the PPACA), made significant changes to the Medicaid Drug Rebate Program that could negatively impact our results of operations.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under PPACA and CMS's issuance of final regulations implementing those changes also could affect our 340B ceiling price calculation for Soliris and could negatively impact our results of operations. As descried below under "U.S. Healthcare Reform and Other U.S. Healthcare Laws," PPACA expanded the 340B program to include additional types of covered entities but exempts "orphan drugs"-those designated under section 526 of the FDCA, such as Soliris-from the ceiling price requirements for these newly-eligible entities.

In order to be eligible to have our products paid for with federal funds under the Medicaid program and purchased by certain federal agencies, we participate in the Department of Veterans Affairs Federal Supply Schedule, or FSS, pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Under this program, we are obligated to make our product available for procurement on an FSS contract and charge a price to four federal agencies, Department of Veterans Affairs, Department of Defense, Public Health Service and Coast Guard that is no higher than the statutory Federal Ceiling Price, or FCP. The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we calculate and report to the Department of Veterans Affairs on a quarterly and annual basis. We also participate in the Tricare Retail Pharmacy program, established by Section 703 of the National Defense Authorization Act for FY 2008 and related regulations, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between Annual Non-FAMP and FCP.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as ASP, average manufacturer price, and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS has begun posting drafts of this retail survey price information on at least a monthly basis in the form of draft National Average Drug Acquisition Cost, or NADAC, files, which reflect retail community pharmacy invoice costs, and National Average Retail Price, or NARP, files, which reflect retail community pharmacy prices to consumers. In July 2013, CMS suspended the publication of draft NARP data, pending funding decisions. In November 2013, CMS moved to publishing final rather than draft NADAC data and has since made updated NADAC data publicly available on a weekly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover Soliris.

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, in the European Union the sole legal instrument at the European Union level governing the pricing and reimbursement of medicinal products is Council Directive 89/105/EEC (the Price Transparency Directive). The aim of the Price Transparency Directive is to ensure that pricing and reimbursement mechanisms established in European Union member states are transparent and objective, do not

hinder the free movement and trade of medicinal products in the European Union and do not hinder, prevent or distort competition on the market. The Price Transparency Directive does not, however, provide any guidance concerning the specific criteria on the basis of which pricing and reimbursement decisions are to be made in individual European Union member states. Neither does it have any direct consequence for pricing or levels of reimbursement in individual European Union member states. The national authorities of the individual European Union member states are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. Individual European Union member states adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other European Union member states adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market, including volume-based arrangements and reference pricing mechanisms.

Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some European Union member states. These countries include the United Kingdom, France, Germany and Sweden. The HTA process in the European Union member states is governed by the national laws of these countries. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of the use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA will often influence the pricing and reimbursement status for specific medicinal products within individual European Union member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of a specific medicinal product vary between the European Union member states.

In 2011, Directive 2011/24/EU was adopted at the European Union level. This Directive concerns the application of patients' rights in cross-border healthcare. The Directive is intended to establish rules for facilitating access to safe and high-quality cross-border healthcare in the European Union. It also provides for the establishment of a voluntary network of national authorities or bodies responsible for HTA in the individual European Union member states. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This could lead to harmonization of the criteria taken into account in the conduct of HTA and their impact on pricing and reimbursement decisions between European Union member states.

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

Fraud and Abuse

Pharmaceutical companies participating in federal healthcare programs like Medicare or Medicaid are subject to various U.S. federal and state laws pertaining to healthcare “fraud and abuse,” including anti-kickback and false claims laws. Violations of U.S. federal and state fraud and abuse laws may be punishable by criminal, civil and administrative sanctions, including fines, damages, civil monetary penalties and exclusion from federal healthcare programs (including Medicare and Medicaid). Applicable U.S. statutes, include, but are not limited to, the following:

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully soliciting, offering, receiving, or paying any remuneration, directly or indirectly, in cash or in kind, to induce or reward purchasing, ordering or arranging for or recommending the purchase or order of any item or service for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. Liability may be established without a person or entity having actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. In addition, PPACA amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. A conviction for violation of the Anti-kickback Statute requires mandatory exclusion from participation in federal health care programs.
- The federal civil False Claims Act (“FCA”) prohibits, among other things, knowingly presenting, or causing to be presented claims for payment of government funds that are false or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. This statute permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. Government enforcement

agencies and private whistleblowers have asserted liability under the FCA for, among others, claims submitted involving inadequate or medically unnecessary care or items or services, kickbacks, promotion of off-label uses, and misreporting of drug prices to federal agencies.

- The federal False Statements Statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items, or services.
- The federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity, such as a pharmaceutical manufacturer, that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payers, including private insurers. Some of these state laws may be broader in scope than their federal analogues, such as state false claims laws that apply where a claim is submitted to any third-party payer, regardless of whether the payer is a private health insurer or a government healthcare program, state laws that prohibit certain marketing-related activities including the provision of gifts, meals or other items to certain health care providers, and state laws that require pharmaceutical companies to implement compliance programs or codes of conduct governing their sales and marketing activities.

Federal and state authorities are continuing to devote significant attention and resources to enforcement of fraud and abuse laws within the pharmaceutical industry, and private individuals have been active in alleging violations of the law and bringing suits on behalf of the government under the FCA. These laws are broad in scope and there may not be regulations, guidance, or court decisions that definitively interpret these laws and apply them to particular industry practices. In addition, these laws and their interpretations are subject to change.

U.S. Healthcare Reform and Other U.S. Healthcare Laws

PPACA was adopted in the United States in March 2010. This law substantially changes the way healthcare is financed by both governmental and private insurers in the U.S., and significantly impacts the pharmaceutical industry. PPACA contains a number of provisions that are expected to impact our business and operations. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges, expansion of the 340B program, expansion of state Medicaid programs, and fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

PPACA contains several provisions that have or could potentially impact our business. PPACA made significant changes to the Medicaid Drug Rebate Program. Effective March 23, 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. With regard to the amount of the rebates owed, PPACA increased the minimum Medicaid rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, PPACA and subsequent legislation changed the definition of average manufacturer price. A final regulation regarding these changes to the Medicaid Drug Rebate Program currently is expected in 2015. Finally, PPACA requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2014 (and set to increase in ensuing years), based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Sales of “orphan drugs” those designated under section 526 of the FDCA, such as Soliris, are excluded from this fee to the extent that no non-orphan indications have been approved for the orphan drug.

Additional provisions of PPACA, some of which became effective in 2011, may negatively affect manufacturer's revenues in the future. For example, as part of PPACA’s provisions closing a coverage gap that currently exists in the Medicare Part D

prescription drug program (commonly known as the “donut hole”), manufacturers are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole.

PPACA also expanded the Public Health Service’s 340B drug pricing discount program. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. PPACA expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by PPACA. PPACA exempts “orphan drugs”-those designated under section 526 of the FDCA, such as Soliris-from the ceiling price requirements for these newly-eligible entities. On July 21, 2014, the Health Resources and Services Administration, or HRSA, which administers the 340B program, issued an interpretive rule to implement the orphan drug exception which interprets the orphan drug exception narrowly. It exempts orphan drugs from the ceiling price requirements for the newly-eligible entities only when the orphan drug is used for its orphan indication. The newly-eligible entities are entitled to purchase orphan drugs at the ceiling price when the orphan drug is not used for its orphan indication. A manufacturer trade group has filed a lawsuit challenging the interpretive rule as inconsistent with the statutory language. That challenge remains ongoing. The uncertainty regarding how the statutory orphan drug exception will be applied will increase the complexity of compliance, will make compliance more time-consuming, and could negatively impact our results of operations. If HRSA’s narrow interpretation of the scope of the orphan drug exemption prevails, it could potentially negatively impact the price we are paid for Soliris by certain entities for some uses and increase the complexity of compliance with the 340B program. Additionally, PPACA enacted the federal “Physician Payment Sunshine Act, being implemented as the Open Payments program, that requires pharmaceutical manufacturers, among others, with products for which payment is available under Medicare, Medicaid or the State Children’s Health Insurance Program, to track and report annually to the federal government (for disclosure to the public) certain payments and other transfers of value made to physicians and teaching hospitals. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures and impose penalties for failures to disclose. Many of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

Finally, numerous federal and state laws, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws govern the collection, use, and disclosure of personal information. In addition, most healthcare providers who prescribe and dispense our products and research institutions with whom we collaborate for our sponsored clinical trials are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and its implementing regulations. Although we are neither a “covered entity” nor a “business associate” under HIPAA, and these privacy and security requirements do not apply to us, the regulations may affect our interactions with health care providers, health plans, and research institutions from whom we obtain patient health information. Further, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA.

Other Regulations

We are also subject to the United States Foreign Corrupt Practices Act (FCPA), the U.K. Bribery Act (U.K. Bribery Act), and other anti-corruption laws and regulations pertaining to our financial relationships with foreign government officials. The FCPA prohibits U.S. companies and their representatives from paying, offering to pay, promising, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate to obtain or retain business or to otherwise seek favorable treatment. In many countries in which we operate or sell Soliris, the health care professionals with whom we interact may be deemed to be foreign government officials for purposes of the FCPA. The U.K. Bribery Act, which applies to any company incorporated or doing business in the UK, prohibits giving, offering, or promising bribes in the public and private sectors, bribing a foreign public official or private person, and failing to have adequate procedures to prevent bribery amongst employees and other agents. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances. Liability in relation to breaches of the Bribery Act is strict. This means that it is not necessary to demonstrate elements of a corrupt state of mind. However, a defense of having in place adequate procedures designed to prevent bribery is available.

Our present and future business has been and will continue to be subject to various other laws and regulations. Laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances,

including radioactive compounds, used in connection with our research work are or may be applicable to our activities. We cannot predict the impact of government regulation, which may result from future legislation or administrative action, on our business.

Competition

There are currently no approved drugs other than Soliris for the treatment of PNH and aHUS. 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. Some 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 United States, Europe and in other countries and regions, as well as a growing number of large pharmaceutical companies that are developing biotechnology products. A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us; in some instances, these products have already entered clinical trials or are already being marketed. Other companies are engaged in research and development based on complement proteins.

Several companies have either publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system or have had programs to develop complement inhibitor therapies. We believe that Soliris differs substantially from compounds of our potential competitors because Soliris has demonstrated to be safe and effective in two clinical indications by regulators in many jurisdictions around the world.

Employees

As of December 31, 2014, we had 2,273 full-time, world-wide employees, of which 914 were engaged in research, product development, manufacturing, and clinical development, 880 in sales and marketing, and 479 in administration, human resources, information technology and finance. Our U.S. employees are not represented by any collective bargaining unit, and we regard the relationships with all our employees as satisfactory.

EXECUTIVE OFFICERS OF THE COMPANY

The executive officers of the Company and their respective ages and positions as of February 3, 2015 are as follows:

Name	Age	Position with Alexion
Leonard Bell, M.D.	56	Chairman and Chief Executive Officer
David L. Hallal	48	Chief Operating Officer and CEO-elect
Clare Carmichael	55	Executive Vice President and Chief Human Resources Officer
Martin Mackay	58	Executive Vice President and Global Head of Research and Development
John B. Moriarty, J.D.	47	Executive Vice President and General Counsel
Julie O'Neill	48	Executive Vice President of Global Operations
Vikas Sinha, M.B.A., C.A., C.P.A.	51	Executive Vice President and Chief Financial Officer
Saqib Islam	45	Senior Vice President and Chief Strategy and Portfolio Officer
Edward Miller	50	Senior Vice President and Global Chief Compliance Officer
Dominique Monnet	54	Senior Vice President and Chief Marketing Officer
Carsten Thiel, Ph.D.	51	Senior Vice President EMEA and Asia Pacific

Leonard Bell, M.D. is the principal founder of Alexion and has been a director of Alexion since February 1992 and the Company's Chief Executive Officer since January 1992 and Chairman since October 2014. 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 received his A.B. from Brown University and M.D. from Yale University School of Medicine. Dr. Bell is currently an Adjunct Assistant Professor of Medicine and Pathology at the Yale University School of Medicine.

David L. Hallal has been with Alexion since June 2006 and has served as Chief Operating Officer since September 2014. On January 29, 2015, Alexion announced that Mr. Hallal was appointed Chief Executive Officer (CEO) and Mr. Hallal will become CEO of Alexion effective April 1, 2015. Mr. Hallal has also been a member of the Board of Directors since September 2014. Since joining Alexion, Mr. Hallal has served in senior commercial positions, including Senior Vice President, US Commercial Operations from June 2006 until November 2008, Senior Vice President, Commercial Operations Americas from November 2008 to May 2010, Senior Vice President, Global Commercial Operations from May 2010 until October 2012 and then Executive Vice President and Chief Commercial Officer from October 2012 to September 2014. Prior to joining Alexion, Mr. Hallal served as Vice President, Sales at OSI Eyetech from April 2004 until June 2006, where he led the U.S. launch of a first-in-class anti-VEGF therapy for age-related macular degeneration. Prior to OSI Eyetech, from 1992 until 2004, Mr. Hallal held various sales and marketing leadership positions at Amgen and Biogen Idec, where he was involved in multiple product launches in the areas of hematology, oncology, nephrology and immunology. Mr. Hallal received a B.A. in Psychology from the University of New Hampshire.

Clare Carmichael has been with Alexion since August 2011 and has served as Executive Vice President and Chief Human Resources Officer since September 2014. From August 2011 to September 2014, Ms. Carmichael served as Senior Vice President and Chief Human Resources Officer. From August 2008 to March 2011, Ms. Carmichael served as Senior Vice President, Global Human Resources at Watson Pharmaceuticals, Inc., where she established and executed global HR strategies. From December 2005 to August 2008, Ms. Carmichael held various human resources positions of increasing responsibility at Schering-Plough Corporation, including Vice President of Global Human Resources at the Schering-Plough Research Institute. From December 2003 to December 2005, Ms. Carmichael was Vice President of Human Resources at Eyetech Pharmaceuticals, Inc. Prior to Eyetech, she held various positions of increasing responsibility in human resources at Pharmacia Corporation. Ms. Carmichael received a B.A. in Psychology from Rider University.

Martin Mackay has been Executive Vice President, Global Head of Research & Development since joining Alexion in May 2013. Prior to joining Alexion, Dr. Mackay served as President, Research and Development at AstraZeneca from June 2010 to February 2012, where he led all R&D functions worldwide, including discovery research, clinical development, regulatory affairs and key related R&D functions. From April 1995 to May 2010, he held various positions of increasing responsibility at Pfizer,

including President, Head of Pfizer Pharmatherapeutics, R&D, where he oversaw all aspects of small molecule discovery and development across multiple therapeutic areas. Dr. Mackay has also worked in the CIBA organization, now Novartis, and held positions within academia. Dr. Mackay received a Microbiology First Class Honors Degree from Heriot-Watt University, Scotland, and a Ph.D. in Molecular Genetics from the University of Edinburgh, Scotland.

John B. Moriarty, J.D. has been with Alexion since December 2012 and has served as Executive Vice President and General Counsel since September 2014. From December 2012 to September 2014, Mr. Moriarty served as Senior Vice President and General Counsel. From December 2010 to December 2012, Mr. Moriarty served as General Counsel and Chief Legal Officer at Elan Corporation plc, an Irish public limited company traded on the New York and Irish Stock Exchanges, and also served as a member of Elan's Executive Management team. Prior to assuming the role of General Counsel, Mr. Moriarty served as Senior Vice President of Law, Litigation and Commercial Operations at Elan from December 2008 to December 2010. From 2002 to 2008, Mr. Moriarty held various positions with Amgen, Inc., including Executive Director and Associate General Counsel, Global Commercial Operations - Amgen Oncology and Senior Counsel, Complex Litigation, Products Liability and Government Investigations. Between 1994 and 2002, Mr. Moriarty served in various capacities in private practice focused on healthcare and as a healthcare fraud prosecutor in the U.S. Attorney's Office and the Virginia Attorney General's Office. Mr. Moriarty received his J.D., cum laude, from the University of Georgia School of Law and his B.A., with distinction, from the University of Virginia

Julie O'Neill has been with Alexion since February 2014 and has served as Executive Vice President of Global Operations since January 2015. From January 2014 to January 2015, Ms. O'Neill was Senior Vice President Global Manufacturing Operations and General Manager of Alexion Pharma International Trading. Prior to joining Alexion, Ms. O'Neill served in various leadership positions at Gilead Sciences from February 1997 to February 2014 including Vice President of Operations and General Manager of Ireland from 2011 to 2014. Prior to Gilead Sciences, Ms. O'Neill held leadership positions in operations, manufacturing and quality functions at Burnil Pharmacies and Helsinn Birex Pharmaceuticals. She is the Chairperson for the National Standards Authority of Ireland and is a member of the Governing Body of University College Cork. Ms. O'Neill received a Bachelor's of Science in Pharmacy from University of Dublin, Trinity College and a Masters of Business Administration from University College Dublin (Smurfit School of Business).

Vikas Sinha, M.B.A., C.A., C.P.A. has been with Alexion since September 2005 and has served as Alexion's Executive Vice President and Chief Financial Officer since October 2012. From September 2005 to October 2012, Mr. Sinha was Senior Vice President and Chief Financial Officer. Prior to joining Alexion, Mr. Sinha held various positions with Bayer AG in the United States, Japan, Germany, and Canada, including Vice President and Chief Financial Officer of Bayer Pharmaceuticals Corporation, USA, Vice President and Chief Financial Officer of Bayer Yakuhin Ltd., in Japan, and Manager, Mergers and Acquisitions with Bayer AG in Germany. He also was a member of the Pharmaceutical Management Committee for North America. Prior to Bayer, Mr. Sinha held several positions of increasing responsibilities with ANZ Bank and Citibank in South Asia. Mr. Sinha holds a Masters of Business Administration from the Asian Institute of Management which included an exchange program with the University of Western Ontario (Richard Ivey School of Business). He is also a qualified Chartered Accountant from the Institute of Chartered Accountants of India and a Certified Public Accountant in the United States.

Saqib Islam has been Senior Vice President, Chief Strategy and Portfolio Officer since joining Alexion in April 2013. Prior to joining Alexion, Mr. Islam worked for 18 years in international business management with a focus on business development, strategic decision-making and planning, and capital markets, and most recently as Managing Director, Head of Healthcare and Diversified Industrials Capital Markets at Credit Suisse Securities from November 2009 until April 2013. Prior to Credit Suisse, Mr. Islam held various positions of increasing responsibility in the investment banking divisions of Merrill Lynch and Morgan Stanley and provided strategic analysis and advice to client firms across diverse industry segments for The Boston Consulting Group. Mr. Islam received a Bachelor of Commerce from McGill University, where he was a Faculty and University Scholar, and a J.D. from Columbia Law School, where he was a Harlan Fiske Stone Scholar.

Edward Miller has been Senior Vice President and Global Chief Compliance Officer since joining Alexion in September 2014. Prior to joining Alexion, Mr. Miller served in various compliance and legal leadership positions at Boehringer Ingelheim from 2000 to August 2014, including Vice President, Associate General Counsel, Global Head of Litigation and Government Investigations; Vice President and Acting Global Compliance Officer and Vice President, Chief Compliance Officer and Head of Litigation. Prior to Boehringer Ingelheim, Mr. Miller was a Senior Trial Attorney at the U. S. Department of Justice in Washington, D.C. Mr. Miller received a Bachelors Degree from Princeton University and his J.D. from Rutgers University School of Law.

Dominique Monnet has been Senior Vice President and Chief Marketing Officer since joining Alexion in May 2014. Prior to joining Alexion, Mr. Monnet served in various marketing leadership positions at Amgen, Inc from 2002 to 2013, including Vice President and General Manager, Inflammation Business Unit, Vice President and Head of Global Marketing and Commercial Development and Vice President International Marketing and Business Operations. Prior to Amgen, Mr. Monnet

held positions of increasing responsibility at Schering-Plough, including General Manager for the company's UK and Ireland entity. Mr. Monnet earned his undergraduate business degree from EDHEC Business School in Lille, France, and his MBA from INSEAD in Fontainebleau, France.

Carsten Thiel, Ph.D. has been with Alexion since September 2014 and has served as Senior Vice President EMEA and Asia Pacific since January 2015. From September 2014 to January 2015, Mr. Thiel was Senior Vice President EMEA and Australasia-Canada. Prior to joining Alexion, Mr. Thiel served in various senior leadership positions at Amgen from 2002 to 2014, including Vice President, Head of Europe, General Manager, Germany, General Manager, CEE and Head of the Oncology Franchise in Europe. Prior to Amgen, Mr. Thiel held several sales and marketing leadership roles across Europe at Roche. Mr. Thiel has a Ph.D. in Molecular Biology and Biochemistry from the Max Planck Institute, Germany, and a Master's Degree in Biochemistry from the University of Marburg, Germany.

Available Information

Our internet website address is http://www.alexion.com. Through our website, we make available, free of charge, our Annual Reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, any amendments to those reports, proxy and registration statements, and all of our insider Section 16 reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission (SEC). These SEC reports can be accessed through the "Investors" section of our website. The information found on our website is not part of this or any other report we file with, or furnish to, the SEC. Paper copies of our SEC reports are available free of charge upon request in writing to Investor Relations, Alexion Pharmaceuticals, Inc., 352 Knotter Drive, Cheshire, CT 06410. In addition, any document we file may be inspected, without charge, at the SEC's public reference room at 100 F Street NE, Washington, DC 20549, or at the SEC's internet address at http://www.sec.gov. (This website address is not intended to function as a hyperlink, and the information contained in the SEC's website is not intended to be a part of this filing). Information related to the operation of the SEC's public reference room may be obtained by calling the SEC at 800-SEC-0330 (800-732-0330).

Item 1A. Risk Factors.

(amounts in thousands, except percentages)

You should carefully consider the following risk factors before you decide to invest in Alexion 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 Products

We depend heavily on the success of our lead product, Soliris. If we are unable to increase sales of Soliris, or obtain approval or commercialize Soliris in new territories for the treatment of PNH, aHUS or for additional indications, or if we are significantly delayed or limited in doing so, our business may be materially harmed.

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

In September and November 2011, we obtained marketing approval in the United States and the European Union, respectively, for Soliris for the treatment of a second indication, aHUS. In September 2013, the MHLW approved Soliris for the treatment of patients with aHUS in Japan.

We dedicate significant resources to the worldwide commercialization of Soliris. We have established sales and marketing capabilities in the United States and in many countries throughout the world. We cannot guarantee that any marketing application for Soliris for the treatment of PNH, aHUS or any other indication, will be approved or maintained in any country where we seek marketing authorization to sell Soliris. In certain countries, we continue discussions with authorities to finalize operational, reimbursement, price approval and funding processes so that we may, upon conclusion of such discussions, commence commercial sales of Soliris for the treatment of PNH in those countries. We have had and will continue to have similar discussions with authorities to facilitate the commercialization of Soliris for the treatment of aHUS in certain countries in the European Union. Our ability to complete such processes successfully is subject to the risks and uncertainties described in this Annual Report on Form 10-K. We cannot guarantee that we will be able to obtain reimbursement for Soliris or successfully commercialize Soliris in any additional countries, or that we will be able to maintain coverage or reimbursement at anticipated levels in any country in which we have already received marketing approval, including the U.S., certain European countries, or Japan. As a result, sales in certain countries may be delayed or never occur, or may be subsequently reduced.

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

- receipt of marketing approvals for Soliris for the treatment of PNH and aHUS in new territories, and the maintenance of marketing approvals in the United States, the European Union, Japan and other territories;
- our ability to obtain sufficient coverage or reimbursement by government or third-party payers and our ability to maintain coverage or reimbursement at anticipated levels;
- establishment and maintenance of commercial manufacturing capabilities ourselves or through third-party manufacturers;
- the number of patients with PNH and aHUS, and the number of those patients who are diagnosed with PNH and aHUS and identified to us;
- the number of patients with PNH and aHUS that may be treated with Soliris;
- successful continuation of commercial sales in the United States, Japan and in European countries where we are already selling Soliris for the treatment of PNH and aHUS, and successful launch in countries where we have not yet obtained, or only recently obtained, marketing approval or commenced sales;

- acceptance of Soliris and maintenance of safety and efficacy in the medical community; and
- our ability to develop, register and commercialize Soliris for indications other than PNH and aHUS.

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

If we are unable to obtain, or maintain at anticipated levels, reimbursement for Soliris from government health administration authorities, private health insurers and other organizations, our pricing may be affected or our product sales, results of operations or financial condition could be harmed.

We may not be able to sell Soliris on a profitable basis or our profitability may be reduced if we are required to sell our product at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. Soliris is significantly more expensive than traditional drug treatments and almost all patients require some form of third party coverage to afford its cost. Our future revenues and profitability will be adversely affected if we cannot depend on governmental payers, such as Medicare and Medicaid in the United States or country specific governmental organizations in foreign countries, and private third-party payers to defray the cost of Soliris to patients. These entities may refuse to provide coverage and reimbursement with respect to Soliris, determine to provide a lower level of coverage and reimbursement than anticipated, or reduce previously approved levels of coverage and reimbursement, including in the form of higher mandatory rebates or modified pricing terms. In any such case, our pricing or reimbursement for Soliris may be affected and our product sales, results of operations or financial condition could be harmed.

In certain countries where we sell or are seeking or may seek to commercialize Soliris, including certain countries where we both sell Soliris for the treatment of PNH and sell or seek to commercialize Soliris for the treatment of aHUS, if approved by the appropriate regulatory authority, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control. We may be unable to timely or successfully negotiate coverage, pricing, and reimbursement on terms that are favorable to us, or such coverage, pricing, and reimbursement may differ in separate regions in the same country. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country, and we cannot guarantee that we will have the capabilities or resources to successfully conclude the necessary processes and commercialize Soliris in every, or even most countries in which we seek to sell Soliris.

Reimbursement sources are different in each country and in each country may include a combination of distinct potential payers, including private insurance and governmental payers. For example, the European Union member states' authorities may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and adopt additional measures to control the prices of medicinal products for human use. This includes the use of reference pricing and Health Technology Assessment (HTA). HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of the use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the healthcare system. These elements of medicinal products are compared with other treatment options available on the market. The national authorities of some European Union member states may from time to time approve a specific price for the medicinal product. Others may adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the national market. Some countries have and others may seek to impose limits on the aggregate reimbursement for Soliris or for the use of Soliris for certain indications. In such cases, our commercial operations in such countries and our results of operations and our business are and may be adversely affected. Our results of operations may suffer if we are unable to successfully and timely conclude reimbursement, price approval or funding processes and market Soliris in such foreign countries or if coverage and reimbursement for Soliris is limited or reduced. If we are not able to obtain coverage, pricing or reimbursement on terms acceptable to us or at all, or if such terms should change in any foreign countries, we may not be able to or we may determine not to sell Soliris for one or more indications in such countries, or we could decide to sell Soliris at a lower than anticipated price in such countries, and our revenues may be adversely affected as a result.

The potential increase in the number of patients receiving Soliris may cause third-party payers to modify or limit coverage or reimbursement for Soliris for the treatment of PNH, aHUS, or both indications.

Changes in pricing or the amount of reimbursement in countries where we currently commercialize Soliris may also reduce our profitability and worsen our financial condition. In the United States, the European Union member states, and elsewhere, there have been, and we expect there will continue to be, efforts to control and reduce health care costs. Third party payers decide which drugs they will pay for and establish reimbursement and co-payment levels. Government and other third-party payers in the United States and the European Union member states are increasingly challenging the prices charged for health care products, examining the cost effectiveness of drugs in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement for prescription drugs.

A significant reduction in the amount of reimbursement or pricing for Soliris in one or more countries may have a material adverse effect on our business. See additional discussion below under the headings "Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy and Government initiatives that affect coverage and reimbursement of drug products may impact our business in ways that we cannot currently predict and these changes could adversely affect our business and financial condition" and "The credit and financial market conditions may aggravate certain risks affecting our business." In addition, certain countries establish pricing and reimbursement amounts by reference to the price of the same or similar products in other countries. If coverage or the level of reimbursement is limited in one or more countries, we may be unable to obtain or maintain anticipated pricing or reimbursement in current or new territories.

Many third-party 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.

Payers in the U.S. also are increasingly considering new metrics as the basis for reimbursement rates, such as ASP, average manufacturer price, and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. The Centers for Medicare and Medicaid Services (CMS), the federal agency that administers Medicare and the Medicaid Drug Rebate Program, has begun posting drafts of this retail survey price information on at least a monthly basis in the form of draft National Average Drug Acquisition Cost, or NADAC, files, which reflect retail community pharmacy invoice costs, and National Average Retail Price, or NARP, files, which reflect retail community pharmacy prices to consumers. In July 2013, CMS suspended the publication of draft NARP data, pending funding decisions. In November 2013, CMS moved to publishing final rather than draft NADAC data and has since made updated NADAC data publicly available on a weekly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payers to cover Soliris.

Even in countries where patients have access to insurance, their insurance co-payment amounts or annual or lifetime caps on reimbursements may represent a barrier to obtaining or continuing Soliris. We have financially supported non-profit organizations which assist patients in accessing treatment for PNH and aHUS, including Soliris. Such organizations assist patients whose insurance coverage leaves them with prohibitive co-payment amounts or other expensive financial obligations. Such organizations' ability to provide assistance to patients is dependent on funding from external sources, and we cannot guarantee that such funding will be provided at adequate levels, if at all. We have also provided Soliris without charge to patients who have no insurance coverage for drugs through 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 profitability in the future.

We are also focusing development efforts on the use of eculizumab for the treatment of additional diseases. The success of these programs depends on many factors, including those described in this report. As Soliris is approved by regulatory agencies for indications other than PNH and aHUS, the potential increase in the number of patients receiving Soliris may cause third-party payers to refuse coverage or reimbursement for Soliris for the treatment of PNH, aHUS or for any other approved indication, or provide a lower level of coverage or reimbursement than anticipated or currently in effect.

We may not be able to maintain market acceptance of Soliris among the medical community or patients, or gain market acceptance of our products in the future, which could prevent us from maintaining profitability or growth.

We cannot be certain that Soliris will maintain market acceptance in a particular country among physicians, patients, health care payers, and others. Although we have received regulatory approval for Soliris in certain territories, including the United States, Japan and the European Union, such approvals do not guarantee future revenue. We cannot predict whether physicians, other health care providers, government agencies or private insurers will determine or continue to accept that Soliris is safe and therapeutically effective relative to its cost. Physicians' willingness to prescribe, and patients' willingness to accept, our products, such as Soliris, depends on many factors, including prevalence and severity of adverse side effects in both clinical trials and commercial use, the timing of the market introduction of competitive drugs, lower demonstrated clinical safety and efficacy compared to other drugs, perceived lack of cost-effectiveness, pricing and lack of availability of reimbursement from third-party payers, convenience and ease of administration, effectiveness of our marketing strategy, publicity concerning the product, our other product candidates or competing products, and availability of alternative treatments, including bone marrow transplant as an alternative treatment for PNH. The likelihood of physicians to prescribe Soliris for patients with aHUS may also depend on how quickly Soliris can be delivered to the hospital or clinic and our distribution methods may not be sufficient to satisfy this need. In addition, we are aware that medical doctors have determined not to continue Soliris treatment for some patients with aHUS.

Health insurance programs may restrict coverage of some products by using payer formularies under which only selected drugs are covered, variable co-payments that make drugs that are not preferred by the payer more expensive for patients, and by using utilization management controls, such as requirements for prior authorization or failure on another type of treatment.

Payers may especially impose these obstacles to coverage for higher-priced drugs, and consequently our drug products may be subject to payer-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, European Union member states may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. A European Union member state may approve a specific price or level of reimbursement for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. The reimbursement or budget identified by a government or non-government payer for our products, including Soliris in a new indication, if obtained, may be adversely affected by the reimbursement or budget for Soliris in previously approved indications and/or adversely affect the reimbursement or budget for Soliris in such previously approved indication by that payer.

If Soliris fails to achieve or maintain market acceptance among the medical community or patients in a particular country, we may not be able to market and sell it successfully in such country, which would limit our ability to generate revenue and could harm our overall business.

If we or any third party manufacturer or provider fails to provide sufficient quantities of Soliris or our product candidates, including Soliris for new indications, we could experience product shortages, our commercialization of Soliris may be stopped or delayed, our clinical trials could be disrupted or regulatory approvals could be delayed.

Soliris is manufactured by Alexion at ARIMF and by Lonza. We depend on a very limited number of third party providers for the manufacture and supply of Soliris and our product candidates. The manufacture of Soliris and our product candidates is difficult, requiring a multi-step controlled process and even minor problems or deviations could result in defects or failures. Manufacture of our products, including Soliris, is highly technical, and only a small number of companies have the ability and capacity to manufacture our products for our development and commercialization needs. Due to the highly technical requirements of manufacturing our products and the strict quality and control specifications, we and our third party providers may be unable to manufacture or supply our products despite our and their efforts. In addition, we cannot be certain that any third party will be able or willing to honor the terms of its agreement, including any obligations to manufacture our products in accordance with regulatory requirements and to our quality specifications and volume requirements.

We cannot be certain that we, Lonza or our other third party providers will be able to perform uninterrupted supply chain services. The failure to manufacture appropriate supplies of Soliris, on a timely basis, or at all, may prevent or interrupt the commercialization of Soliris. If we, Lonza or our other third party providers were unable to manufacture Soliris for any period for any reason, including due to the loss of approvals, or if we, Lonza or our other third party providers do not obtain approval for the manufacturing of Soliris in the respective facility by the applicable regulatory agencies, we may incur substantial loss of sales. See also our Risk Factor "If we or our contract manufacturers fail to comply with continuing United States and foreign regulations, we could lose our approvals to market Soliris or our manufacturers could lose their approvals to manufacture Soliris or our product candidates, and our business would be seriously harmed." We may also lose any redundancy in our manufacturing capabilities if we are no longer able to perform operations at ARIMF or any other facility. The failure to manufacture appropriate supplies of our product candidates, on a timely basis, or at all, may prevent or interrupt clinical development of our products, including Soliris for new indications. If we are forced to find an alternative supplier or other third party providers, in addition to loss of sales and disruption to patients, we may also incur significant costs and experience significant delay in establishing a new arrangement.

We are authorized to sell Soliris that is manufactured by Lonza and at ARIMF in the United States, the European Union, Japan and certain other territories. However, manufacturing Soliris for commercial sale in certain other territories may only be performed at a single facility until such time as we have received the required regulatory approval for an additional facility, if ever. We will continue to depend entirely on one facility to manufacture Soliris for commercial sale in such other territories until that time.

We have obtained marketing approval for Soliris for the treatment of patients with aHUS in the United States, the European Union, Japan and other territories. We expect that the demand for Soliris will increase. We may underestimate demand, or experience product interruptions at ARIMF, Lonza or a facility of a third party provider, including as a result of risks and uncertainties described in this report. If we, Lonza or our other third party providers do not manufacture sufficient quantities of Soliris to satisfy demand, our business will be materially harmed.

We depend on a very limited number of third party providers for other services with respect to our clinical and commercial requirements, including product filling, finishing, packaging, and labeling. We have changed or added third party fill/finish providers in the past in order to support uninterrupted supply, and may do so in the future. We currently rely on three third party fill/finish providers to support our commercial requirements in the United States and the European Union, and two to support requirements in Japan. No guarantee can be made that regulators will approve additional third party fill/finish providers in a timely manner or at all, or that any third party fill/finish providers will be able to perform such services for sufficient product volumes for any country or territory. We do not have control over any third party provider's compliance with

our internal or external specifications or the rules and regulations of the FDA, EMA, competent authorities of the European Union member states, MHLW or any other applicable regulations or standards. In the past, we have had to write off and incur other charges and expenses for production that failed to meet requirements, including with respect to recalls initiated in 2013 and 2014.

Any difficulties or delays in our third party manufacturing of Soliris, or any failure of our third party providers to comply with our internal and external specifications or any applicable rules, regulations and standards could increase our costs, constrain our ability to satisfy demand for Soliris from customers, cause us to lose revenue or incur penalties for failure to deliver product, make us postpone or cancel clinical trials, or cause our products to be recalled or withdrawn, such as the voluntary recalls, that we initiated in 2013 and 2014 due to the presence of visible particles in a limited number of vials in specific lots. Even if we are able to find alternatives they may ultimately be insufficient for our needs.

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

In April 2014, we acquired a fill/finish facility in Ireland to support global distribution of Soliris and Alexion's other clinical and commercial products. To date, we have relied entirely on third party fill/finish providers and have never operated our own fill/finish facility. We cannot guarantee that we will be able to successfully complete the appropriate validation processes or obtain the necessary regulatory approvals, or that we will be able to perform fill/finish services at this facility to support our product requirements.

Many additional factors could cause production interruptions at ARIMF or at the facilities of Lonza or our third party providers, including natural disasters, labor disputes, acts of terrorism or war, human error, equipment malfunctions, contamination, or raw material shortages. The occurrence of any such event could adversely affect our ability to satisfy demand for Soliris, which could materially and adversely affect our operating results.

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

We cannot guarantee that we will be able to maintain our regulatory approvals for Soliris. If we do not maintain our regulatory approvals for Soliris, the value of our company and our results of operations will be materially harmed. We and our current and future partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by governmental authorities around the world, including the FDA, EMA, the competent authorities of the European Union member states, and MHLW. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us. For example, in March 2013, we received a Warning Letter from the FDA relating to compliance with cGMP at ARIMF. In August 2014 we announced that we received a Form 483 with three observations following an FDA inspection at ARIMF. If we do not resolve outstanding concerns expressed by the FDA in the Warning Letter and the August 2014 Form 483 to the satisfaction of the FDA, EMA or any other regulatory agency, or we or our third-party providers, including our product fill/finish providers, packagers and labelers, fail to comply fully with applicable regulations then we may be required to initiate a recall or withdrawal of our products.

The safety profile of any product continues to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. Regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, finishing, filling, labeling, advertising, promotion, risk mitigation, adverse event reporting requirements, and export of biologics. For example, the risk management program established in 2007 upon the FDA's approval of Soliris for the treatment of PNH was replaced with a Risk Evaluation and Mitigation Strategy (REMS) program, approved by the FDA in 2010. The REMS program requires mandatory physician certification in the United States. Each physician must certify that the physician is aware of the potential risks associated with the administration of Soliris and that the physician will inform each patient of these risks using educational material approved by the FDA. In November 2014, we met with the FDA Drug Safety and Risk Management Advisory Committee to discuss adjustments to the REMS with elements to assure safe use (ETASU). A majority of the Committee favored revising the REMS and made suggestions for streamlining prescriber assessments and broadening the program’s educational outreach. Changes to the Soliris REMS could be costly and burdensome to implement.

As a condition of approval for marketing Soliris, governmental authorities may require us to conduct additional studies. For example, in connection with the approval of Soliris in the United States, European Union and Japan, for the treatment of PNH, we agreed to establish a PNH Registry, monitor immunogenicity, monitor compliance with vaccination requirements, and determine the effects of anticoagulant withdrawal among PNH patients receiving eculizumab, and, specifically in Japan, we

agreed to conduct a trial in a limited number of Japanese PNH patients to evaluate the safety of a meningococcal vaccine. Further, in connection with the approval of Soliris in the United States for the treatment of aHUS, we agreed to establish an aHUS Registry and complete additional human clinical studies in adult and pediatric patients. In the United States, for example, the FDA can propose to withdraw approval for a product if it determines that such additional studies are inadequate or if new clinical data or information shows that a product is not safe for use in an approved indication. We are required to report any serious and unexpected adverse experiences and certain quality problems with Soliris to the FDA, the EMA, the competent authorities of the European Union member states, MHLW, and certain other health agencies. We or any health agency may have to notify health care providers of any such developments.

The discovery of any previously unknown problems with Soliris, a manufacturer or a facility may result in restrictions on Soliris, a manufacturer or a facility, including withdrawal of Soliris from the market, batch failures, or interruption of production or a product recall such as the recalls we announced and voluntarily initiated in 2013 and 2014. Certain changes to an approved product, including the way it is manufactured or promoted, often require prior regulatory approval before the product as modified may be marketed. Our manufacturing and other facilities and those of any third parties manufacturing Soliris will be subject to inspection prior to grant of marketing approval by each regulatory authority where we seek marketing approval and subject to continued review and periodic inspections by the regulatory authorities, such as the inspections that resulted in issuance of the Warning Letter. We and any third party we would use to manufacture Soliris for sale, including Lonza, must also be licensed by applicable regulatory authorities.

The FDA requires reporting of certain information on side effects and adverse events reported during clinical studies and after marketing approval. Non-compliance with safety reporting requirements could result in regulatory action that may include civil action or criminal penalties.

Failure to comply with the laws and requirements, including statutes and regulations, administered by the FDA, the EMA, the competent authorities of the European Union member states, the MHLW or other agencies, including without limitation, failures or delays in resolving the concerns raised by the FDA in the Warning Letter, could result in:

- a product recall;
- a product withdrawal;
- significant administrative and judicial sanctions, including, warning letters or untitled letters;
- significant fines and other civil penalties;
- suspension, variation or withdrawal of a previously granted approval for Soliris;
- interruption of production;
- operating restrictions, such as a shutdown of production facilities or production lines, or new manufacturing requirements;
- suspension of ongoing clinical trials;
- delays in approving or refusal to approve our products including pending BLAs or BLA supplements for Soliris or asfotase alfa, or a facility that manufactures our products;
- seizing or detaining product;
- requiring us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- injunctions; and/or
- criminal prosecution.

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

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

We tested Soliris in only a small number of patients. The FDA marketing approval for the treatment of patients with aHUS was based on two prospective studies in a total of 37 adult and adolescent patients, together with a retrospective study

that included 19 pediatric patients. PNH and aHUS are ultra-rare diseases. As more patients use Soliris, including more children and adolescents, new risks and side effects may be discovered, the rate of known risks or side effects may increase, and risks previously viewed as less significant could be determined to be significant. Previously unknown risks and adverse effects of Soliris may also be discovered in connection with unapproved uses of Soliris, which may include administration of Soliris under acute emergency conditions, such as the Enterohemorrhagic E. coli health crisis in Europe, primarily Germany, that began in May 2011. We do not promote, or in any way support or encourage the promotion of Soliris for unapproved uses in violation of applicable law, but physicians are permitted to use products for unapproved purposes and we are aware of such uses of Soliris. In addition, we are studying and expect to continue to study Soliris in diseases other than PNH and aHUS in controlled clinical settings, and independent investigators are doing so as well. In the event of any new risks or adverse effects discovered as new patients are treated for approved indications and as Soliris is studied in or used by patients for other indications, regulatory authorities may delay or revoke their approvals, we may be required to conduct additional clinical trials and safety studies, make changes in labeling of Soliris, reformulate Soliris or make changes and obtain new approvals for our and our suppliers' manufacturing facilities. We may also experience a significant drop in the potential sales of Soliris, experience harm to our reputation and the reputation of Soliris in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of Soliris or substantially increase the costs and expenses of commercializing and marketing Soliris.

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

Patients who use Soliris already often have severe and advanced stages of disease and known as well as unknown significant pre-existing and potentially life-threatening health risks, including, for example, bone marrow failure, kidney failure and thrombosis. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to Soliris. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market Soliris, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to Soliris, the investigation into the circumstance may be time consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals Soliris receives or maintains.

Some patients treated with Soliris for PNH and other diseases, including patients who have participated in our clinical trials, have died or suffered potentially life-threatening diseases either during or after ending their Soliris treatments. In particular, use of C5 Inhibitors, such as Soliris, is associated with an increased risk for certain types of infection, including meningococcal infection. Serious cases of meningococcal infection can result in severe illness, including but not limited to brain damage, loss of limbs or parts of limbs, kidney failure, or death. Under controlled settings, patients in our eculizumab trials all receive vaccination against meningococcal infection prior to first administration of Soliris and patients who are prescribed Soliris in most countries are required by prescribing guidelines to be vaccinated prior to receiving their first dose. A physician may not have the opportunity to timely vaccinate a patient in the event of an acute emergency episode, such as in a patient presenting with aHUS or during the health crisis that began in May 2011 in Europe, principally in Germany, due to the epidemic of infections from Enterohemorrhagic E. coli. Vaccination does not, however, eliminate all risk of meningococcal infection. Additionally, in some countries there may not be any vaccine approved for general use or approved for use in infants and children. Some patients treated with Soliris who had been vaccinated have nonetheless experienced meningococcal infection, including patients who have suffered serious illness or death. Each such incident is required to be reported to appropriate regulatory agencies in accordance with relevant regulations.

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

We are aware of a risk for aHUS patients who delay or miss a dose of Soliris or discontinue their treatment of Soliris. Treatment with Soliris blocks complement and inhibits complement-mediated TMA. After missing a dose or discontinuing Soliris, blood clots may form in small blood vessels throughout the body, causing a reduction in platelet count. The reduction in platelet count may lead to numerous complications, including changes in mental status, seizures, angina, thrombosis, renal failure or even death. In our aHUS clinical studies, such TMA complications were observed in some patients who missed a dose.

Clinical evaluations of outcomes in the post-marketing setting are required to be reported to appropriate regulatory agencies in accordance with relevant regulations. Determination of significant complications associated with the delay or discontinuation of Soliris could have a material adverse effect on our ability to sell Soliris.

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, Europe, Japan and several other territories. If we are unable to establish and/or expand our capabilities to sell, market and distribute Soliris for the treatment of PNH, aHUS or, if approved by the necessary regulatory agencies, other future indications, either through our own capabilities or by entering into agreements with others, or to maintain such capabilities in countries where we have already commenced commercial sales, we will not be able to successfully sell Soliris. In that event, we will not be able to generate significant revenues. We cannot guarantee that we will be able to establish and maintain our own capabilities or enter into and maintain any marketing or distribution agreements with third-party providers on acceptable terms, if at all. Even if we hire the qualified sales and marketing personnel we need to support our objectives, or enter into marketing and distribution agreements with third parties on acceptable terms, we may not do so in an efficient manner or on a timely basis. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell Soliris. Establishing and maintaining sales, marketing and distribution capabilities are expensive and time-consuming. Our expenses associated with building up and maintaining the sales force and distribution capabilities around the world may be disproportionate compared to the revenues we may be able to generate on sales of Soliris. We cannot guarantee that we will be successful in commercializing Soliris.

If we market Soliris in a manner that violates health care fraud and abuse laws and other laws regulating marketing and promotion, we may be subject to investigations and 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. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind to induce, or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federal health care programs. This statute has been interpreted to apply broadly to arrangements between pharmaceutical manufacturers on the one hand and prescribers, patients, purchasers and formulary managers on the other. Liability may be established without a person or entity having actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. In addition, PPACA amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (FCA). A conviction for violation of the Anti-kickback Statute requires mandatory exclusion from participation in federal health care programs. 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 to those who prescribe, purchase, or recommend pharmaceutical products, including certain discounts, education and research grants, purchase of speaking or consulting services, and patient assistance programs, may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor. We seek to comply with the anti-kickback laws and with the available statutory exemptions and safe harbors. However, our practices may not in all cases fit within the safe harbors, and our practices may therefore be subject to case-by-case scrutiny.

The FCA prohibits any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim. Pharmaceutical companies have been investigated and have reached substantial financial settlements with the Federal government under the FCA 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; providing consulting fees and other benefits to physicians to induce them to prescribe products; reporting inflated prices to private publications 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 Federal programs for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program.

The majority of states also have statutes similar to the federal anti-kickback law and false claims laws, that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. In addition, several U.S. states and localities have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Some state laws prohibit certain marketing-related activities including the provision of gifts, meals or other items to certain health care providers. Similar legislation is being considered in other states. Additionally, PPACA enacted the Physician Payment Sunshine Act, being implemented as the Open Payments program, that requires manufacturers to track and report to the federal government, for public dissemination, payments and other transfers of value made to physicians and teaching hospitals. Many of these requirements are new and there is limited guidance on many aspects of how they will be interpreted, implemented and enforced. , 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.

Sanctions under these federal and state fraud and abuse laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, monetary damages, criminal fines, and imprisonment. Efforts to ensure that our business arrangements continue to comply with applicable healthcare laws and regulations could be costly. Because of the breadth of these laws and the narrowness of the safe harbors and because government scrutiny in this area is high, it is possible that some of our business activities could come under that scrutiny. 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 could also harm our financial condition. Responding to government investigations or whistleblower lawsuits, defending any claims raised, and any resulting fines, damages, penalties, settlement payments or administrative actions, as well as any related actions brought by stockholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business.

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

Similar strict restrictions are imposed on the promotion and marketing of drug products in the European Union, where a large portion of our non-U.S. business is conducted, and other territories. Laws in the European Union, including in the individual European Union member states, require promotional materials and advertising for drug products to comply with the product's Summary of Product Characteristics (SmPC), which is approved by the competent authorities. Promotion of a medicinal product which does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the European Union and in other territories. The promotion of medicinal products that are not subject to a marketing authorization is also prohibited in the European Union. Laws in the European Union, including in the individual European Union member states, also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the European Union and in other territories could be penalized by administrative measures, fines and imprisonment.

Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual European Union member states. The provision of any inducements to physicians to prescribe, recommend, endorse, order, purchase, supply, use or administer a medicinal product is prohibited. A number of European Union member states have introduced additional rules requiring pharmaceutical companies to publicly disclose their interactions with physicians and to obtain approval from employers, professional organizations and/or competent authorities before entering into agreements with physicians. These rules have been supplemented by provisions of related industry codes. Additional countries may consider or implement similar laws and regulations. Violations of these rules could lead to reputational risk, public reprimands, and/or the imposition of fines or imprisonment.

We are also subject to the United States Foreign Corrupt Practices Act (FCPA), the U.K. Bribery Act, and other anti-corruption laws and regulations that generally prohibit companies and their intermediaries from making improper payments to

government officials and/or other persons for the purpose of obtaining or retaining business. Worldwide regulators are increasing their regulatory and enforcement efforts in this area. For example, the Bribery Act in the United Kingdom, effective as of July 2011 applies to any company incorporated in or "carrying on business" in the United Kingdom, regardless of the country in which the alleged bribery activity occurs and even if the inappropriate activity is undertaken by our international distribution partners.

Recent years have seen a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice ("DOJ") and the U.S. Securities and Exchange Commission ("SEC"), increased enforcement activity by non-U.S. regulators, and increases in criminal and civil proceedings brought against companies and individuals. Our policies mandate compliance with these anti-bribery laws. We may operate in many parts of the world that are recognized as having a greater potential for governmental and commercial corruption. We cannot assure that our policies and procedures will always protect us from reckless or criminal acts committed by our employees or third-party intermediaries. From time-to-time, we may conduct internal investigations and compliance reviews, the findings of which could negatively impact our business. Any determination that our operations or activities are not, or were not, in compliance with existing United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence. Violations of these laws may result in criminal or civil sanctions, which could disrupt our business and result in a material adverse effect on our reputation, business, results of operations or financial condition. Increasing regulatory scrutiny of the promotional activities of pharmaceutical companies also has been observed in a number of European Union member states.

Laws, including those governing promotion, marketing and anti-kickback/anti-bribery provisions, and industry regulations are often strictly enforced. In the United States, additional governmental resources are being added to enforce these laws and to prosecute companies and individuals believed to be violating them. For example, PPACA included a number of provisions aimed at strengthening the government's ability to pursue anti-kickback and false claims cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers for government authorities, and amendments to the civil False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations. We anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and whistleblower lawsuits. Responding to a government investigation or whistleblower lawsuit would be expensive and time-consuming, and could have a material adverse effect on our business and financial condition and growth prospects.

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 and aHUS. If we are unable to obtain regulatory approvals to market one or more of our product candidates, including asfotase alfa and Soliris for other indications, our business may be adversely affected.

All of our product candidates except Soliris and asfotase alfa are in early stages of development, and we do not expect our early stage product candidates to be commercially available for several years, if at all. Although we are preparing for a commercial launch of asfotase alfa for the treatment of hypophosphatasia, we do not know when or if asfotase alfa will be approved by the FDA, EMA or any other regulatory agency. We completed a rolling submission of our BLA for asfotase alfa in the U.S., which allowed completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. While we believe a rolling submission will allow us to expedite the review of the application, we cannot predict how long the approval process will take or when we will receive approval, if at all. We do not know when or if our other product candidates will be approved. Unfavorable clinical trial results, failure to comply with regulatory requirements, resolve pending concerns described in the Warning Letter, and inadequate manufacturing processes are examples of problems that could prevent approval. In addition, we may encounter delays or rejections due to additional government regulation from future legislation, administrative action or changes in the FDA policy. Even if the FDA approves a product, the approval will be limited to those indications covered in the approval.

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

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

Completion of preclinical studies or clinical trials does not guarantee that we will initiate additional studies or trials for our product candidates, that if further studies or trials are initiated what the scope and phase of the trial will be or that they will be completed, or that if these further studies or trials are completed, that the design or results will provide a sufficient basis to apply for or receive regulatory approvals or to commercialize products. Results of clinical trials could be inconclusive,

requiring additional or repeat trials. Data obtained from preclinical studies and clinical trials are subject to varying interpretations that could delay, limit or prevent regulatory approval. Data that we believe is highly clinically significant, including the results of our HPP trials, could be interpreted differently by the FDA or other regulatory agencies. The results generated in clinical studies of asfotase alfa which we believe to be positive, do not ensure that the product will be approved and the FDA or other regulatory agency could require additional preclinical or clinical data. If the design or results achieved in our clinical trials are insufficient to proceed to further trials or to regulatory approval of our product candidates, our company could be materially adversely affected. Failure of a clinical trial to achieve its pre-specified primary endpoint, such as the Phase 2 Soliris trial for AMR that we announced in January 2015, 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. Many of our programs focus on diseases with small patient populations and insufficient patient enrollment in our clinical trials could delay or cause us to abandon a product development program. We may decide to abandon development of a product candidate at any time due to unfavorable results or other reasons, or we may have to spend considerable resources repeating clinical trials or conducting additional trials, either of which would increase costs and delay any revenue from those product candidates, if any.

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

- delay or failure in obtaining institutional review board (IRB), approval or the approval of other reviewing entities to conduct a clinical trial at each site;
- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations(CROs), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- slow patient enrollment, including, for example, due to the rarity of the disease being studied;
- delay or failure in having patients complete a trial or return for post-treatment follow-up;
- 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, and the threat of legal claims and litigation alleging injuries;
- failure of patients taking the placebo to continue to participate in our clinical trials;
- insufficient clinical trial data to support effectiveness of the product candidates;
- lack of effectiveness or safety of the product candidate being tested;
- lack of sufficient funds;
- inability to meet required specifications or to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner;
- decisions by regulatory authorities, the IRB, ethics committee, or us, or recommendation by a data safety monitoring board, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- failure to obtain the necessary regulatory approvals for the product candidate or the approvals for the facilities in which such product candidate is manufactured; and
- decisions by competent authorities, IRBs or ethics committees to demand variations in protocols or conduct of clinical trials.

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

In April 2014, Alexion initiated a BLA with the FDA for asfotase alfa as a treatment for patients with hypophosphatasia (HPP). In July 2014, the Marketing Authorization Application (MAA) for asfotase alfa was validated by the European Medicines Agency (EMA). In October 2014, Alexion submitted a New Drug Application for asfotase alfa to Japan's MHLW.

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

- failure of our product candidates to meet a regulatory agency's requirements for safety, efficacy and quality;
- disagreement over interpretation of data from preclinical studies or clinical trials;
- restricted distribution or limitation on the indicated uses for which a product may be marketed;
- unforeseen safety issues or side effects and potential requirements to establish REMS or post-marketing obligations;
- disapproval of the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- governmental or regulatory delays and changes in regulatory requirements and guidelines.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that is not desirable for the successful commercialization of that product candidate. In addition, if our product candidate produces undesirable side effects or safety issues, the FDA may require the establishment of Risk Evaluation Mitigation Strategies, or REMS, or a comparable foreign regulatory authority may require the establishment of a similar strategy, that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us. Any of the foregoing scenarios could materially harm the commercial prospects of our product candidates.

Risks Related to Intellectual Property

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

In order to protect our drugs and technology more effectively, we need to obtain and maintain patents covering the drugs and technologies we develop. We have and may in the future obtain patents or the right to practice patents through ownership or license. Our patent applications may not result in the issue of patents in the United States or other countries. Our patents may not afford adequate protection for our products. Third parties may challenge our patents, and have challenged our patents in the past. If any of our patents are narrowed, invalidated or become unenforceable, competitors may develop and market products similar to ours that do not conflict with or infringe our patents rights, which could have a material adverse effect on our financial condition. We may also finance and collaborate in research conducted by government organizations, hospitals, universities or other educational or research institutions. Such research partners may be unwilling to grant us exclusive rights to technology or products developed through such collaborations. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties. Soliris and our drug candidates are expensive and time-consuming to test and develop. Even if we obtain and maintain patents, our business may be significantly harmed if the patents are not broad enough to protect our drugs from copycat products.

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

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

Parts of our technology, techniques and proprietary compounds and potential drug candidates, including those which are or may be in-licensed, may be found to infringe patents owned by or granted to others. We previously reported that Novartis and other third parties have filed civil lawsuits against us claiming infringement of their intellectual property rights. Each of these matters has been resolved, however, additional third parties may claim that the manufacture, use or sale of Soliris or other drugs under development infringes patents owned or granted to such third parties. In addition to the civil actions referenced above, we have in the past received, and may in the future receive, notices from third parties claiming that their patents may be infringed by the development, manufacture or sale of Soliris or some of our drug candidates. We are aware of patents owned by third parties that might be claimed by such third parties to be infringed by the development and commercialization of Soliris and some of our drug candidates. In respect to some of these patents, we have obtained licenses, or expect to obtain licenses. However, with regard to such other patents, we have determined in our judgment that:

- Soliris and our product candidates do not infringe the patents;
- the patents are not valid; or
- we have identified and tested or are testing various modifications that we believe should not infringe the patents and which should permit commercialization of our product candidates.

Any holder of these patents or other patents covering similar technology could sue us for damages and seek to prevent us from manufacturing, selling or developing our drugs. Legal disputes can be costly and time consuming to defend. If we cannot successfully defend against any future actions or conflicts, if they arise, we may incur substantial legal costs and may be liable for damages, be required to obtain costly licenses or need to stop manufacturing, using or selling Soliris, which would adversely affect our business. We may seek to obtain a license prior to or during legal actions in order to reduce further costs and the risk of a court determination that our product infringes the third party's patents. 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 or that we would be able to obtain a license to any third-party patent on commercially reasonable terms or any terms at all; successfully develop non-infringing alternatives on a timely basis; or license alternative non-infringing technology, if any exists, on commercially reasonable terms. Any impediment to our ability to manufacture, use or sell approved forms of Soliris or our product candidates could have a material adverse effect on our business and prospects.

It is possible that we could lose market exclusivity for a product earlier than expected, which would harm our competitive position.

In our industry, much of an innovative product’s commercial value is realized while it has market exclusivity. When market exclusivity expires and biosimilar or generic versions of the product are approved and marketed, there can be substantial decline in the innovative product’s sales.

Market exclusivity for Soliris is based upon patent rights and certain regulatory forms of exclusivity. The scope of Soliris patent rights vary from country to country and are dependent on the availability of meaningful legal remedies in each country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or loss of such rights, could be material to our business. In some countries, patent protections for Soliris may not exist because certain countries did not historically offer the right to obtain specific types of patents or we did not file patents in those markets. Also, the patent environment is unpredictable and the validity and enforceability of patents cannot be predicted with certainty. Absent relevant patent protection for a product, once regulatory exclusivity periods expire, biosimilar or generic versions of the product can be approved and marketed. Even prior to the expiration of regulatory exclusivity, a competitor could seek to obtain marketing approval by submitting its own clinical trial data.

Risks Related to Our Operations

We cannot guarantee that we will achieve our financial goals, including our ability to maintain profitability on a quarterly or annual basis in the future.

Until the quarter ended June 30, 2008, we had never been profitable since we were incorporated in January 1992. We have maintained profitability on a quarterly basis since the quarter ended June 30, 2008 and on an annual basis beginning with the year ended December 31, 2008. We believe that we formulate our annual operating budgets with reasonable assumptions and targets, however we cannot guarantee that we will be able to generate sufficient revenues or control expenses to achieve our financial goals, including continued profitability. Even if we do achieve profitability in any subsequent quarters, we may not be able to sustain or increase profitability on a quarterly or annual basis. You should not consider our revenue growth in recent periods as indicative of our future performance. Our revenue in future periods could decline. We may make errors in predicting and reacting to relevant business trends or our business may be subject to factors beyond our control, which could harm our operations. Since we began our business, we have focused on research and development of product candidates. We cannot guarantee that we will be successful in marketing and selling Soliris on a continued basis in countries or regions where we have obtained marketing approval, including the United States, Europe and Japan, and we do not know when we will have Soliris available for sale in territories where we have applied or will apply for marketing approval, if ever. We will have substantial expenses as we continue our research and development efforts, continue to conduct clinical trials and continue to develop manufacturing, sales, marketing and distribution capabilities in the United States and abroad. The achievement of our financial goals, including the extent of our future profitability, depends on many factors, including our ability to successfully market Soliris in the United States, the European Union and Japan and other territories, our ability to obtain regulatory, pricing, coverage, and reimbursement approvals of our drug candidates, such as asfotase alfa, and for Soliris in additional territories and other indications, our ability to successfully market Soliris in additional territories, our ability to successfully manufacture and commercialize our drug candidates and our ability to successfully bring our other product candidates to the major commercial markets throughout the world.

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

The FDA, EC and the MHLW granted orphan drug designation for Soliris in the treatment of PNH and the FDA and EC granted orphan drug designation for aHUS. Orphan drug status entitles Soliris to market exclusivity for a total of seven years in the United States and for ten years in the European Union and Japan. However, if a competitive product that is the same as or similar to Soliris, as defined under the applicable regulations, is shown to be clinically superior to Soliris in the treatment of PNH or aHUS, or if a competitive product is different from Soliris, as defined under the applicable regulations, the orphan drug exclusivity we have obtained may not block the approval of such competitive product. Several biotechnology and pharmaceutical companies throughout the world have programs to develop complement inhibitor therapies or have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. Pharmaceutical companies have publicly announced intentions to establish or develop rare disease programs and these companies may introduce products that are competitive with ours. These and other companies, many of which have significantly greater resources than us, may develop, manufacture, and market better or cheaper drugs than Soliris or our product candidates. They may establish themselves in the marketplace before us for Soliris for other indications or for any of our other product candidates. Other pharmaceutical companies also compete with us to attract academic research institutions as drug development partners, including for licensing these institutions' proprietary technology. If our competitors successfully enter into such arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may not be able to find equivalent opportunities elsewhere.

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

We are highly dependent upon the efforts of our executive officers, and other key personnel in our commercial and technical organizations. There is intense competition in the biopharmaceutical industry for qualified commercial and technical personnel. Our business is specialized and global and we must attract and retain highly qualified individuals across many geographies. We may not be able to continue to attract and retain the qualified personnel necessary for developing, manufacturing and commercializing our products and product candidates.

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 our manufacturing operations at ARIMF and in Ireland, the handling and disposal of non-hazardous and hazardous wastes, such as medical and biological wastes, and emissions and discharges into the environment, such as 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 are seeking to expand our business through acquisitions and we may not realize the benefits of such acquisitions.

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

- substantial cash expenditures;
- potentially dilutive issuance of equity securities;
- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- difficulties in assimilating the operations of the acquired companies;
- diverting our management's attention away from other business concerns;
- risks of entering markets in which we have limited or no direct experience;
- the potential loss of our key employees or key employees of the acquired companies; and
- failure of any acquired businesses or products or in-licensed products to achieve the scientific, medical, commercial or other results anticipated.

A substantial portion of our strategic efforts are focused on opportunities for rare disorders and life-saving therapies. The availability of such development opportunities is limited. We may not be able to identify opportunities that are acceptable to us or our shareholders. Several companies have publicly announced intentions to establish or develop rare disease programs. For these and other reasons, we may not be able to acquire the rights to additional product candidates and approved products on terms that we or our shareholders find acceptable, or at all. The development or expansion of our business, any acquired business or any acquired or in-licensed products may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our capital stock, which could dilute current stockholders' ownership interest in our company, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest in our company upon conversion.

Even if we are able to successfully identify and complete acquisitions and other strategic transactions, we may not be able to integrate them or take full advantage of them. An acquisition or other strategic transaction may not result in short-term or long-term benefits to us. We may also incorrectly judge the value or worth of an acquired company or business or an acquired or in-licensed product.

To effectively manage our current and future potential growth, we must continue to effectively grow and manage our global employee base, and enhance our operational and financial processes. Supporting our growth strategy will require significant capital expenditures and management resources, including investments in research and development, sales and marketing, manufacturing and other areas of our operations. If we do not successfully manage our current growth and do not successfully execute our strategy, then our business and financial results may be adversely affected and we may incur asset impairment or restructuring charges.

Our business could be affected by litigation, government investigations and enforcement actions.

We operate in many jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, Qui Tam, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment, and other claims and legal proceedings which may arise from conducting our business. Legal proceedings, government investigations and enforcement actions can be expensive and time consuming. An adverse outcome could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations.

The intended efficiency of our corporate structure depends on the application of the tax laws and regulations in the countries where we operate and we may have exposure to additional tax liabilities or our effective tax rate could change, which could have a material impact on our results of operations and financial position.

As a company with international operations, we are subject to income taxes, as well as non-income based taxes, in both the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities. Although we believe our estimates are reasonable, the ultimate outcome with respect to the taxes we owe may differ from the amounts recorded in our financial statements. If the Internal Revenue Service, or other taxing authority, disagrees with the positions we take, we could have additional tax liability, and this could have a material impact on our results of operations and financial position. Our effective tax rate could be adversely affected by changes in the mix of earnings in countries with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in tax laws and regulations, changes in interpretations of tax laws, including pending tax law changes, changes in our manufacturing activities and changes in our future levels of research and development spending.

We have designed our corporate structure, the manner in which we develop and use our intellectual property, and our intercompany transactions between our affiliates in a way that is intended to enhance our operational and financial efficiency and increase our overall profitability. The application of the tax laws and regulations of various countries in which we operate and to our global operations is subject to interpretation. We also must operate our business in a manner consistent with our corporate structure to realize such efficiencies. The tax authorities of the countries in which we operate may challenge our methodologies for valuing developed technology or for transfer pricing. If tax authorities determine that the manner in which we operate results in our business not achieving the intended tax consequences, our effective tax rate could increase and harm our financial position and results of operations.

In addition, the United States government and other governments are considering and may adopt tax reform measures that significantly increase our worldwide tax liabilities. The U.S. Congress, the Organization for Economic Co-operation and Development and other government agencies in countries where we and our affiliates operate have focused on issues related to the taxation of multinational corporation, including , for example, in the area of "base erosion and profit shifting," where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. We established operations in Ireland in 2013 and recently, Ireland tax authorities announced changes to the treatment of non-resident Irish entities. The changes are not expected to impact existing non-resident Irish entities, such as ours, until after December 31, 2020. These changes, and other prospective changes in the United States and other countries in which we and our affiliates operate could increase our effective tax rate, and harm our financial position and results of operations.

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

Since 2007, we have significantly expanded our operations and expect to continue to do so in the future. Our operations in foreign countries subject us to the following additional risks:

- fluctuations in currency exchange rates;
- political or economic determinations that adversely impact pricing or reimbursement policies;
- economic problems or political instability that disrupt health care payment systems;
- difficulties or inability to obtain financing in markets;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- difficulties enforcing contractual and intellectual property rights;
- changes in laws, regulations or enforcement practices with respect to our business, including without limitation laws relating to reimbursement, competition, pricing and sales and marketing of our products;
- trade restrictions and restrictions on direct investments by foreign entities;
- compliance with tax, employment and labor laws;
- costs and difficulties in recruiting and retaining qualified managers and employees to manage and operate the business in local jurisdictions;
- costs and difficulties in managing and monitoring international operations; and
- longer payment cycles.

Our business and marketing methods are also subject to regulation by the governments of the countries in which we operate. The FCPA and similar anti-bribery laws in other countries prohibit companies and their representatives from offering,

promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business. We have policies and procedures designed to help ensure that we and our representatives, including our employees, comply with such laws, however we cannot guarantee that these policies and procedures will protect us against liability under the FCPA or other anti-bribery laws for actions taken by our representatives. Failure to comply with the laws and regulations of the countries in which we operate could materially harm our business.

We conduct, or anticipate that we will conduct, a substantial portion of our business in currencies other than the U.S. dollar and we are exposed to fluctuations in foreign currency exchange rates in the normal course of our business. See also Risk Factor "Currency fluctuations and changes in exchange rates could adversely affect our revenue growth, increase our costs and negatively affect our profitability."

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

Sales of Soliris and other products are or will be dependent, in large part, on reimbursement from government health administration organizations and private and governmental third-party payers, and also co-payments from individual patients in certain situations. As a result of adverse credit and financial market conditions, and the overall financial climate, these governmental organizations and payers, and/or individuals, may reduce or delay initiation of treatment, may be unable to satisfy their reimbursement obligations, may delay payment or may seek to reduce reimbursement for our products, including Soliris, in the future, which could have a material adverse effect on our business and results of operations. Soliris is approved for the treatment of patients with PNH and aHUS in the United States, the European Union and Japan and for the treatment of PNH in several other territories. If Soliris is approved in additional territories for PNH, aHUS, or for additional indications that are under clinical development, the reimbursement risks and uncertainties associated with adverse credit and financial market conditions may be exacerbated due to increases in the number of patients receiving Soliris that require reimbursement. Payment defaults by a government payer could require us to expense previously recorded revenue as uncollectible, and might cause us to end or restrict sales to patients in that country. Further, the risk of payment default by a government payer could require us to revise our revenue recognition policies in regard to that payer, causing revenue to be recorded only on a cash basis, and we may be required to end or restrict sales to patients in that country.

We continue to monitor economic conditions, including volatility associated with U.S. and international economies, associated impacts on the financial markets and our business, and the sovereign debt issues in Europe.

We may not be able to successfully mitigate or prevent our exposures to volatile economic and financial conditions and our failure to operate successfully or adapt to changes in these conditions could cause our sales and operations to be limited or disrupted or otherwise harm our business.

Additionally, we rely upon third-parties for certain parts of our business, including Lonza, licensees, wholesale distributors of Soliris, contract clinical trial providers, contract manufacturers and other third-party suppliers and financial institutions. Because of the volatility in the financial markets, there may be a disruption or delay in the performance or satisfaction of commitments to us by these third parties which could have a material adverse effect on our business and results of operations.

Currency fluctuations and changes in exchange rates could adversely affect our revenue growth, increase our costs and negatively affect our profitability.

We conduct, or anticipate that we will conduct, a substantial portion of our business in currencies other than the U.S. dollar. We are exposed to fluctuations in foreign currency exchange rates in the normal course of our business and we expect these exposures to increase during 2015 due to the strengthening of the U.S. dollar. The exposures result from portions of our revenues, as well as the related receivables, and expenses that are denominated in currencies other than the U.S. dollar, including the Euro, Japanese Yen, British Pound, Swiss Franc, and Russian Ruble. We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. We enter into foreign exchange forward contracts, with durations of up to 60 months, to hedge exposures resulting from portions of our forecasted revenues, including intercompany revenues, that are denominated in currencies other than the U.S. dollar. The purpose of the hedges of revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. Further, we enter into foreign exchange forward contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results. Gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. While we attempt to hedge certain currency risks, currency fluctuations between the U.S. dollar and the currencies in which we do business have, in the past, caused foreign currency transaction gains and losses and have also impacted the amounts of revenues and expenses calculated in U.S. dollars and will likely do so in the future. Likewise, past currency fluctuations have at times resulted in foreign currency transaction gains, and there can be no assurance that these gains can be reproduced.

Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy and coverage and reimbursement of drug products may impact our business in ways that we cannot currently predict and these changes could adversely affect our business and financial condition.

Governments in countries where we operate have adopted or have shown significant interest in pursuing legislative initiatives to reduce costs of health care. Any such government-adopted health care measures could adversely impact the pricing of Soliris or the amount of coverage and reimbursement available for Soliris from governmental agencies or other third-party payers.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the PPACA), was adopted in the United States in March 2010. This law substantially changes the way healthcare is financed by both governmental and private insurers in the U.S., and significantly impacts the pharmaceutical industry. PPACA contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under health insurance exchanges, expansion of the 340B program, expansion of state Medicaid programs, and fraud and abuse enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

PPACA contains several provisions that have or could potentially impact our business. PPACA made significant changes to the Medicaid Drug Rebate Program. Effective March 23, 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. With regard to the amount of the rebates owed, PPACA increased the minimum Medicaid rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, PPACA and subsequent legislation changed the definition of average manufacturer price. Finally, PPACA requires pharmaceutical manufacturers of branded prescription drugs, such as Soliris, to pay a branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2014 (and set to increase in ensuing years), based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Sales of "orphan drugs"-those designated under section 526 of the FDCA, like Soliris-are excluded from this fee as long as no non-orphan indications have been approved for the orphan drug.

In 2012, CMS issued proposed regulations to implement the changes to the Medicaid Drug Rebate Program under PPACA but has not yet issued final regulations. CMS is currently expected to release the final regulations in 2015. Moreover, in the future, Congress could enact legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate Program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate Program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Additional provisions of PPACA, some of which became effective in 2011, may negatively affect our revenues in the future. For example, as part of PPACA's provisions closing a coverage gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole.

PPACA also expanded the Public Health Service's 340B drug pricing discount program. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. PPACA expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by PPACA. PPACA exempts "orphan drugs"-those designated under section 526 of the FDCA, such as Soliris-from the ceiling price requirements for these newly-eligible entities. On July 21, 2014, the Health Resources and Services Administration, or HRSA, which administers the 340B program, issued an interpretive rule to implement the orphan drug exception which interprets the orphan drug exception narrowly. It exempts orphan drugs from the ceiling price requirements for the newly-eligible entities only when the orphan drug is used for its orphan indication. The newly-eligible entities are entitled to purchase orphan drugs at the ceiling price when the orphan drug is not used for its orphan indication. A manufacturer trade group has filed a lawsuit challenging the interpretive rule as inconsistent with the statutory language. That challenge remains ongoing. The uncertainty regarding how the statutory orphan drug exception will be applied will increase the complexity of compliance, will make compliance more time-consuming, and could negatively impact our results of operations. If HRSA's narrow interpretation of the scope of the orphan drug exemption prevails, it could potentially negatively

impact the price we are paid for Soliris by certain entities for some uses and increase the complexity of compliance with the 340B program.

In addition, our industry may be affected by broader legislation addressing federal spending, including, for example, a sequester required by the Budget Control Act of 2011, Pub. L. No. 112-25, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240, that took effect in April 2013 and was expended by the Bipartisan Budget Act of 2013, Pub. L. No. 113-67. Under the sequestration, Medicare payments for all items and services, including drugs and biologicals, have been reduced by 2%. This 2% reduction in Medicare payments affects all Parts of the Medicare program and could impact sales of Soliris. As another example, the governments of Germany and Spain each approved increases to mandatory rebates on the sales of pharmaceutical products.

We expect that the implementation of current laws and policies, the amendment of those laws and policies in the future, as well as the adoption of new laws and policies, could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales or successfully commercialize our product candidates, or could limit or eliminate our future spending on development projects. In many cases, these government initiatives, even if enacted into law, are subject to future rulemaking by regulatory agencies. Although we have evaluated these government initiatives and the impact on our business, we cannot know with certainty whether any such law, rule or regulation will adversely affect coverage and reimbursement of Soliris, or to what extent, until such laws, rules and regulations are promulgated, implemented and enforced. The announcement or adoption of regulatory or legislative proposals could delay or prevent our entry into new markets, affect our reimbursement or sales in the markets where we are already selling Soliris and materially harm our business, financial condition and results of operations.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program, Medicare, or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Medicare is a U.S. federal government insurance program that covers individuals aged 65 years or older, certain younger individuals with certain disabilities, and individuals with End-Stage Renal Disease. The primary Medicare programs that may affect reimbursement for Soliris are Medicare Part B, which covers physician services and outpatient care, and Medicare Part D, which provides a voluntary outpatient prescription drug benefit. Medicare Part B provides limited coverage of certain outpatient drugs and biologicals that are reasonable and necessary for diagnosis or treatment of an illness or injury. Under Part B, reimbursement is based on a fixed percentage of the applicable product's average sales price (ASP). Manufacturers calculate ASP based on a statutory formula and must report ASP information to the Centers for Medicare and Medicaid Services (CMS), the federal agency that administers Medicare and the Medicaid Drug Rebate Program, on a quarterly basis.

Medicaid is a government health insurance program for low-income children, families, pregnant women, and people with disabilities. It is jointly funded by the federal and state governments, and it is administered by individual states within parameters established by the federal government. Coverage and reimbursement for drugs and biologicals thus varies by state. Drugs and biologicals may be covered under the medical or pharmacy benefit. State Medicaid programs may impose utilization management controls, such as prior authorization, step therapy, or quantity limits on drugs and biologicals. Medicaid also includes the Medicaid Drug Rebate Program, under which we are required to pay a rebate to each state Medicaid program for quantities of Soliris that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for Soliris under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS. These data include the average manufacturer price and the best price for Soliris.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer price and best price for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the

Medicaid Drug Rebate Program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug discount program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price, ASP, or best price information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. If we are found to have made a misrepresentation in the reporting of our average sales price, the Medicare statute provides for civil monetary penalties of up to $10,000 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly average manufacturer price, ASP, and best price data on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

In September 2010, CMS and the Office of Inspector General (OIG) indicated that they intend to pursue more aggressively those companies who fail to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

Federal law requires that for a company to be eligible to have its products paid for with federal funds under the Medicaid program as well as to be purchased by certain federal agencies and grantees, it also must participate in the Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. To participate, we are required to enter into an FSS contract with the VA, under which we must make our innovator "covered drugs" available to the "Big Four" federal agencies - the VA, the Department of Defense, or DoD, the Public Health Service, and the Coast Guard - at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992, or VHCA. The FCP is based on a weighted average non-federal average manufacturer price, or Non-FAMP, which manufacturers are required to report on a quarterly and annual basis to the VA. If a company misstates Non-FAMPs or FCPs it must restate these figures. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of $100,000 for each item of false information.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an agreed "tracking customer." Further, in addition to the "Big Four" agencies, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies "negotiated pricing" for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor’s commercial "most favored customer" pricing. We offer dual pricing on our FSS contract.

In addition, pursuant to regulations issued by the DoD TRICARE Management Activity, now the Defense Health Agency, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, each of our covered drugs is listed on a Section 703 Agreement under which we have agreed to pay rebates on covered drug prescriptions dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. Companies are required to list their innovator products on Section 703 Agreements in order for those products to be eligible for DoD formulary inclusion. The formula for determining the rebate is established in the regulations and our Section 703 Agreement and is based on the difference between the annual Non-FAMP and the FCP (as described above, these price points are required to be calculated by us under the VHCA).

If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., some of the laws that may

apply include state security breach notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure and transmission of personal information. Each of these laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions. Accordingly, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA.

In addition, the receipt of personal health information in connection with our clinical trial initiatives is subject to state and federal human subject protection laws. These laws could create liability for us if one of our research collaborators were to use or disclose research subject information without consent and in violation of applicable laws.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. European Union member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from different EU member states may interpret the EU Data Protection Directive and national laws differently, which adds to the complexity of processing personal data in the EU, and guidance on implementation and compliance practices are often updated or otherwise revised. The EU Data Protection Directive prohibits the transfer of personal data to countries outside of the EU member states that are not considered by the European Commission to provide an adequate level of data protection. These countries include the United States. Any failure to comply with the rules arising from the EU Data Protection Directive and related national laws of European Union member states could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results

A proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, is currently under consideration. The EU Data Protection Regulation is expected to introduce new data protection requirements in the EU and substantial fines for breaches of the data protection rules. If the draft EU Data Protection Regulation is adopted in its current form, it may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules.

Security breaches, cyber-attacks, or other disruptions could expose us to liability and affect our business and reputation.

We collect, store, and transmit sensitive information including intellectual property, proprietary business information and personal information in connection with business operations. We have implemented information security measures to protect patients' personal information against the risk of inappropriate and unauthorized external use and disclosure. However, despite these measures, and due to the ever changing information cyber-threat landscape, we may be subject to data breaches through cyber-attacks perpetrated by individuals that attempt to compromise our security controls. If our systems were to fail or be disrupted for an extended period of time we could lose product sales and our revenue and reputation would suffer. In the event our systems were to be breached by an unauthorized third-party, they could potentially access confidential personal information, which could cause us to suffer reputational damage and loss of customer confidence. Such incidents would result in notification obligations to affected individuals and government agencies, legal claims or proceedings, and liability under federal and state laws that protect the privacy and security of personal information. Any one of these events could cause our business to be materially harmed and our results of operations would be adversely impacted.

Risks Related to Our Common Stock

If the trading price of our common stock continues to fluctuate in a wide range, our stockholders will have 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, failure to resolve, delays in resolving or other developments with respect to the issues raised in the Warning Letter, and market conditions for biopharmaceutical stocks in general could have a significant impact on the future trading prices of our common stock. In particular, the trading price of the common stock of many biopharmaceutical companies, including ours, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of the companies whose stocks were affected. This is due to several factors, including general market conditions, sales of Soliris, the announcement of the results of our clinical trials or product development and the results of our efforts to obtain regulatory approval for our products. While we cannot predict our future performance, if our stock price continues to fluctuate in a wide range, an investment in our common stock may result in considerable uncertainty for an investor.

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

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

Our corporate charter and by-law provisions and stockholder rights plan may discourage certain types of transactions involving an actual or potential change of control that might be beneficial to us or our stockholders. Our bylaws provide that special meetings of our stockholders may be called only by the Chairman of the Board, the President, the Secretary, or a majority of the Board of Directors, or upon the written request of stockholders who together own of record 50% of the outstanding stock of all classes entitled to vote at such meeting. Our bylaws also specify that the authorized number of directors may be changed only by resolution of the board of directors. Our charter 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 charter, our board of directors has the authority, without further action by stockholders, to designate up to 5,000 shares of preferred stock in one or more series. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any class or series of preferred stock that may be issued in the future.

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

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

None.

Item 2. ***PROPERTIES.***

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

Location	Operations Conducted	Approximate Square Feet	Lease Expiration Dates
Cheshire, Connecticut	Corporate headquarters and executive, sales, research and development offices	254,000	2016 and 2020
Smithfield, Rhode Island	Commercial, research and development manufacturing	67,000	N/A
Lausanne, Switzerland	Regional executive and sales offices	48,000	2019
Dublin, Ireland	Global supply chain and distribution	15,800	2023

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

In November 2012, we entered into a new lease agreement for approximately 328,000 square feet of office and laboratory space to be constructed in New Haven, Connecticut. We amended the lease in July 2013 to expand the building and increase the leased space to a total of approximately 408,000 square feet. The construction of the facility began in June 2013 and is expected to be completed in 2015. Upon completion of the new facility, we will relocate our headquarters and Cheshire operations to New Haven.

In April 2014, we purchased a fill/finish facility in Athlone, Ireland. Following refurbishment of the facility, and after successful completion of the appropriate validation processes and regulatory approvals, the facility will become our first company-owned fill/finish and packaging facility for Soliris and other clinical and commercial products. Our plans for future expansion in Ireland also include the construction of office and laboratory facilities on property in Dublin, Ireland, which we purchased in April 2014.

In January 2015, we entered into a new lease agreement for approximately 44,000 square feet of office space in Zurich, Switzerland to support the relocation of the European headquarters. The term of the new lease is estimated to commence in the second quarter of 2015 and will expire 10 years later, with a minimum renewal option of 5 years and a maximum renewal option of 10 years.

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

From time to time, we are party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse impact on our business or financial condition.

Item 4. ***MINE SAFETY DISCLOSURES.***

Not applicable.

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, 2013.

Fiscal 2013	High	Low
First Quarter		
(January 1, 2013 to March 31, 2013)	$ 103.20	$ 81.82
Second Quarter		
(April 1, 2013 to June 30, 2013)	$ 108.13	$ 87.01
Third Quarter		
(July 1, 2013 to September 30, 2013)	$ 125.65	$ 93.34
Fourth Quarter		
(October 1, 2013 to December 31, 2013)	$ 133.75	$ 100.89
Fiscal 2014		
First Quarter		
(January 1, 2014 to March 31, 2014)	$ 185.43	$ 126.76
Second Quarter		
(April 1, 2014 to June 30, 2014)	$ 172.50	$ 136.37
Third Quarter		
(July 1, 2014 to September 30, 2014)	$ 173.70	$ 154.38
Fourth Quarter		
(October 1, 2014 to December 31, 2014)	$ 203.30	$ 155.01

As of January 28, 2015, we had approximately 57 stockholders of record of our common stock and an estimated 146,830 beneficial owners. The closing sale price of our common stock on January 28, 2015 was $177.78 per share.

DIVIDEND POLICY

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

ISSUER PURCHASES OF EQUITY SECURITIES *(amounts in thousands except per share amounts)*

The following table summarizes our common stock repurchase activity during the fourth quarter of 2014:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Dollar Value of Shares that May Yet Be Purchased Under the Programs
October 1-31, 2014	100	169.58	100	22,273
November 1-30, 2014	—	—	—	22,273
December 1-31, 2014	14	178.88	14	519,712
Total	114	170.72	114	

On November 8, 2012, we announced that our Board of Directors authorized the repurchase of up to $400,000 of our common stock. On December 15, 2014 we announced that our Board of Directors authorized the repurchase of up to an additional $500,000 of our common stock. The repurchase program does not have an expiration date. As of December 31, 2014, the maximum dollar value of shares remaining for purchase under the program was $519,712.

EQUITY COMPENSATION PLAN INFORMATION *(amounts in thousands except per share amounts)*

Plan Category	Number of shares of common stock to be issued upon exercise of outstanding options (2)		Weighted-average exercise price of outstanding options	Weighted-average term to expiration of options outstanding	Number of shares of common stock remaining available for future issuance under equity compensation plans
Equity compensation plans approved by stockholders (1)	6,420	$	85.65	6.98	12,043
Equity compensation plans not approved by stockholders	—	$	—	—	—

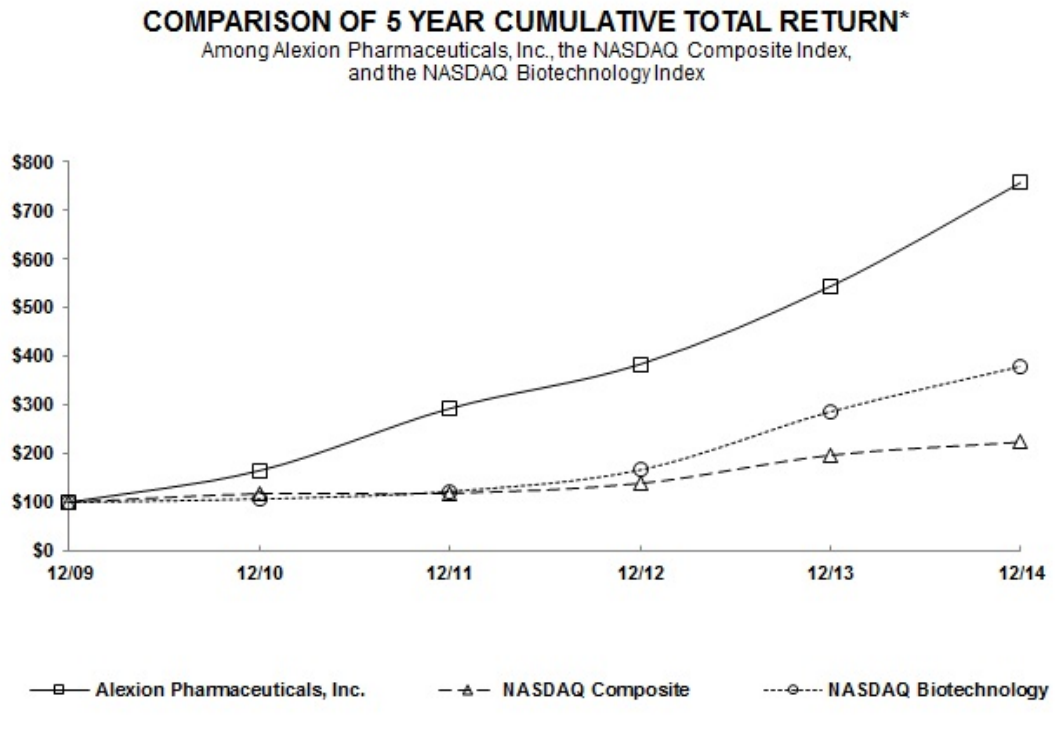
(1) Reflects number of shares of common stock to be issued upon exercise of outstanding options under all our equity compensation plans, including our Amended and Restated 2004 Incentive Plan. All 12,043 shares of common stock remaining available for future issuance are available under the Amended and Restated 2004 Incentive Plan.

(2) Does not include 1,808 restricted shares outstanding that were issued under the Amended and Restated 2004 Incentive Plan.

The outstanding options and restricted shares are not transferable for consideration and do not have dividend equivalent rights attached.

THE COMPANY'S STOCK PERFORMANCE

The following graph compares cumulative total return of the Company's Common Stock with the cumulative total return of (i) the NASDAQ Stock Market-United States, and (ii) the NASDAQ Biotechnology Index. The graph assumes (a) $100 was invested on December 31, 2009 in each of the Company's Common Stock, the stocks comprising the NASDAQ Stock Market-United States and the stocks comprising the NASDAQ Biotechnology Index, and (b) the reinvestment of dividends. The comparisons shown in the graph are based on historical data and the stock price performance shown in the graph is not necessarily indicative of, or intended to forecast, future performance of our stock.



CUMULATIVE TOTAL RETURN

	12/09	12/10	12/11	12/12	12/13	12/14
Alexion Pharmaceuticals, Inc.	100.00	164.99	292.91	384.02	544.38	758.01
NASDAQ Composite	100.00	117.61	118.70	139.00	196.83	223.74
NASDAQ Biotechnology	100.00	106.73	122.40	166.72	286.55	379.71

Item 6. ***SELECTED FINANCIAL DATA.***

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

(amounts in thousands, except per share amounts)

Consolidated Statements of Operations Data:					
	Year Ended December 31,				
	2014	**2013**	**2012**	**2011**	**2010**
Net product sales	$ 2,233,733	$ 1,551,346	$ 1,134,114	$ 783,431	$ 540,957
Cost of sales:					
Cost of sales	173,862	168,375	126,214	93,140	64,437
Change in contingent liability from intellectual property settlements	—	9,181	(53,377)	—	—
Total cost of sales	173,862	177,556	72,837	93,140	64,437
Operating expenses:					
Research and development	513,782	317,093	222,732	137,421	98,394
Selling, general and administrative	630,209	489,720	384,678	308,176	226,766
Acquisition-related costs	20,295	5,029	22,812	13,486	722
Impairment of intangible assets	11,514	33,521	26,300	—	—
Restructuring expenses	15,365	—	—	—	—
Amortization of purchased intangible assets	—	417	417	382	—
Total operating expenses	1,191,165	845,780	656,939	459,465	325,882
Operating income	868,706	528,010	404,338	230,826	150,638
Other income (expense)	3,401	(1,741)	(6,772)	(1,158)	(1,627)
Income before income taxes	872,107	526,269	397,566	229,668	149,011
Income tax provision	215,195	273,374	142,744	54,353	51,981
Net income	$ 656,912	$ 252,895	$ 254,822	$ 175,315	$ 97,030
Earnings per common share					
Basic	$ 3.32	$ 1.29	$ 1.34	$ 0.96	$ 0.54
Diluted	$ 3.26	$ 1.27	$ 1.28	$ 0.91	$ 0.52
Shares used in computing earnings per common share					
Basic	198,103	195,532	190,461	183,220	178,542
Diluted	201,623	199,712	198,501	191,806	186,074

Consolidated Balance Sheet Data:					
	As of December 31,				
	2014	**2013**	**2012**	**2011**	**2010**
Cash, cash equivalents and marketable securities	$ 1,961,566	$ 1,514,851	$ 989,501	$ 540,865	$ 361,605
Total assets	4,201,962	3,317,696	2,613,560	1,394,751	1,012,037
Long-term debt and convertible notes (current and noncurrent)	57,500	113,000	149,000	—	3,718
Contingent consideration (current and noncurrent)	162,971	142,676	141,670	18,120	—
Facility lease obligation	107,099	32,230	—	—	—
Total stockholders' equity	3,302,018	2,382,079	1,970,850	1,134,492	859,736

Item 7. ***MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.*** *(amounts in thousands, except percentages and 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 Annual Report on Form 10-K. The risks and uncertainties can cause actual results to differ significantly from those forecast 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 Annual Report on Form 10-K.

Overview

We are a biopharmaceutical company focused on serving patients with severe and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Our marketed product Soliris is the first and only therapeutic approved for patients with either of two severe and ultra-rare disorders resulting from chronic uncontrolled activation of the complement component of the immune system: paroxysmal nocturnal hemoglobinuria (PNH), a life-threatening and ultra-rare genetic blood disorder, and atypical hemolytic uremic syndrome (aHUS), a life-threatening and ultra-rare genetic disease. We are also evaluating additional potential indications for Soliris in severe and devastating diseases in which we believe that uncontrolled complement activation is the underlying mechanism, and we are progressing in various stages of development with additional biotechnology product candidates as treatments for patients with severe and life-threatening ultra-rare disorders. We were incorporated in 1992 and began commercial sale of Soliris in 2007.

Soliris is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation associated with chronic disorders in several therapeutic areas, including hematology, nephrology, transplant rejection and neurology. Soliris is a humanized monoclonal antibody that effectively blocks terminal complement activity at the doses currently prescribed. The initial indication for which we received approval for Soliris is PNH. PNH is a debilitating and life-threatening, ultra-rare genetic blood disorder defined by chronic uncontrolled complement activation leading to the destruction of red blood cells (hemolysis). The chronic hemolysis in patients with PNH may be associated with life-threatening thromboses, recurrent pain, kidney disease, disabling fatigue, impaired quality of life, severe anemia, pulmonary hypertension, shortness of breath and intermittent episodes of dark-colored urine (hemoglobinuria).

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

In September and November 2011, Soliris was approved by the FDA and EC, respectively, for the treatment of pediatric and adult patients with aHUS in the United States and Europe. In September 2013, the MHLW approved Soliris for the treatment of pediatric and adult patients with aHUS in Japan. aHUS is a severe and life-threatening genetic ultra-rare disease characterized by chronic uncontrolled complement activation and thrombotic microangiopathy (TMA), the formation of blood clots in small blood vessels throughout the body, causing a reduction in platelet count (thrombocytopenia) and life-threatening damage to the kidney, brain, heart and other vital organs. In addition, the FDA and EC have granted Soliris orphan drug designation for the treatment of patients with aHUS.

In addition to PNH and aHUS, we believe that Soliris may be useful in the treatment of a variety of other serious diseases and conditions resulting from uncontrolled complement activation. We are currently evaluating additional potential indications for Soliris in severe and ultra-rare diseases in which uncontrolled complement activation is the underlying mechanism. We are also progressing in various stages of development with additional biotechnology product candidates that target severe and life-threatening ultra-rare diseases for which we believe current treatments are either non-existent or inadequate. These therapeutics focus on metabolic and inflammatory diseases. We are also involved in the research associated with the identification and development of new therapeutics pursuant to ongoing license and collaboration agreements.

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" of the Consolidated Financial Statements included in

this Annual Report on Form 10-K. Under accounting principles generally accepted in the United States, we are required to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingent assets and liabilities in our financial statements. Actual results could differ from those estimates.

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

- Revenue recognition;
- Contingent liabilities;
- Inventories;
- Share-based compensation;
- Valuation of goodwill, acquired intangible assets and in-process research and development (IPR&D);
- Valuation of contingent consideration; and
- Income taxes.

Revenue Recognition

Net Product Sales

Our principal source of revenue is 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. Depending on these criteria, revenue is usually recorded upon receipt of the product by the end customer, which is typically a hospital, physician's office, private or government pharmacy or other health care facility. On a regular basis, we review revenue arrangements, such as distributor relationships, to determine whether changes in these criteria have an impact on revenue recognition. Amounts collected from customers and remitted to governmental authorities, such as value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in our consolidated statements of operations and do not impact net product sales.

Our customers are primarily comprised of distributors, pharmacies, hospitals, hospital buying groups, and other health care providers. In some cases, we may also sell Soliris to governments and government agencies.

Because of factors such as the pricing of Soliris, the limited number of patients, the short period from product sale to patient infusion and the lack of contractual return rights, Soliris customers often carry limited inventory. We also monitor inventory within our sales channels to determine whether deferrals are appropriate based on factors such as inventory levels compared to demand, contractual terms and financial strength of distributors. In certain countries, exact quantities of inventory in the channel are not precisely known, requiring us to estimate these amounts. If actual amounts of inventory differ from these estimates, these adjustments could have an impact in the period in which these estimates change.

In addition to sales in countries where Soliris is commercially available, we have also recorded revenue on sales for patients receiving Soliris treatment through named-patient programs. The relevant authorities or institutions in those countries have agreed to reimburse for product sold on a named-patient basis where Soliris has not received final approval for commercial sale.

We record estimated rebates payable under governmental programs, including Medicaid in the United States and other programs outside the United States, as a reduction of revenue at the time of product sale. Our calculations related to these rebate accruals require analysis of historical claim patterns and estimates of customer mix to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period and record any necessary adjustments, which may have an impact on revenue in the period in which the adjustment is made. Generally, the length of time between product sale and the processing and reporting of the rebates is three to six months.

We have entered into volume-based arrangements with governments in certain countries in which reimbursement is limited to a contractual amount. Under this type of arrangement, amounts billed in excess of the contractual limitation are repaid to these governments as a rebate. We estimate incremental discounts resulting from these contractual limitations, based on estimated sales during the limitation period, and we apply the discount percentage to product shipments as a reduction of revenue. Our calculations related to these arrangements require estimation of sales during the limitation period, and adjustments in these estimates may have an impact in the period in which these estimates change.

We have provided balances and activity in the rebates payable account for the years ended December 31, 2014, 2013 and 2012 as follows:

	Rebates Payable
Balance at December 31, 2011	**$ 21,746**
Current provisions relating to sales in current year	80,131
Adjustments relating to prior years	(2,566)
Payments/credits relating to sales in current year	(22,634)
Payments/credits relating to sales in prior years	(14,343)
Balance at December 31, 2012	**$ 62,334**
Current provisions relating to sales in current year	149,247
Adjustments relating to prior years	(2,180)
Payments/credits relating to sales in current year	(29,574)
Payments/credits relating to sales in prior years	(55,530)
Balance at December 31, 2013	**$ 124,297**
Current provisions relating to sales in current year	62,478
Adjustments relating to prior years	(87,004)
Payments/credits relating to sales in current year	(33,922)
Payments/credits relating to sales in prior years	(29,022)
Balance at December 31, 2014	**$ 36,827**

In March 2014, we entered into an agreement with the French government which positively impacts prospective reimbursement of Soliris and also provides for reimbursement for shipments in years prior to January 1, 2014. As a result of this agreement, in the first quarter 2014, we reduced the rebate payable and recognized $87,830 of net product sales from Soliris in France relating to years prior to January 1, 2014. In addition, our current provisions relating to sales in the current year decreased by $86,769 during 2014 primarily due to this agreement.

In 2013 compared to 2012, current provisions relating to sales in the current year increased by $69,116 primarily due to estimated rebates payable in France during 2013. The increase in rebates payable in France of approximately $57,900 in 2013 was due to increased unit volumes and contractual reimbursement limitations. The remaining increase in current provisions related to increased unit volumes in the United States and Europe which were subject to rebates.

We record distribution and other fees paid to our customers as a reduction of revenue, unless we receive an identifiable and separate benefit for the consideration and we can reasonably estimate the fair value of the benefit received. If both conditions are met, we record the consideration paid to the customer as an operating expense. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

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

We evaluate the creditworthiness of customers on a regular basis. In certain European countries, sales by us are subject to payment terms that are statutorily determined. This is primarily the case in countries where the payer is government-owned or government-funded, which we consider to be creditworthy. The length of time from sale to receipt of payment in certain countries exceeds our credit terms. In countries in which collections from customers extend beyond normal payment terms, we seek to collect interest. We record interest on customer receivables as interest income when collected. For non-interest bearing receivables with an estimated payment beyond one year, we discount the accounts receivable to present value at the date of sale, with a corresponding adjustment to revenue. Subsequent adjustments for further declines in credit rating are recorded as bad debt expense as a component of selling, general and administrative expense. We also use judgments as to our ability to collect outstanding receivables and provide allowances for the portion of receivables if and when collection becomes doubtful, and we also assess on an ongoing basis whether collectibility is reasonably assured at the time of sale.

We continue to monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. For additional information related to our concentration of credit

risk associated with certain international accounts receivable balances, refer to the *"Financial Condition, Liquidity and Capital Resources"* section below.

Contingent liabilities

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

Inventories

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

We capitalize inventory produced for commercial sale, which may include costs incurred for certain products awaiting regulatory approval. We capitalize inventory produced in preparation of product launches sufficient to support estimated initial market demand. Capitalization of such inventory begins when we have (i) obtained positive results in clinical trials that we believe are necessary to support regulatory approval, (ii) concluded that uncertainties regarding regulatory approval have been sufficiently reduced, and (iii) determined that the inventory has probable future economic benefit. In evaluating whether these conditions have been met, we consider clinical trial results for the underlying product candidate, results from meetings with regulatory authorities, and the compilation of the regulatory application. If we are aware of any material risks or contingencies outside of the standard regulatory review and approval process, or if there are any specific negative issues identified relating to the safety, efficacy, manufacturing, marketing or labeling of the product that would have a significant negative impact on its future economic benefits, the related inventory would not be capitalized.

Products that have been approved by the FDA or other regulatory authorities, such as Soliris, are also used in clinical programs to assess the safety and efficacy of the products for usage in diseases that have not been approved by the FDA or other regulatory authorities. The form of Soliris utilized for both commercial and clinical programs is identical and, as a result, the inventory has an "alternative future use" as defined in authoritative guidance. Raw materials and purchased drug product associated with clinical development programs are included in inventory and charged to research and development expense when the product enters the research and development process and no longer can be used for commercial purposes and, therefore, does not have an "alternative future use".

For products which are under development and have not yet been approved by regulatory authorities, purchased drug product is charged to research and development expense when the inventory passes quality inspection and ownership transfers to us. Nonrefundable advance payments for research and development activities, including production of purchased drug product, are deferred and capitalized until the goods are delivered. We also recognize expense for raw materials purchased when the raw materials pass quality inspection, and we have an obligation to pay for the materials.

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 no longer meet quality specifications or may expire, which would require adjustments to our inventory values. We also apply judgment related to the results of quality tests that we perform throughout the production process, as well as our understanding of regulatory guidelines, to determine if it is probable that inventory will be saleable. These quality tests are performed throughout the pre- and post-production process, and we continually gather information regarding product quality for periods after the manufacturing date. Soliris currently has a maximum estimated life of 48 months and, based on our sales forecasts, we expect to realize the carrying value of the Soliris inventory. In the future, reduced demand, quality issues or excess supply beyond those anticipated by management may result in a material adjustment to inventory levels, which would be recorded as an increase to cost of sales.

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. For inventories that are capitalized in preparation of product launch, we also consider the expected approval date in assessing realizability. 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.

Share-Based Compensation

We have one share-based compensation plan known as the Amended and Restated 2004 Incentive Plan. Under this plan, restricted stock, restricted stock units, stock options and other stock-related awards may be granted to our directors, officers, employees and consultants or advisors of the Company or any subsidiary. To date, share-based compensation issued under the plan consists of incentive and non-qualified stock options, restricted stock and restricted stock units, including restricted stock units with market and non-market performance conditions. Stock-related awards are also outstanding under other share-based compensation plans, but we have not granted awards under these plans since 2004.

Compensation expense for our share-based awards is recognized based on the estimated fair value of the awards on the grant date. Compensation expense reflects an estimate of the number of awards expected to vest and is primarily recognized on a straight-line basis over the requisite service period of the individual grants, which typically equals the vesting period. Compensation expense for awards with performance conditions is recognized using the graded-vesting method.

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 and the reduction in the expense from expected forfeitures. We currently use historical exercise and cancellation patterns as our best estimate of future estimated life. Actual volatility and lives of options may be significantly different from our estimates.

For our non-market performance-based awards, we estimate the anticipated achievement of the performance targets, including forecasting the achievement of future financial targets. These estimates are revised periodically based on the probability of achieving the performance targets and adjustments are made throughout the performance period as necessary. We use payout simulation models to estimate the grant date fair value of market performance-based awards. The payout simulation models assume volatility of our common stock and the common stock of a comparator group of companies, as well as correlations of returns of the price of our common stock and the common stock prices of the comparator group.

If factors change or we employ different assumptions to value our stock-based awards, the share-based compensation expense that we record in future periods may differ materially from our prior recorded amounts.

Valuation of Goodwill, Acquired Intangible Assets and In-Process Research and Development (IPR&D)

We have recorded goodwill, acquired intangible assets and IPR&D related to our business combinations. When identifiable intangible assets, including IPR&D, are acquired, we determine the fair values of the assets as of the acquisition date. Discounted cash flow models are typically used in these valuations if quoted market prices are not available, and the models require the use of significant estimates and assumptions including but not limited to:

- timing and costs to complete the in-process projects;
- timing and probability of success of clinical events or regulatory approvals;
- estimated future cash flows from product sales resulting from completed products and in-process projects; and
- discount rates.

We may also utilize a cost approach, which estimates the costs that would be incurred to replace the assets being purchased. Significant inputs into the cost approach include estimated rates of return on historical costs that a market participant would expect to pay for these assets.

Intangible assets related to IPR&D are treated as indefinite-lived intangible assets and are not amortized until the product is approved for sale by regulatory authorities in specified markets. At that time, we will determine the useful life of the asset, reclassify the asset out of IPR&D and begin amortization. Impairment testing is performed at least annually or when a triggering event occurs that could indicate a potential impairment. In 2014, 2013, and 2012, we recognized impairment charges of $11,514, $29,736, and $26,300, respectively, associated with early stage indefinite-lived intangible assets acquired in connection with the purchases of Taligen and Orphatec. As of December 31, 2014, the remaining carrying value of our IPR&D was not impaired.

Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events occur. In 2013, we also recognized an impairment charge of $3,785 associated with a purchased technology asset acquired in connection with the Taligen acquisition.

If projects are not successfully developed, our sales and profitability may be adversely affected in future periods. Additionally, the value of the acquired intangible assets, including IPR&D, may become impaired if the underlying projects do not progress as we initially estimated. We believe that the assumptions used in developing our estimates of intangible asset values were reasonable at the time of the respective acquisitions. However, the underlying assumptions used to estimate expected project sales, development costs, profitability, or the events associated with such projects, such as clinical results, may not occur as we estimated at the acquisition date.

Goodwill represents the excess of purchase price over fair value of net assets acquired in a business combination and is not amortized. Goodwill is subject to impairment testing at least annually or when a triggering event occurs that could indicate a potential impairment. We are organized and operate as a single reporting unit and therefore the goodwill impairment test is performed using our overall market value, as determined by our traded share price, compared to our book value of net assets. We completed our annual impairment test as of December 31, 2014 and determined the carrying value of goodwill was not impaired.

Valuation of Contingent Consideration

We record contingent consideration resulting from a business combination at its fair value on the acquisition date. We determine the fair value of the contingent consideration based primarily on the following factors:

- timing and probability of success of clinical events or regulatory approvals;
- timing and probability of success of meeting commercial milestones, such as estimated future sales levels of a specific compound; and
- discount rates.

Our contingent consideration liabilities arose in connection with our business combinations. On a quarterly basis, we revalue these obligations and record increases or decreases in their fair value as an adjustment to operating earnings. Changes to contingent consideration obligations can result from adjustments to discount rates, accretion of the discount rates due to the passage of time, changes in our estimates of the likelihood or timing of achieving development or commercial milestones, changes in the probability of certain clinical events or changes in the assumed probability associated with regulatory approval.

The assumptions related to determining the value of contingent consideration include a significant amount of judgment, and any changes in the underlying estimates could have a material impact on the amount of contingent consideration expense recorded in any given period.

Income Taxes

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

We follow the authoritative guidance regarding accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. These unrecognized tax benefits relate primarily to issues common among multinational corporations in our industry. We apply a variety of methodologies in making these estimates which include studies performed by independent economists, advice from industry and subject experts, evaluation of public actions taken by the Internal Revenue Service and other taxing authorities, as well as our own industry experience. We provide estimates for unrecognized tax benefits which may be subject to material adjustments until matters are resolved with taxing authorities or statutes expire. If our estimates are not representative of actual outcomes, our results of operations could be materially impacted.

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

deferred tax assets are not realizable in a future period, we would record material adjustments to income tax expense in that period.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2016 and allows for adoption using a full retrospective method, or a modified retrospective method. We are currently assessing the method of adoption and the expected impact the new standard has on our financial position and results of operations.

Results of Operations

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

	Year Ended December 31,		
	2014	2013	2012
Net product sales	$ 2,233,733	$ 1,551,346	$ 1,134,114
Cost of sales:			
Cost of sales	173,862	168,375	126,214
Change in contingent liability from intellectual property settlements	—	9,181	(53,377)
Total cost of sales	173,862	177,556	72,837
Operating expenses:			
Research and development	513,782	317,093	222,732
Selling, general and administrative	630,209	489,720	384,678
Acquisition-related costs	20,295	5,029	22,812
Impairment of intangible assets	11,514	33,521	26,300
Restructuring expenses	15,365	—	—
Amortization of purchased intangible assets	—	417	417
Total operating expenses	1,191,165	845,780	656,939
Operating income	868,706	528,010	404,338
Other income and expense	3,401	(1,741)	(6,772)
Income before income taxes	872,107	526,269	397,566
Income tax provision	215,195	273,374	142,744
Net income	$ 656,912	$ 252,895	$ 254,822
Earnings per common share:			
Basic	$ 3.32	$ 1.29	$ 1.34
Diluted	$ 3.26	$ 1.27	$ 1.28

Comparison of the Year Ended December 31, 2014 to the Year Ended December 31, 2013

Net Product Sales

Net product sales by significant geographic region are as follows:

	Year Ended December 31,		
	2014	2013	% Change
Net product sales:			
United States	$ 730,089	$ 561,405	30%
Europe (1)	836,134	514,987	62%
Asia Pacific	244,059	203,538	20%
Other	423,451	271,416	56%
	$ 2,233,733	$ 1,551,346	44%

(1) In March 2014, we entered into an agreement with the French government which positively impacts prospective reimbursement of Soliris and also provides for reimbursement for shipments made in years prior to January 1, 2014. As a result of the agreement, in the first quarter of 2014, we recognized $87,830 of net product sales from Soliris in France relating to years prior to January 1, 2014.

The components of the increase in net product sales for the year ended December 31, 2014, exclusive of the $87,830 recognized related to prior years, are as follows:

	Year Ended December 31,
	2014
Components of change:	
Price	6 %
Volume	34 %
Foreign exchange	(2)%
Total change in net product sales	**38 %**

The increase in net product sales for fiscal year 2014 as compared to the same period in 2013, was primarily due to an increase in unit volumes of 34% due to increased physician demand globally for Soliris therapy for patients with PNH or aHUS during the respective periods.

Price had a positive impact on net product sales of 6%,for the year ended December 31, 2014, as compared to the same period in 2013. The positive price impact was primarily due to the agreement with the French government and a reduction in estimated rebates in Germany.

The positive impacts of volume and price on net product sales were offset by the negative impact on foreign exchange of 2%, for the year ended December 31, 2014, as compared to the same period in 2013. The negative impact on foreign exchange of $27,993, or 2%, was due to changes in foreign currency exchange rates (inclusive of hedging activity) versus the U.S. dollar for the year ended December 31, 2013. The negative impact was primarily due to the weakening of the Japanese Yen, Russian Ruble and the Canadian Dollar, partly offset by the positive impacts of the British Pound during the same respective period. We recorded a gain in revenue of $18,873 and $20,569 related to our foreign currency cash flow hedging program, for the years ended December 31, 2014 and 2013, respectively. We expect the strong dollar compared to other currencies, especially the Euro, Japanese Yen and Russian Ruble, to continue to have a negative impact on revenue in 2015 compared to 2014.

Cost of Sales

Cost of sales includes manufacturing costs as well as actual and estimated royalty expenses associated with sales of Soliris.

The following table summarizes cost of sales for the year ended December 31, 2014 and 2013:

	Year Ended December 31,		
	2014	2013	% Change
Cost of sales	$ 173,862	$ 168,375	$ 5,487
Cost of sales as a percentage of net product sales	8%	11%	(3)%

The decrease in cost of sales as a percentage of net product sales for the year ended December 31, 2014 was partially due to a $14,277 of voluntary recall expense recognized in 2013. Additionally, in the first quarter of 2014, we entered into a settlement agreement with a third party related to the calculation of royalties payable to such third party under a pre-existing license agreement. Based on this settlement agreement, the Company recorded a reversal of accrued royalties of $5,124 as a reduction of cost of sales.

In the first quarter of 2014, we also recorded an incremental impact in cost of sales of $2,055 for additional royalties related to the $87,830 of net product sales from prior year shipments.

The remaining decrease in cost of sales for the years ended December 31, 2014 as a percentage of net product sales resulted from a decrease in royalties paid on sales of Soliris.

In October 2013, we entered into a settlement agreement and dismissal with Novartis Vaccines and Diagnostics, Inc. pursuant to which Alexion was granted a nonexclusive, fully paid license and the case was dismissed with prejudice. As a result, we recorded expense of $9,181 in cost of sales in the third quarter 2013 related to our change in contingent liabilities resulting from this litigation settlement agreement.

Research and Development Expense

Our research and development expense includes personnel, facility and external costs associated with the research and development of our product candidates, as well as product development costs. We group our research and development expenses into two major categories: external direct expenses and all other research and development (R&D) expenses.

External direct expenses are comprised of costs paid to outside parties for clinical development, product development and discovery research, as well as costs associated with strategic licensing agreements we have entered into with third parties. Clinical development costs are comprised of costs to conduct and manage clinical trials related to eculizumab and other product candidates. Product development costs are those incurred in performing duties related to manufacturing development and regulatory functions, including manufacturing of material for clinical and research activities. Discovery research costs are incurred in conducting laboratory studies and performing preclinical research for other uses of eculizumab and other product candidates. Licensing agreement costs include upfront and milestone payments made in connection with strategic licensing arrangements we have entered into with third parties. Clinical development costs have been accumulated and allocated to each of our programs, while product development and discovery research costs have not been allocated.

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

The following table provides information regarding research and development expenses:

	Year Ended December 31, 2014	Year Ended December 31, 2013	$ Change	% Change
Clinical development	$ 111,435	$ 72,281	$ 39,154	54%
Product development	63,235	62,832	403	1%
Licensing agreements	109,925	14,500	95,425	658%
Discovery research	13,403	5,546	7,857	142%
Total external direct expenses	**297,998**	**155,159**	**142,839**	**92%**
Payroll and benefits	190,669	144,034	46,635	32%
Operating and occupancy	11,050	7,765	3,285	42%
Depreciation and amortization	14,065	10,135	3,930	39%
Total other R&D expenses	**215,784**	**161,934**	**53,850**	**33%**
Research and development expense	**$ 513,782**	**$ 317,093**	**$ 196,689**	**62%**

During the year ended December 31, 2014, we incurred research and development expenses of $513,782, an increase of $196,689, or 62%, versus the $317,093 incurred during the year ended December 31, 2013. The increase was primarily related to the following:

- Increase of $39,154 in external clinical development expenses related primarily to an expansion of studies for eculizumab and asfotase alfa (see table below).
- Increase of $95,425 in licensing agreement costs primarily due to the upfront payment of $100,000 on the option agreement entered into with Moderna Therapeutics, Inc. in the first quarter of 2014.
- Increase of $7,857 in discovery research expenses primarily related to increases in external research expenses associated with our Moderna agreement and other external research expenses.
- Increase of $46,635 in R&D payroll and benefit expense related primarily to the continued global expansion of staff supporting our increasing number of clinical and development programs.
- Increases of $3,285 and $3,930 in R&D operating and occupancy and depreciation and amortization expenses. respectively, related primarily to the continued expansion of global supply chain facilities and support services.

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

	Year Ended December 31, 2014	Year Ended December 31, 2013	Accumulated Expenditures (Non-Approved Products)
External direct expenses			
Eculizumab	$ 67,224	$ 44,577	(a)
Asfotase alfa	25,034	13,677	$ 43,511
cPMP	7,802	6,408	16,354
Other programs	5,947	5,546	19,037
Unallocated	5,428	2,073	(b)
	$ 111,435	**$ 72,281**	**$ 78,902**

(a) From 1992 through 2006, substantially all research and development expenses were related to two products, eculizumab and pexelizumab. We obtained approval in the U.S. for eculizumab for PNH in 2007 and for aHUS in 2010, and we ceased development of pexelizumab in 2006.

(b) External costs shared across various development programs.

The successful development of our drug candidates is uncertain and subject to a number of risks. We cannot guarantee that results of clinical trials will be favorable or sufficient to support regulatory approvals for our other programs. We could decide to

abandon development or be required to spend considerable resources not otherwise contemplated. For additional discussion regarding the risks and uncertainties regarding our development programs, please refer to Item 1A "Risk Factors" in this Annual Report on Form 10-K.

We expect our research and development expenses to increase in 2015 due to clinical development and manufacturing costs related to our expanding development programs. For additional information on these programs, please refer to “Product and Development Programs” in Item I "Business" of this Annual Report on Form 10-K.

Selling, General and Administrative Expense

Our selling, general and administrative expense includes commercial and administrative personnel, corporate facility and external costs required to support the marketing and sales of our commercialized products. These selling, general and administrative costs include: corporate facility operating expenses and depreciation; marketing and sales operations in support of Soliris; human resources; finance, legal, information technology and support personnel expenses; and other corporate costs such as telecommunications, insurance, audit, government affairs and our global corporate compliance program.

The table below provides information regarding selling, general and administrative expense:

	Year Ended December 31, 2014	Year Ended December 31, 2013	$ Change
Salary, benefits and other labor expense	$ 388,738	$ 292,881	$ 95,857
External selling, general and administrative expense	241,471	196,839	44,632
Total selling, general and administrative expense	**$ 630,209**	**$ 489,720**	**$ 140,489**

During the year ended December 31, 2014, we incurred selling, general and administrative expenses of $630,209, an increase of $140,489, or 29%, versus the $489,720 incurred during the year ended December 31, 2013. The increase was primarily related to the following:

- Increase in salary, benefits and other labor expenses of $95,857. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of $49,023 related to our global commercial staff to support global expansion. This increase was also due to increases in payroll and benefits of $46,835 within our general and administrative functions to support our infrastructure growth as a global commercial entity.
- Increase in external selling, general and administrative expenses of $44,632. This increase was primarily due to an increase in marketing costs to support the continued growth in global sales of Soliris, as well as an increase in other administrative costs to support our infrastructure growth.

We expect our selling, general and administrative expenses to increase, at a lower rate than our revenue, in 2015, reflecting our continued growth as a commercial organization throughout the world.

Acquisition-related Costs

For the years ended December 31, 2014 and 2013, acquisition-related costs associated with our business combinations included the following:

	Year Ended December 31, 2014	Year Ended December 31, 2013
Separately-identifiable employee costs	$ —	$ 248
Professional fees	—	775
Changes in fair value of contingent consideration	20,295	4,006
	$ 20,295	**$ 5,029**

The increase in expense associated with changes in the fair value of contingent consideration for the year ended December 31, 2014 as compared the prior year resulted primarily from increases in the likelihood of payments for contingent consideration and related to a decrease in discount rates.

Restructuring Expenses

In the fourth quarter of 2014 we announced plans to move the European headquarters from Lausanne, Switzerland to Zurich, Switzerland resulting in restructuring expenses of $15,365. The relocation of the European headquarters will support our growing operational needs based on current business forecasts. We expect to incur approximately $10,000 to $15,000 of additional restructuring related charges in 2015 related to additional employee costs and contract terminations costs. We expect to pay all accrued amounts related to this restructuring activity in 2015.

Impairment of Intangible Asset

During the fourth quarter of 2014, we reviewed for impairment the value of the early stage, Phase II indefinite-lived intangible asset related to the Orphatec acquisition. We initiated such review as part of our annual impairment testing and increased costs associated with clinical trial studies. Although we will continue to develop this asset, the estimated fair value that can be obtained from a market participant in an arm's length transaction was determined to be de minimis as of December 31, 2014. As a result, in the fourth quarter 2014, we recognized an impairment charge of $8,050 to write-down these assets to fair value.

During the first quarter of 2014 and the fourth quarter of 2013, we reviewed for impairment the value of an early stage, Phase I indefinite-lived intangible asset related to our acquisition of Taligen Therapeutics, Inc. We initiated such review based on a reassessment of scientific findings associated with this acquired asset. In the fourth quarter 2013, we also reviewed for impairment the value of purchased technology associated with the Taligen acquisition. As a result, we recognized impairment charges of $3,464 and $33,521 for the years ended December 31, 2014 and 2013 to adjust these assets to fair value, which was determined to be de minimis.

Other Income and Expense

The following table provides information regarding other income and expense:

	Year Ended December 31, 2014	Year Ended December 31, 2013	$ Change
Investment income	$ 8,373	$ 3,346	$ 5,027
Interest expense	(2,982)	(4,112)	1,130
Foreign currency loss	(1,990)	(975)	(1,015)
Total other income (expense)	**$ 3,401**	**$ (1,741)**	**$ 5,142**

Income Taxes

During the year ended December 31, 2014, we recorded an income tax provision of $215,195 and an effective tax rate of 24.7%, compared to an income tax provision of $273,374 and an effective tax rate of 51.9% for the year ended December 31, 2013. The reduction in the effective tax rate is primarily attributable to the centralization of our global supply chain and technical operations in Ireland.

The income tax provision for 2014 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. Additionally, included for the year ended December 31, 2014 is $2,128 of tax attributable to our agreement with the French government that provided reimbursement for shipments of Soliris made prior to January 1, 2014.

The income tax provision for 2013 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations, as well as the tax expense of resulting from the centralization of our global supply chain and technical operations in Ireland undertaken in the fourth quarter of 2013 in the amount of approximately $95,800. We were also impacted by a tax benefit of $2,719 attributable to the 2012 U.S. Federal tax credit for research and experimentation due to retroactive extension of this credit signed into law in January 2013.

We were granted an incentive tax holiday in the Canton of Vaud in Switzerland effective January 1, 2010. This tax holiday had exempted us from most local corporate income taxes in Switzerland through the end of 2014 and was renewable for an

additional 5 years with final expiration in 2019. During 2013, we undertook a restructuring which significantly changed our business model in Switzerland and we converted from a principal company to a distribution and service company. As a result of the significant change to our business activities in Switzerland, the Canton of Vaud in Switzerland provided final notification to us in December 2014 that our structure no longer complied with the conditions of the incentive tax holiday. In the fourth quarter of 2014, we made a payment of $22,817 in satisfaction of the clawback of previously exempted cantonal income taxes for tax years 2010 through 2013. This amount was fully accrued on our balance sheet as of December 31, 2013. Prospectively, our federal and cantonal tax will be based on the current enacted tax rates in Switzerland.

The U.S. Federal tax credit for research and experimentation expenses expired December 31, 2013. In connection with this expiration, our 2014 tax expense for the first three quarters of the year did not include any benefit from the U.S. Federal tax credit for research and experimentation. In December 2014, the Tax Increase Prevention Act of 2014, which retroactively extended the tax credit for research and experimentation back to January 1, 2014 through the end of 2014, was signed into law. The effects of a change in tax law is recognized in the period that includes the date of enactment and, therefore, our tax benefit attributable to the 2014 U.S. Federal tax credit of $3,222 for research and experimentation was recorded in the fourth quarter of 2014.

We continue to maintain a valuation allowance against certain other deferred tax assets where the realization is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized.

Comparison of the Year Ended December 31, 2013 to the Year Ended December 31, 2012

Net Product Sales

Net product sales by significant geographic region are as follows:

	Year Ended December 31,		
Net product sales:	2013	2012	% Change
United States	$ 561,405	$ 400,483	40%
Europe	514,987	418,321	23%
Asia Pacific	203,538	161,480	26%
Other	271,416	153,830	76%
	$ 1,551,346	$ 1,134,114	37%

The increase in revenue for fiscal year 2013 versus 2012 was primarily due to an increased volume of unit shipments, partially offset by a negative impact of price and foreign exchange.

The increase in revenue of 37% for the year ended December 31, 2013 was due to an increase in unit volumes of 40%, offset by a negative price impact of 2%, and a negative impact on foreign exchange of 1%. The increase in volume was largely due to physicians globally requesting Soliris therapy for additional patients. The negative price impact of 2% for the year ended December 31, 2013 was primarily due to increased rebates in certain countries in Europe, offset by a price increase in the United States.

The negative impact on foreign exchange of $15,876, or 1%, for the year ended December 31, 2013 was due to changes in foreign currency exchange rates (inclusive of hedging activity) versus the U.S. dollar for the year ended December 31, 2012. The negative impact was primarily due to the weakening of the Japanese Yen. We recorded a gain in revenue of $20,569 and $12,869 related to our foreign currency cash flow hedging program, which is included in revenue from outside the United States, for the years ended December 31, 2013 and 2012, respectively.

Cost of Sales

In October 2013, we entered into a settlement agreement and dismissal with Novartis pursuant to which Alexion was granted a non-exclusive, fully paid license and the case was dismissed with prejudice. As a result, we recorded expense of $9,181 in cost of sales in the third quarter 2013 related to this litigation settlement agreement.

In the third quarter of 2012, we reduced our estimate for probable contingent liabilities as of September 30, 2012 due to the execution of a settlement and non-exclusive license agreement in October 2012 with a third party related to the third party's intellectual property. The adjustment reflected the actual, negotiated royalty rate set forth in the agreement. This change in estimate resulted in a positive impact in cost of sales of $53,377 during the third quarter 2012.

Exclusive of the changes in estimates of contingent liabilities for the settlements noted above, cost of sales were $168,375 and $126,214, or 11% of product revenue, for the years ended December 31, 2013 and 2012, respectively. Cost of sales includes manufacturing costs as well as actual and estimated royalty expenses associated with sales of Soliris. Included in cost of sales for the year ended December 31, 2013, was $14,277 or 1% of product sales related to the expected disposal of inventory in 2014 associated with our voluntary recall announced in November 2013. Offsetting this increase in cost of sales was a decrease in our ongoing royalty expense as a result of the settlement and non-exclusive license agreement we entered into in October 2012.

Research and Development Expense

The following table provides information regarding research and development expenses:

	Year Ended December 31, 2013	Year Ended December 31, 2012	$ Change	% Change
Clinical development	$ 72,281	$ 46,711	$ 25,570	55 %
Product development	62,832	57,028	5,804	10 %
Discovery research	20,046	8,271	11,775	142 %
Total external direct expenses	**155,159**	**112,010**	**43,149**	**39 %**
Payroll and benefits	144,034	95,609	48,425	51 %
Operating and occupancy	7,765	7,958	(193)	(2)%
Depreciation and amortization	10,135	7,155	2,980	42 %
Total other R&D expenses	**161,934**	**110,722**	**51,212**	**46 %**
Research and development expense	**$ 317,093**	**$ 222,732**	**$ 94,361**	**42 %**

During the year ended December 31, 2013, we incurred research and development expenses of $317,093, an increase of $94,361, or 42%, versus the $222,732 incurred during the year ended December 31, 2012. The increase was primarily related to the following:

- Increase of $25,570 in external clinical development expenses related primarily to an expansion of studies of eculizumab, asfotase alfa and cPMP programs (see table below).
- Increase of $5,804 in external product development expenses related primarily to costs associated with the preparation of regulatory filings for asfotase alfa and an increase in manufacturing costs related to our other product development programs, offset by a decrease in costs associated with the production of asfotase alfa for clinical studies.
- Increase of $11,775 in discovery research expenses primarily related to the upfront payment of $14,500 on the license agreements entered into in 2013.
- Increase of $48,425 in R&D payroll and benefit expense related primarily to global expansion of staff supporting our increasing number of clinical and development programs.

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

	Year Ended December 31, 2013	Year Ended December 31, 2012
External direct expenses		
Eculizumab	$ 44,577	$ 35,732
Asfotase alfa	13,677	4,800
cPMP	6,408	2,144
Other programs	5,546	3,396
Unallocated	2,073	639
	$ 72,281	**$ 46,711**

(a) From 1992 through 2006, substantially all research and development expenses were related to two products, eculizumab and pexelizumab. We obtained approval in the U.S. for eculizumab for PNH in 2007 and for aHUS in 2010, and we ceased development of pexelizumab in 2006.

Selling, General and Administrative Expense

The table below provides information regarding selling, general and administrative expense:

	Year Ended December 31, 2013	Year Ended December 31, 2012	$ Change
Salary, benefits and other labor expense	$ 292,881	$ 223,053	$ 69,828
External selling, general and administrative expense	196,839	161,625	35,214
Total selling, general and administrative expense	**$ 489,720**	**$ 384,678**	**$ 105,042**

During the year ended December 31, 2013, we incurred selling, general and administrative expenses of $489,720, an increase of $105,042, or 27%, versus the $384,678 incurred during the year ended December 31, 2012. The increase was primarily related to the following:

- Increase in salary, benefits and other labor expenses of $69,828. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of $51,700 related to our global commercial staff to support global expansion. This increase was also due to increases in payroll and benefits of $18,100 within our general and administrative functions to support our infrastructure growth as a global commercial entity.
- Increase in external selling, general and administrative expenses of $35,214. This increase was primarily due to an increase in legal costs associated with the Novartis litigation, an increase in consulting fees related to our global supply chain expansion in Ireland, an increase in marketing costs to support the continued growth in global sales, as well as an increase in general administrative expenses due to infrastructure growth.

Acquisition-related Costs

For the years ended December 31, 2013 and 2012, acquisition-related costs associated with our business combinations included the following:

	Year Ended December 31, 2013	Year Ended December 31, 2012
Separately-identifiable employee costs	$ 248	$ 3,669
Professional fees	775	12,593
Changes in fair value of contingent consideration	4,006	6,550
	$ 5,029	**$ 22,812**

The following table provides information for acquisition-related costs for each business combination:

	Year Ended December 31, 2013	Year Ended December 31, 2012
Enobia Pharma Corp.	$ 9,625	$ 23,673
Taligen Therapeutics, Inc.	(5,777)	(2,948)
Orphatec Pharmaceuticals GmbH	1,181	2,087
	$ 5,029	**$ 22,812**

Included in the acquisition-related costs for Taligen for the year ended December 31, 2013 and 2012 is a gain of $5,973 and $4,331, respectively, related to the decrease in the fair value of the contingent consideration related to this acquisition. The decrease in fair value was a result of a decreased likelihood of payments for contingent consideration due to a reassessment of scientific findings.

Impairment of Intangible Asset

During the fourth quarter of 2013, we reviewed for impairment the value of an early stage, Phase I indefinite-lived intangible asset related to the Taligen acquisition. We initiated such review as part of our annual impairment testing and based our evaluation on preliminary scientific findings of a Phase I clinical trial which led us to reassess the development of this acquired asset. Based on these factors, the estimated value that can be obtained from a market participant in an arm's length transaction of $3,464 was lower than the carrying amount. We also reviewed for impairment the value of purchased technology associated with the Taligen acquisition and determined the estimated fair value to be de minimis. As a result, in the fourth quarter 2013, we recognized an impairment charge of $33,521 to write-down these assets to fair value.

During the year ended December 31, 2012, we reviewed for impairment the value of an early stage, preclinical indefinite-lived intangible asset related to the Taligen acquisition. We initiated such review based on our evaluation of negative scientific findings associated with our development of a different asset for the treatment of age-related macular degeneration, the likelihood of success for ophthalmic use and the value that can be obtained from a market participant in an arm's length transaction. These developments led us to deprioritize the development of this acquired asset. As a result, in the third quarter 2012, we recognized an impairment charge of $26,300 to write-down this asset to fair value, which was determined to be de minimis.

Other Income and Expense

The following table provides information regarding other income and expense:

	Year Ended December 31, 2013	Year Ended December 31, 2012	$ Change
Investment income	$ 3,346	$ 1,838	$ 1,508
Interest expense	(4,112)	(7,402)	3,290
Foreign currency loss	(975)	(1,208)	233
Total other income (expense)	**$ (1,741)**	**$ (6,772)**	**$ 5,031**

We recognize investment income primarily from our portfolio of cash equivalents. During the year ended December 31, 2013, investment income increased $1,508, or 82%, to $3,346.

We incur interest on our term notes and revolving credit facility. During the year ended December 31, 2013, interest expense decreased $3,290 to $4,112 due to a decrease in amounts outstanding under our credit facility.

Foreign currency transaction gains and losses relate to changes in the fair value of monetary assets and liabilities denominated in foreign currencies. The foreign currency transaction losses totaled $975 and $1,208 for the years ended December 31, 2013 and December 31, 2012, respectively. The amounts recorded in these periods were a result of the costs of hedging our exposures, as well as the fluctuation in exchange rates on the portion of our monetary assets and liabilities that were not fully hedged as part of our hedging programs.

Income Taxes

During the year ended December 31, 2013, we recorded an income tax provision of $273,374 and an effective tax rate of 51.9%, compared to an income tax provision of $142,744 and an effective tax rate of 35.9% for the year ended December 31, 2012.

The income tax provision for 2013 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations, as well as the tax expense of resulting from the centralization of our global supply chain and technical operations in Ireland undertaken in the fourth quarter of 2013 in the amount of approximately $95,800. We were also impacted by a tax benefit of $2,719 attributable to the 2012 U.S. Federal tax credit for research and experimentation due to retroactive extension of this credit signed into law in January 2013.

The tax provision for 2012 is principally attributable to the U.S. federal, state, and foreign income taxes in our profitable operations, as well as the tax expense of $21,812 associated with the structuring of the Enobia business.

We were granted an incentive tax holiday in the Canton of Vaud in Switzerland effective January 1, 2010. This tax holiday will exempt us from most local corporate income taxes in Switzerland through the end of 2014 and is renewable for an additional 5 years with final expiration in 2019. The impact of this tax holiday decreased foreign tax expense by $4,351 in 2013 and $3,173 in 2012.

We continue to maintain a valuation allowance against certain other deferred tax assets where the realization is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized.

Financial Condition, Liquidity and Capital Resources

The following table summarizes the components of our financial condition as of December 31, 2014 and 2013:

	December 31, 2014	December 31, 2013	$ Change
Cash and cash equivalents	$ 943,999	$ 529,857	$ 414,142
Marketable securities	1,017,567	984,994	32,573
Long-term debt (includes current portion)	57,500	113,000	(55,500)
Current assets	$ 2,796,029	$ 2,186,857	$ 609,172
Current liabilities	606,740	582,429	24,311
Working capital	$ 2,189,289	$ 1,604,428	$ 584,861

The increase in cash and cash equivalents was primarily attributable to cash generated from operations, proceeds from the maturity or sale of available-for-sale securities, and net proceeds from the exercise of stock options. Offsetting these increases in cash were purchases of marketable securities, payments on our outstanding term loan, purchases of property, plant and equipment, and the repurchase of common stock. We also paid an upfront fee of $100,000 during the first quarter of 2014 related to an option agreement we entered into with Moderna Therapeutics, Inc. and an additional $37,500 for the purchase of Moderna LLC preferred equity during 2014.

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

We have financed our operations and capital expenditures primarily through positive cash flows from operations. We expect to continue to be able to fund our operations, including principal and interest payments on our credit facility and contingent payments from our acquisitions principally through our cash flows from operations. We may, from time to time, also seek additional funding through a combination of equity or debt financings or from other sources, if necessary for future acquisitions or other strategic purposes.

Financial Instruments

Until required for use in the business, we may invest our cash reserves in money market funds or high-quality marketable securities in accordance with our investment policy. The stated objectives of our investment policy is to preserve capital, provide

liquidity consistent with forecasted cash flow requirements, maintain appropriate diversification and generate returns relative to these investment objectives and prevailing market conditions.

Financial instruments that potentially expose us to concentrations of credit risk are cash equivalents, marketable securities, accounts receivable and our foreign exchange derivative contracts. At December 31, 2014, four individual customers accounted for 58% of the accounts receivable balance, with individual customers accounting for 10% to 23% of the accounts receivable balance. At December 31, 2013, two individual customers accounted for 30% of the accounts receivable balance, with individual customers accounting for 10% and 20% of the accounts receivable balance. For the years ended December 31, 2014 and 2013, one customer accounted for 18% and 20%, respectively, of our product sales.

We continue to monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. Substantially all of our accounts receivable due from these countries are due from or backed by sovereign or local governments, and the amount of non-sovereign accounts receivable is not material. Although collection of our accounts receivables from certain countries may extend beyond our standard credit terms, we do not expect any such delays to have a material impact on our financial condition or results of operations.

We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. As of December 31, 2014, we have foreign exchange forward contracts with notional amounts totaling $1,748,931. These outstanding foreign exchange forward contracts had a net fair value of $135,166, of which an unrealized gain of $136,046 is included in other assets, offset by an unrealized loss of $880 included in other liabilities. The counterparties to these foreign exchange forward contracts are large multinational commercial banks, and we believe the risk of nonperformance is not material.

At December 31, 2014, our financial assets and liabilities were recorded at fair value. We have classified our financial assets and liabilities as Level 1, 2 or 3 within the fair value hierarchy. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Our Level 1 assets consist of mutual fund investments. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, but substantially the full term of the financial instrument. Our Level 2 assets consist primarily of institutional money market funds, commercial paper, municipal bonds, U.S. and foreign government-related debt, corporate debt securities, certificates of deposit and foreign exchange forward contracts. Our Level 2 liabilities consist also of foreign exchange forward contracts. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. Our Level 3 liabilities consist of contingent consideration related to acquisitions.

Business Combinations and Contingent Consideration Obligations

The purchase agreements for our business combinations include contingent payments totaling up to $876,000 that will become payable if and when certain development and commercial milestones are achieved. Of these milestone amounts, $561,000 and $315,000 of the contingent payments relate to development and commercial milestones, respectively. We do not expect these amounts to have an impact on our liquidity in the near-term, and, during the next 12 months, we expect to make milestone payments totaling approximately $50,000. As additional future payments become probable, we will evaluate methods of funding payments, which could be made from available cash and marketable securities, cash generated from operations or proceeds from other financing.

Financing Lease Obligation

In November 2012, we entered into a lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. Although we will not legally own the premises, we are deemed to be the owner of the building during the construction period based on applicable accounting guidance for build-to-suit leases due to our involvement during the construction period. Accordingly, the landlord's costs of constructing the facility are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our consolidated balance sheet. As of December 31, 2014, we recorded a construction-in-process asset of $126,566, inclusive of the landlord's costs as well as costs incurred by Alexion, and an offsetting facility lease obligation of $107,099, associated with the new facility.

License Agreements

In January 2015, we entered into a license agreement with a third party to obtain certain intellectual property rights and technology related to specific therapeutic compounds. The agreement provides an exclusive research, development and commercial license for products to be developed using such compounds. Pursuant to the terms of the agreement, we made an upfront payment of $50,000 during the first quarter 2015. We could be required to pay up to an additional $213,000 in development and regulatory milestones related to a product developed under the agreement for a single disease indication. An

additional $437,000 in milestone payments could be due if certain development and regulatory milestones are achieved for additional disease indications. The agreement also provides for royalty payments and potential milestone payments of up to $180,000 on commercial sales of products developed under the agreement.

In December 2014, we entered into an agreement with X-Chem Pharmaceuticals (X-Chem) that allows us to identify novel drug candidates from X-Chem's proprietary drug discovery engine. Alexion will have the exclusive worldwide rights to develop and commercialize products arising from the collaboration in up to three program targets. Due to the early stage of these assets, we recorded expense for an upfront payment of $8,000. In addition, for each program target, for a maximum of three targets, we could be required to make additional payments upon the achievement of specified research, development and regulatory milestones up to $75,000, as well as royalties on commercial sales.

In January 2014, we entered into an agreement with Moderna Therapeutics, Inc. (Moderna) that allows us to purchase ten product options to develop and commercialize treatments for rare diseases with Moderna's messenger RNA (mRNA) therapeutics platform. Alexion will lead the discovery, development and commercialization of the treatments produced through this broad, long-term strategic agreement, while Moderna will retain responsibility for the design and manufacture of the messenger RNA against selected targets. Due to the early stage of these assets, we recorded expense for an upfront payment of $100,000. We will also be responsible for funding research activities under the program. In addition, for each drug target, up to a maximum of ten targets, we could be required to make an option exercise payment of $15,000 and to pay up to an additional $120,000 with respect to a rare disease product and $400,000 with respect to a non-rare disease product in development and sales milestones if the specific milestones are met over time as well as royalties on commercial sales.

Long-term Debt

In February 2012, we entered into a Credit Agreement (Credit Agreement) with a syndicate of lenders and other parties named in the Credit Agreement that provides for a $240,000 senior secured term loan facility payable in equal quarterly installments of $12,000 starting June 30, 2012 and a $200,000 senior secured revolving credit facility, which includes up to a $60,000 sublimit for letters of credit and a $10,000 sublimit for swingline loans. We may also use the facilities for working capital requirements, acquisitions and other general corporate purposes. Any of Alexion's wholly-owned foreign subsidiaries may borrow funds under the facilities upon satisfaction of certain conditions described in the Credit Agreement. As of December 31, 2014, we had $57,500 outstanding on the term loan of which $12,000 was paid in January 2015. As of December 31, 2014, we had open letters of credit of $10,284, and our borrowing availability under the revolving facility was $189,716 at December 31, 2014. We expect that cash generated from operations will be sufficient to meet debt service obligations.

Lonza Agreement

We have supply agreements with Lonza through 2026 relating to the manufacture of eculizumab and asfotase alfa, which requires payments to Lonza at the inception of contract and upon the initiation and completion of product manufactured. On an ongoing basis, we evaluate our plans for future levels of manufacturing by Lonza, which depends upon our commercial requirements, the progress of our clinical development programs and the production levels of ARIMF.

We have various agreements with Lonza, with remaining total non-cancellable commitments of approximately $383,500 through 2018. Our agreements with Lonza also include potential payments totaling up to $5,000 that will become payable if and when certain milestones are achieved. Such commitments may be canceled only in limited circumstances. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at ARIMF and a payment with respect to sales of Soliris manufactured at Lonza facilities.

Taxes

We do not record U.S. tax expense on the undistributed earnings of our controlled foreign corporation (CFC) subsidiaries as these earnings are intended to be permanently reinvested offshore. At December 31, 2014, the cumulative amount of these earnings was approximately $359,000. During the fourth quarter of 2013, in connection with the centralization of our global supply chain and technical operations in Ireland, our U.S. parent company became a direct partner in a foreign partnership subsidiary. To the extent that our U.S. parent company receives its allocation of partnership taxable income, the amounts will be taxable in the U.S. and therefore the permanent reinvestment assertion will no longer apply.

We do not have any present or anticipated future need for cash held by our CFCs, as cash generated in the U.S., as well as borrowings, are expected to be sufficient to meet U.S. liquidity needs for the foreseeable future. At December 31, 2014, approximately $674,000 of our cash and cash equivalents was held by foreign subsidiaries, a significant portion of which is required for liquidity needs of our foreign subsidiaries. Due to the liability position of our foreign subsidiaries, these subsidiaries

will repay any outstanding intercompany debt, prior to having excess cash available which could be used to repatriate to our entities in the United States. While our expectation is that all future undistributed earnings of our CFCs will be permanently reinvested, there could be certain unforeseen future events that could impact our permanent reinvestment assertion. Such events include acquisitions, corporate restructurings or tax law changes not currently contemplated.

Common Stock Repurchase Program

In November 2012 and December 2014, we announced that our Board of Directors authorized the repurchase of up to $400,000 and $500,000 of our common stock. The repurchase program does not have an expiration date, and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at the Company's discretion. We expect that cash generated from operations and our existing available cash and cash equivalents are sufficient to fund any share repurchases.

Under the program, we repurchased 1,903 and 758 shares of our common stock at a cost of $302,599 and $66,136 during the years ended December 31, 2014 and 2013, respectively. At December 31, 2014, there is a total of $519,712 remaining for repurchases under these repurchase program.

Subsequent to December 31, 2014, we repurchased 87 shares of our common stock under our repurchase program at a cost of $15,531.

Cash Flows

The following summarizes our net change in cash and cash equivalents:

	Year Ended December 31,		
	2014	2013	$ Change
Net cash provided by operating activities	$ 640,075	$ 497,349	$ 142,726
Net cash used in investing activities	(222,869)	(1,027,141)	804,272
Net cash provided by financing activities	7,126	71,639	(64,513)
Effect of exchange rate changes on cash	(10,190)	(1,491)	(8,699)
Net change in cash and cash equivalents	$ 414,142	$ (459,644)	$ 873,786

The increase in cash and cash equivalents was primarily attributable to cash generated from operations, proceeds from the maturity or sale of available-for-sale securities, net proceeds from the exercise of stock options and a reduction of income taxes payable due to excess tax benefits from stock options. Offsetting these increases in cash were purchases of marketable securities, payments on our outstanding term loan, purchases of property, plant and equipment, and the repurchase of common stock. We also paid an upfront fee of $100,000 during the first quarter of 2014 related to an option agreement we entered into with Moderna Therapeutics, Inc. and an additional $37,500 for the purchase of Moderna LLC preferred equity during 2014.

Operating Activities

The components of cash flows from operating activities, as reported in our Consolidated Statements of Cash Flows, are as follows:

- Our reported net income was $656,912 and $252,895 for the years ended December 31, 2014 and 2013, respectively. During the first quarter of 2014, we recorded expense of $100,000 for an upfront payment related to an option agreement we entered into with Moderna Therapeutics, Inc.
- Non-cash items included depreciation and amortization, impairment of intangible assets, change in fair value of contingent consideration, share-based compensation expense, premium amortization of available-for-sale securities, and deferred taxes, and were increases to reconcile net income to net cash flows from operating activities of $76,869 and $240,529 for the years ended December 31, 2014 and 2013, respectively.
- Non-cash items also included $251,136 and $105,714 of windfall tax benefits for the years ended December 31, 2014 and 2013, respectively. The amount of the windfall tax benefit was significantly higher during the year ended December 31, 2014 due to an increased stock price and increased level of stock option exercises.

- Net cash inflows due to changes in operating assets and liabilities was $157,430 and $109,639 for the years ended December 31, 2014 and 2013, respectively. The $157,430 change in operating assets and liabilities primarily relates to:
  - Increase in accounts receivable of $28,137 due primarily to increasing revenue.
  - Increase of $66,812 in inventory related to increased production of inventory to support commercial growth and the capitalization of $22,005 of inventory produced for commercial sale for products awaiting regulatory approval.
  - Increase of $18,392 in prepaid expenses and other assets related to an increase in prepaid manufacturing costs.
  - Increase of $264,572 in accounts payable, accrued expenses and other liabilities primarily related to an increase in trade accounts payable, accrued manufacturing, accruals for purchases of property, plant and equipment, clinical costs, accrued compensation and a change in accrued income taxes. These increases were offset by a decrease in accruals for rebates of approximately $87,800 resulting from the agreement with the French government for reimbursement of prior year shipments and a decrease in accruals for royalties of approximately $20,100 resulting from the settlement agreement we entered into with a third party related to the calculation of royalties under a pre-existing license agreement.

In 2015, we expect increases in cash flow from operations which will be highly dependent on sales levels, and the related cash collections from Soliris.

Investing Activities

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

- Purchases of available-for-sale marketable securities of $664,228 and $1,048,429 for the year ended December 31, 2014 and 2013, respectively, offset by proceeds from the maturity or sale of available-for-sale marketable securities of $619,447 and $60,917 during the same periods.
- Purchase of $37,500 of preferred equity of Moderna LLC during the year ended December 31, 2014.
- Additions to property, plant and equipment of $136,650 and $29,329 for the years ended December 31, 2014 and 2013, respectively.

We expect to increase spending on property, plant and equipment in 2015 due to the capital projects for our New Haven headquarters and our two facilities in Ireland.

Financing Activities

Net cash flows from financing activities reflected proceeds from the exercise of stock options of $114,350 and $71,281 for the years ended December 31, 2014 and 2013, respectively. Net cash flows from financing activities for the years ended December 31, 2014 and 2013 also include $251,136 and $105,714, respectively, of excess tax benefits from stock options attributable to the utilization of the excess tax benefit portion of federal and state net operating losses and tax credits.

During the years ended December 31, 2014 and 2013, we made payments of $55,500 and $36,000 against the term loan facility. As of December 31, 2014, the facility had $57,500 remaining outstanding.

During the years ended December 31, 2014 and 2013, we repurchased $302,599 and $66,136 worth of shares of our common stock under a repurchase program that was approved by our Board of Directors in November 2012. In December 2014, our Board of Directors approved an additional $500,000 to repurchase shares. As of December 31, 2014, there is a total of $519,712 remaining for repurchases under these repurchase program.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2014 and the effect such obligations and commercial commitments are expected to have on our liquidity and cash flow in future fiscal years. These do not include potential milestone payments and assume non-termination of agreements.

These obligations, commitments and supporting arrangements represent payments based on current operating forecasts, which are subject to change:

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Contractual obligations:					
Long-term debt	$ 57,500	$ 10,000	$ 47,500	$ —	$ —
Interest expense (1)	1,308	807	501	—	—
Pension obligations	12,342	1,985	2,961	2,474	4,922
Facility Lease Obligation (2)	149,529	1,941	23,302	23,915	100,371
Operating leases	72,561	21,481	30,952	13,868	6,260
Total contractual obligations	$ 293,240	$ 36,214	$ 105,216	$ 40,257	$ 111,553
Commercial commitments:					
Clinical and manufacturing development (3)	$ 383,500	$ 81,810	$ 198,710	$ 102,980	$ —
Licenses (4)	17,080	8,964	2,878	4,228	1,010
Total commercial commitments	$ 400,580	$ 90,774	$ 201,588	$ 107,208	$ 1,010

(1) Interest on variable rate debt calculated based on interest rates at December 31, 2014.

(2) Facility lease obligation includes the lease agreement signed in November 2012, for office and laboratory space to be constructed in New Haven, Connecticut. Although we will not legally own the premises, we are deemed to be the owner of the building during the construction period based on applicable accounting guidance for build-to-suit leases due to our involvement during the construction period. Accordingly, the landlord's costs of constructing the facility are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our consolidated balance sheet. Construction of the new facility began in June 2013 and commitments included within this schedule assume an estimated November 2015 occupancy date.

(3) Clinical and manufacturing development commitments include only non-cancellable commitments at December 31, 2014.

(4) License commitments do not include the $50,000 upfront payment associated with the license agreement we entered into in January 2015.

The contractual obligations table above does not include contingent royalties and other contingent contractual payments we may owe to third parties in the future because such payments are contingent on future sales of our products and the existence and scope of third party intellectual property rights and other factors described in Item 1A "Risk Factors" and Note 9 "Commitments and Contingencies" of the Consolidated Financial Statements included in the Annual Report on Form 10-K.

The table above also does not include a liability for unrecognized tax benefits related to various federal, state and foreign income tax matters of $28,675 at December 31, 2014. The timing of the settlement of these amounts was not reasonably estimable at December 31, 2014. We do not expect payment of amounts related to the unrecognized tax benefits within the next twelve months.

We also did not include contingent payments related to business acquisitions completed in prior years, as the timing of payment for these amounts was not reasonably estimable at December 31, 2014. Contingent payments associated with these business combinations total up to $876,000 which will become payable if and when certain development and commercial milestones are achieved. During the next 12 months, we expect to make milestone payments totaling approximately $50,000.

Credit Facilities

In February 2012, we entered into a credit agreement, as amended (the Credit Agreement) with a syndicate of lenders and other parties named in the Credit Agreement that provides for a $240,000 senior secured term loan facility payable in equal quarterly installments of $12,000 beginning on June 30, 2012 and a $200,000 senior secured revolving credit facility through February 7, 2017.

We may elect that the loans under the Credit Agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.25% to 2.00% depending on our consolidated leverage ratio (as calculated in accordance with the Credit Agreement), or (ii) in the case of loans denominated in U.S. dollars, a Base Rate equal to the higher of the (A) Prime Rate then in effect, (B) Federal Funds Rate then in effect plus 0.50%, and (C) Eurodollar Rate then in effect plus 1.00%, plus in each case of (A), (B) or (C), 0.25% to 1.00% depending on our consolidated leverage ratio of our cash to liabilities (as calculated in accordance with the Credit 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 7, 2017, the maturity date.

Our obligations under the credit facilities are unconditionally guaranteed, jointly and severally, by certain of our existing domestic subsidiaries and are required to be guaranteed by certain of our future domestic subsidiaries. The obligations of our non-U.S. subsidiaries under the credit facilities are unconditionally guaranteed, jointly and severally, by us, certain of our existing domestic subsidiaries, and certain of our foreign subsidiaries, and are required to be guaranteed by certain of our future subsidiaries. All obligations of each borrower under the credit facilities, and the guarantees of those obligations, are secured, subject to certain exceptions, by substantially all of each borrower's assets and the assets of certain guarantors, including the pledge of the equity interests of certain of our subsidiaries and real estate located in Smithfield, Rhode Island, but excluding intellectual property and assets of certain foreign subsidiaries.

The Credit Agreement requires us to comply with certain financial covenants on a quarterly basis. Further, the Credit Agreement includes negative covenants, subject to exceptions, restricting or limiting our ability and the ability of our subsidiaries to, among other things, incur additional indebtedness, grant liens, engage in certain investment, acquisition and disposition transactions, pay dividends, repurchase capital stock and enter into transactions with affiliates. The Credit 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.

Operating Leases

Our operating leases are principally for facilities and equipment. We currently lease office and laboratory space at our headquarters and research and development facility in Cheshire, Connecticut, as well as office space at our regional executive and sales offices in Lausanne, Switzerland. We also lease space at our global supply chain and distribution headquarters in Dublin, Ireland. In addition to the locations above, we also lease space in other U.S. states and foreign countries to support our operations as a global organization.

In January 2015, we entered into a new lease agreement of office space in Zurich, Switzerland to support the relocation of the European headquarters currently located in Lausanne, Switzerland. The term of the lease is 10 years with a minimum renewal option of 5 years and a maximum renewal option of 10 years. Annual lease payments of approximately $2,600 will commence in the second quarter of 2015.

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.

Commercial Commitments

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

Item 7A. ***QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.***
(amounts in thousands, except percentages)

Interest Rate Risk

As of December 31, 2014, we invested our cash in a variety of financial instruments, principally money market funds, corporate bonds, municipal bonds, commercial paper and government-related obligations. Most of our interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate. Our investment portfolio is comprised of marketable securities of highly rated financial institutions and investment-grade debt instruments, and we have guidelines to limit the term-to-maturity of our investments. Based on the type of securities we hold, we do not believe a change in interest rates would have a material impact on our financial statements. If interest rates were to increase or decrease by 1%, the fair value of our investment portfolio would (decrease) increase by approximately $(11,195) and $8,455, respectively.

In February 2012, we entered into the Credit Agreement with a floating rate of interest based on LIBOR, Prime Rate, Federal Funds Rate or Eurodollar Rate, at our election, plus an applicable credit spread. We do not expect changes in interest rates related to the Credit Agreement to have a material effect on our financial statements. As of December 31, 2014, we had approximately $57,500 of variable rate debt outstanding. If interest rates were to increase or decrease by 1% for the year, annual interest expense would increase or decrease by approximately $575.

Foreign Exchange Market Risk

Our operations include activities in many countries outside the United States, including, countries in Europe, Latin America and Asia Pacific. As a result, our financial results are impacted by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets where we operate. We have exposure to movements in foreign currency exchange rates, the most significant of which are the Euro and Japanese Yen, against the U.S. dollar. We are a net receiver of many foreign currencies, and our consolidated financial results benefit from a weaker U.S. Dollar and are adversely impacted by a stronger U.S. Dollar relative to foreign currencies in which we sell our product.

Our monetary exposures on our balance sheet arise primarily from cash, accounts receivable, intercompany receivables and payables denominated in foreign currencies. Approximately 60% of our product sales were denominated in foreign currencies during 2014, and our revenues are also exposed to fluctuations in the foreign currency exchange rates over time. In certain foreign countries, we may sell in U.S. Dollar, but our customers may be impacted adversely in fluctuations in foreign currency exchange rates which may also impact us in the future.

Both positive and negative impacts to our international product sales from movements in foreign currency exchange rates are only partially mitigated by the natural, opposite impact that foreign currency exchange rates have on our international operating expenses. Additionally, we have operations based in Switzerland, and accordingly, our expenses are impacted by fluctuations in the value of the Swiss Franc against the U.S. dollar.

We currently have a derivative program in place to achieve the following: 1) limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet, using contracts with durations of up to 30 days and 2) hedge a portion of our forecasted product sales (in some currencies), including intercompany sales, using contracts with durations of up to 60 months. The objectives of this program are to reduce the volatility of our operating results due to fluctuation of foreign exchange and to increase the visibility of the foreign exchange impact on forecasted revenues. This program utilizes foreign exchange forward contracts intended to reduce, not eliminate, the volatility of operating results due to fluctuations in foreign exchange rates.

As of December 31, 2014 and 2013, we held foreign exchange forward contracts with notional amounts totaling $1,748,931 and $1,222,464, respectively. The increase in outstanding foreign exchange forward contracts resulted primarily from increases in forecasted revenues and, for certain currencies, extended duration of hedges. As of December 31, 2014 and 2013, our outstanding foreign exchange forward contracts had a net fair value of $135,166 and $(3,438), respectively. The increase in the net fair value of outstanding foreign exchange forward contracts is primarily due to the strengthening of the U.S. dollar in 2014.

We do not use derivative financial instruments for speculative trading purposes. The counterparties to these foreign exchange forward contracts are multinational commercial banks. We believe the risk of counterparty nonperformance is not material.

Based on our foreign currency exchange rate exposures at December 31, 2014, a hypothetical 10% adverse fluctuation in exchange rates would decrease the fair value of our foreign exchange forward contracts that are designated as cash flow hedges by approximately $136,500 at December 31, 2014. The resulting loss on these forward contracts would be offset by the gain on the underlying transactions and therefore would have minimal impact on future anticipated earnings and cash flows. Similarly,

adverse fluctuations in exchange rates that would decrease the fair value of our foreign exchange forward contracts that are not designated as hedge instruments would be offset by a positive impact of the underlying monetary assets and liabilities.

Credit Risk

As a result of our foreign operations, we are exposed to changes in the general economic conditions in the countries in which we conduct business. Substantially all of our accounts receivable due from these countries are due from or backed by sovereign or local governments, and the amount of non-sovereign accounts receivable is not material. We continue to monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. Although collection of our accounts receivables from certain countries may extend beyond our standard credit terms, we do not expect any such delays to have a material impact on our financial condition or results of operations.

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, 2014. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2014, 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 (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission to conduct an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2014. Based on the assessment, management has concluded that, as of December 31, 2014, our internal control over financial reporting is effective.

The effectiveness of our internal control over financial reporting as of December 31, 2014 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Changes in Internal Control over Financial Reporting.

There has been no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2014 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.

PART III

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

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

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

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

CODE OF ETHICS

We have adopted the Alexion Pharmaceuticals, Inc. Code of Conduct, or code of ethics, that applies to directors, officers and employees of Alexion and its subsidiaries and complies with the requirements of Item 406 of Regulation S-K and the listing standards of the NASDAQ Global Select Market. Our code of ethics is located on our website (http://ir.alexionpharm.com/governance.cfm). We amended the code of ethics in April 2011 and any future amendments or waivers to our code of ethics will be promptly disclosed on our website and as required by applicable laws, rules and regulations of the SEC and NASDAQ.

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

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

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

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

Item 13. ***CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.***

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

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

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

PART IV

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

Item 15(a)

(1) Financial Statements

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

(2) Financial Statement Schedules

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

(3) Exhibits:

2.1 Agreement and Plan of Merger by and among Alexion, TPCA Corporation, Taligen Therapeutics, Inc., each stockholder of Taligen that signed the Agreement as a seller of Series Bl Call Rights, and, only for the limited purposes described therein as Stockholders' Representatives (and not in their individual capacities), Nick Galakatos, Ed Hurwitz and Timothy Mills, dated as of January 28, 2011.(1)+

2.2 Agreement and Plan of Merger by and among Alexion, EMRD Corporation, Enobia Pharma Corp., and the Stockholder Representatives named therein, dated as of December 28, 2011.(2)+

2.3 Amendment No. 1 to the Agreement and Plan of Merger, dated December 28, 2011, by and among Alexion, EMRD Corporation, Enobia Pharma Corp., and the Stockholder Representatives named therein, dated February 1, 2012.(3)

3.1 Certificate of Incorporation, as amended.(4)

3.2 Certificate of Amendment of the Certificate of Incorporation.(5)

3.3 Bylaws, as amended.(6)

4.1 Specimen Common Stock Certificate.(7)

4.2 Rights Agreement between Alexion and Continental Stock Transfer & Trust Company, Rights Agent, dated as of February 14, 1997.(8)

4.3 Amendment No. 1 to Rights Agreement, dated as of September 18, 2000, between Alexion and Continental Stock Transfer and Trust Company. (9)

4.4 Amendment No. 2 to Rights Agreement, dated as of December 12, 2001, between Alexion and Continental Stock Transfer and Trust Company, which includes as Exhibit B the form of Right Certificate.(10)

4.5 Amendment No. 3 to Rights Agreement, dated as of November 16, 2004, between Alexion and Continental Stock Transfer and Trust Company. (11)

4.6 Amendment No. 4 to Rights Agreement, dated February 23, 2007, between Alexion and Continental Stock Transfer and Trust Company.(12)

10.1 Employment Agreement, dated as of February 14, 2006, between Alexion and Dr. Leonard Bell.(13)**

10.2 Amendment No. 1 to the Employment Agreement, dated as of December 23, 2009, between Alexion and Dr. Leonard Bell.(14)**

10.3 Employment Agreement, dated as of February 14, 2006, between Alexion and Dr. Stephen P. Squinto.(13)**

10.4 Amendment No. 1 to the Employment Agreement, dated as of December 23, 2009, between Alexion and Dr. Stephen P. Squinto.(14)**

10.5 Employment Agreement, dated as of February 14, 2006, between Alexion and Vikas Sinha.(13)**

10.6 Amendment No. 1 to the Employment Agreement, dated as of December 23, 2009, between Alexion and Vikas Sinha.(14)**

10.7 Form of Employment Agreement (Senior Vice Presidents).(13)**

10.8 Form of Amendment No. 1 to Employment Agreements (Senior Vice Presidents). (14)**

10.9 Form of Indemnification Agreement for Officers and Directors. (15)

10.10 Agreement of Lease, dated May 9, 2000, between Alexion and WE Knotter L.L.C.(16)+

10.11 Lease, dated November 15, 2012, between Alexion and WE Route 34, LLC.(17)

10.12 Alexion's 2000 Stock Option Plan, as amended.(18)**

10.13 Alexion's 1992 Outside Directors Stock Option Plan, as amended.(19)**

10.14 Alexion's Amended and Restated 2004 Incentive Plan.**

10.15 License Agreement dated March 27, 1996 between Alexion and Medical Research Council.(20)+

10.16 Master Manufacturing and Supply Agreement, dated December 16, 2014 between Alexion Pharma International Trading, Alexion Pharmaceuticals, Inc,, Lonza Group AG, Lonza Biologics Tuas PTE LTD and Lonza Sales AG*

10.17 Form of Stock Option Agreement for Directors.(22)**

10.18 Form of Stock Option Agreement for Executive Officers (Form A).(23)**

10.19 Form of Stock Option Agreement for Executive Officers (Form B).(23)**

10.20 Form of Restricted Stock Award Agreement for Executive Officers (Form A).(24)**

10.21 Form of Stock Option Agreement (Incentive Stock Options).(21)

10.22 Form of Stock Option Agreement (Nonqualified Stock Options).(21)

10.23 Form of Restricted Stock Award Agreement.(21)

10.24 Form of Restricted Stock Unit Award Agreement.(25)

10.25 Form of Stock Option Agreement for Participants in France.(21)**

10.26 Form of Restricted Stock Unit Agreement for Participants in France.(21)**

10.27 Credit Agreement by and among Alexion**,** certain subsidiaries of Alexion, the lenders party hereto, Bank of America, N.A., as Administrative Agent, Merrill Lynch, Pierce, Fenner & Smith Incorporated and J.P. Morgan Securities LLC, as joint lead arrangers and joint book managers. (3)

10.28 First Amendment to Credit Agreement dated November 14, 2012 by and among Alexion, certain subsidiaries of Alexion, the lenders party thereto and Bank of America, N.A., as Administrative Agent.

10.29 Consent and Second Amendment to Credit Agreement and First Amendment to Administrative Borrower Guaranty, Domestic Subsidiary Guaranty and Foreign Subsidiary Guaranty dated December 17, 2013 by and among Alexion, certain subsidiaries of Alexion, the lenders party thereto and Bank of America, N.A., as Administrative Agent.

21.1 Subsidiaries of Alexion Pharmaceuticals, Inc.

23.1 Consent of PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm

31.1 Certificate of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002.

31.2 Certificate of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.

32.1 Certificate of Chief Executive Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.

32.2 Certificate of Chief Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.

101 The following materials from the Alexion Pharmaceuticals, Inc. Annual Report on Form 10-K for the year ended December 31, 2014 formatted in eXtensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Operations, (ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Changes in Stockholders' Equity, (v) the Consolidated Statements of Cash Flows and (vi) related notes, tagged as blocks of text.

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(1) Incorporated by reference to our Report on Form 8-K, filed on February 3, 2011.
(2) Incorporated by reference to our Report on Form 8-K, filed on January 4, 2012.
(3) Incorporated by reference to our Report on Form 8-K, filed on February 7, 2012.
(4) Incorporated by reference to our Registration Statement on Form S-3 (Reg. No. 333-128085), filed on September 2, 2005.

(5) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.
(6) Incorporated by reference to our Report on Form 10-Q, filed on October 25, 2013.
(7) Incorporated by reference to our Registration Statement on Form S-1 (Reg. No. 333-00202).
(8) Incorporated by reference to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on February 21, 1997.
(9) Incorporated by reference to Amendment No. 1 to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on October 6, 2000.
(10) Incorporated by reference to Amendment No. 2 to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on February 12, 2002.
(11) Incorporated by reference to Amendment No. 3 to our Registration Statement on Form 8-A (Reg. No. 000-27756), filed on November 17, 2004.
(12) Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2006.
(13) Incorporated by reference to our Report on Form 8-K filed on February 16, 2006.
(14) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2009.
(15) Incorporated by reference to our Report on Form 8-K, filed on September 17, 2010.
(16) Incorporated by reference to our Registration Statement on Form S-3 (Reg. No. 333-36738) filed on May 10, 2000.
(17) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013.
(18) Incorporated by reference to our quarterly report on Form 10-Q for the quarter ended January 31, 2004.
(19) Incorporated by reference to our Registration Statement on Form S-8 (Reg. No. 333-71879) filed on February 5, 1999.(20) Incorporated by reference to our Annual Report on Form 10-K/A for the fiscal year ended July 31, 1996.

(21) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.
(22) Incorporated by reference to our report on Form 8-K, filed on December 16, 2004.
(23) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2005.
(24) Incorporated by reference to our report on Form 8-K, filed on March 14, 2005.
(25) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2010.

+ Confidential treatment was granted for portions of such exhibit.

* Confidential treatment requested under 17 C.F.R. §§200.80(b)(4) and 24b-2. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been filed separately with the SEC pursuant to the confidential treatment request.

** Indicates a management contract or compensatory plan or arrangement required to be filed pursuant to Item 15(b) of Form 10-K.

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.
Chairman and Chief Executive Officer
Dated: February 6, 2015

By: /s/ Vikas Sinha

Vikas Sinha, M.B.A., C.A.
Executive Vice President and Chief Financial Officer
Dated: February 6, 2015

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 **Leonard Bell, M.D.**	Chairman and Chief Executive Officer, (principal executive officer)	February 6, 2015
/s/ Vikas Sinha **Vikas Sinha, M.B.A., C.A., C.P.A.**	Executive Vice President and Chief Financial Officer (principal financial officer)	February 6, 2015
/s/ Scott Phillips **Scott Phillips, C.P.A.**	Vice President, Corporate Controller and Chief Accounting Officer (principal accounting officer)	February 6, 2015
/s/ David R. Brennan **David R. Brennan**	Director	February 6, 2015
/s/ M. Michele Burns **M. Michele Burns**	Director	February 6, 2015
/s/ Christopher J. Coughlin **Christopher J. Coughlin**	Director	February 6, 2015
/s/ David Hallal **David Hallal**	Director, Chief Operating Officer and CEO-elect	February 6, 2015
/s/ William Keller **William Keller**	Director	February 6, 2015
/s/ John T. Mollen **John T. Mollen**	Director	February 6, 2015
/s/ R. Douglas Norby **R. Douglas Norby**	Director	February 6, 2015
/s/ Alvin S. Parven **Alvin S. Parven**	Director	February 6, 2015
/s/ Andreas Rummelt **Andreas Rummelt, Ph.D.**	Director	February 6, 2015
/s/ Ann Veneman **Ann Veneman**	Director	February 6, 2015

Alexion Pharmaceuticals, Inc.

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Report of Independent Registered Public Accounting Firm

To 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, 2014 and December 31, 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements, and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

/s/ PricewaterhouseCoopers LLP

Hartford, Connecticut
February 6, 2015

Alexion Pharmaceuticals, Inc.

Consolidated Balance Sheets
(amounts in thousands, except per share amounts)

	December 31,	
	2014	2013
Assets		
Current Assets:		
Cash and cash equivalents	$ 943,999	$ 529,857
Marketable securities	1,017,567	984,994
Trade accounts receivable, net	432,888	421,752
Inventories	176,441	102,602
Deferred tax assets	35,733	41,432
Prepaid expenses and other current assets	189,401	106,220
Total current assets	2,796,029	2,186,857
Property, plant and equipment, net	392,248	201,109
Intangible assets, net	587,046	609,719
Goodwill	254,073	254,073
Deferred tax assets	34,939	3,394
Other assets	137,627	62,544
Total assets	$ 4,201,962	$ 3,317,696
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 44,016	$ 21,596
Accrued expenses	395,232	402,344
Deferred revenue	58,837	53,801
Current portion of long-term debt	48,000	48,000
Other current liabilities	60,655	56,688
Total current liabilities	606,740	582,429
Long-term debt, less current portion	9,500	65,000
Contingent consideration	116,425	106,744
Facility lease obligation	107,099	32,230
Deferred tax liabilities	7,046	101,241
Other liabilities	53,134	47,973
Total liabilities	899,944	935,617
Commitments and contingencies (Note 9)		
Stockholders' Equity:		
Preferred stock, $.0001 par value; 5,000 shares authorized, no shares issued or outstanding	—	—
Common stock, $.0001 par value; 290,000 shares authorized; 201,944 and 197,941 shares issued at December 31, 2014 and 2013, respectively	20	20
Additional paid-in capital	2,592,167	2,106,183
Treasury stock, at cost, 2,888 and 985 shares at December 31, 2014 and 2013, respectively	(382,964)	(80,365)
Accumulated other comprehensive income (loss)	56,785	(22,857)
Retained earnings	1,036,010	379,098
Total stockholders' equity	3,302,018	2,382,079
Total liabilities and stockholders' equity	$ 4,201,962	$ 3,317,696

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

Alexion Pharmaceuticals, Inc.

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

	Year Ended December 31,		
	2014	2013	2012
Net product sales	$ 2,233,733	$ 1,551,346	$ 1,134,114
Cost of sales:			
Cost of sales	173,862	168,375	126,214
Change in contingent liability from intellectual property settlements	—	9,181	(53,377)
Total cost of sales	173,862	177,556	72,837
Operating expenses:			
Research and development	513,782	317,093	222,732
Selling, general and administrative	630,209	489,720	384,678
Acquisition-related costs	20,295	5,029	22,812
Impairment of intangible assets	11,514	33,521	26,300
Restructuring expenses	15,365	—	—
Amortization of purchased intangible assets	—	417	417
Total operating expenses	1,191,165	845,780	656,939
Operating income	868,706	528,010	404,338
Other income and expense:			
Investment income	8,373	3,346	1,838
Interest expense	(2,982)	(4,112)	(7,402)
Foreign currency loss	(1,990)	(975)	(1,208)
Income before income taxes	872,107	526,269	397,566
Income tax provision	215,195	273,374	142,744
Net income	$ 656,912	$ 252,895	$ 254,822
Earnings per common share			
Basic	$ 3.32	$ 1.29	$ 1.34
Diluted	$ 3.26	$ 1.27	$ 1.28
Shares used in computing earnings per common share			
Basic	198,103	195,532	190,461
Diluted	201,623	199,712	198,501

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

Alexion Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Income
(amounts in thousands)

	Year Ended December 31,		
	2014	2013	2012
Net income	$ 656,912	$ 252,895	$ 254,822
Other comprehensive income (loss), net of tax:			
Foreign currency translation	(6,337)	(4,573)	150
Unrealized losses on marketable securities, net of tax of $99, $(75) and $0, respectively	(88)	(146)	—
Unrealized losses on pension obligation, net of tax of $(1,574), $(547) and $(143), respectively	(5,068)	(5,790)	(1,529)
Unrealized gains (losses) on hedging activities, net of tax of $45,448, $(871) and $232, respectively	91,135	(18,983)	3,835
Other comprehensive income (loss), net of tax	79,642	(29,492)	2,456
Comprehensive income	$ 736,554	$ 223,403	$ 257,278

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

Alexion Pharmaceuticals, Inc.

Consolidated Statements of Changes in Stockholders' Equity
(amounts in thousands)

	Common Stock		Additional Paid-In Capital	Treasury Stock at Cost		Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Deficit)	Total Stockholders Equity
	Shares Issued	Amount		Shares	Amount			
Balances, December 31, 2011	185,616	$ 19	$ 1,261,589	97	$ (2,676)	$ 4,179	$ (128,619)	$ 1,134,492
Issuance of common stock, net of issuance costs of $207	5,000	1	462,212	—	—	—	—	462,213
Conversion of convertible notes to common stock	91	—	718	—	—	—	—	718
Repurchase of common stock	—	—	—	130	(11,553)	—	—	(11,553)
Issuance of common stock from exercise of options	3,918	—	66,438	—	—	—	—	66,438
Issuance of restricted common stock	293	—	—	—	—	—	—	—
Excess tax benefit from stock options	—	—	7,228	—	—	—	—	7,228
Share-based compensation expense	—	—	54,036	—	—	—	—	54,036
Net income	—	—	—	—	—	—	254,822	254,822
Other comprehensive income	—	—	$ —	—	—	2,456	—	$ 2,456
Balances, December 31, 2012	194,918	$ 20	$ 1,852,221	227	$ (14,229)	$ 6,635	$ 126,203	$ 1,970,850
Repurchase of common stock	—	—	—	758	(66,136)	—	—	(66,136)
Issuance of common stock from exercise of options	2,481	—	71,281	—	—	—	—	71,281
Issuance of restricted common stock	542	—	—	—	—	—	—	—
Excess tax benefit from stock options	—	—	105,714	—	—	—	—	105,714
Share-based compensation expense	—	—	76,967	—	—	—	—	76,967
Net income	—	—	—	—	—	—	252,895	252,895
Other comprehensive loss	—	—	—	—	—	(29,492)	—	(29,492)
Balances, December 31, 2013	197,941	$ 20	$ 2,106,183	985	$ (80,365)	$ (22,857)	$ 379,098	$ 2,382,079
Repurchase of common stock	—	—	—	1,903	(302,599)	—	—	(302,599)
Issuance of common stock from exercise of options	3,408	—	114,350	—	—	—	—	114,350
Issuance of restricted common stock	595	—	—	—	—	—	—	—
Excess tax benefit from stock options	—	—	251,136	—	—	—	—	251,136
Share-based compensation expense	—	—	120,498	—	—	—	—	120,498
Net income	—	—	—	—	—	—	656,912	656,912
Other comprehensive loss	—	—	—	—	—	79,642	—	79,642
Balances, December 31, 2014	201,944	$ 20	$ 2,592,167	2,888	$ (382,964)	$ 56,785	$ 1,036,010	$ 3,302,018

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

Alexion Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows
(amounts in thousands)

	Year Ended December 31,		
	2014	2013	2012
Cash flows from operating activities:			
Net income	$ 656,912	$ 252,895	$ 254,822
Adjustments to reconcile net income to net cash flows from operating activities:			
Depreciation and amortization	46,939	28,693	23,887
Impairment of intangible assets	11,514	33,521	26,300
Change in fair value of contingent consideration	20,295	4,006	6,550
Share-based compensation expense	114,461	76,203	54,013
Premium amortization of available-for-sale securities	15,519	3,235	—
Deferred taxes	(153,905)	92,831	71,155
Excess tax benefit from stock options	(251,136)	(105,714)	(7,228)
Other	22,046	2,040	(4,833)
Changes in operating assets and liabilities, excluding the effect of acquisitions:			
Accounts receivable	(28,137)	(116,439)	(72,870)
Inventories	(66,812)	126	(6,265)
Prepaid expenses and other assets	(18,392)	(39,879)	(17,041)
Accounts payable, accrued expenses and other liabilities	264,572	242,355	68,951
Deferred revenue	6,199	23,476	13,172
Net cash provided by operating activities	640,075	497,349	410,613
Cash flows from investing activities:			
Purchases of available-for-sale securities	(664,228)	(1,048,429)	—
Proceeds from maturity or sale of available-for-sale securities	619,447	60,917	—
Purchases of trading securities	(3,431)	(985)	—
Purchases of property, plant and equipment	(136,650)	(29,329)	(21,846)
Purchases of other investments	(37,500)	—	—
Payments for acquisitions of businesses, net of cash acquired	—	—	(605,735)
Other	(507)	(9,315)	(4)
Net cash used in investing activities	(222,869)	(1,027,141)	(627,585)
Cash flows from financing activities:			
Debt issuance costs	—	—	(6,184)
Proceeds from revolving credit facility	—	—	115,000
Payments on revolving credit facility	—	—	(115,000)
Proceeds from term loan	—	—	240,000
Payments on term loan	(55,500)	(36,000)	(91,000)
Excess tax benefit from stock options	251,136	105,714	7,228
Repurchase of common stock	(302,599)	(66,136)	(11,553)
Net proceeds from issuance of common stock	—	—	462,212
Net proceeds from the exercise of stock options	114,350	71,281	66,438
Payment of contingent consideration		(3,000)	—
Other	(261)	(220)	(765)
Net cash provided by financing activities	7,126	71,639	666,376
Effect of exchange rate changes on cash	(10,190)	(1,491)	(768)
Net change in cash and cash equivalents	414,142	(459,644)	448,636
Cash and cash equivalents at beginning of period	529,857	989,501	540,865
Cash and cash equivalents at end of period	$ 943,999	$ 529,857	$ 989,501
Supplemental cash flow disclosures:			
Cash paid for interest (net of amounts capitalized)	$ 1,910	$ 2,831	$ 4,475
Cash paid for income taxes	$ 91,195	$ 76,165	$ 18,272
Supplemental cash flow disclosures from investing and financing activities:			
Contingent consideration issued in acquisitions	$ —	$ —	$ 117,000
Construction in process related to facility lease obligation	$ 74,869	$ 32,230	$ —
Increase in accrued expenses for purchases of property, plant and equipment	$ 17,092	$ —	$ —

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

1. Business Overview and Summary of Significant Accounting Policies

Business

Alexion Pharmaceuticals, Inc. (Alexion, the Company, we, our or us) is a biopharmaceutical company focused on serving patients with severe and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Our marketed product Soliris is the first and only therapeutic approved for patients with either of two severe and ultra-rare disorders resulting from chronic uncontrolled activation of the complement component of the immune system: paroxysmal nocturnal hemoglobinuria (PNH), a life-threatening and ultra-rare genetic blood disorder, and atypical hemolytic uremic syndrome (aHUS), a life-threatening and ultra-rare genetic disease. We are also evaluating additional potential indications for Soliris in other severe and devastating diseases in which uncontrolled complement activation is the underlying mechanism, and we are progressing in various stages of development with additional product candidates as potential treatments for patients with severe and life-threatening ultra-rare disorders. We were incorporated in 1992 and began commercial sale of Soliris in 2007.

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Alexion and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. For each of our business combinations, all of the assets acquired and liabilities assumed were recorded at their respective fair values as of the date of acquisition, and their results of operations are included in the consolidated financial statements from the date of acquisition.

Dividend Policy

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

Critical Accounting Estimates

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

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

- Revenue recognition;
- Contingent liabilities;
- Inventories;
- Research and development expenses;
- Share-based compensation;
- Valuation of goodwill, acquired intangible assets and in-process research and development (IPR&D);
- Valuation of contingent consideration; and
- Income taxes.

Foreign Currency Translation

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

comprehensive income (loss), net of tax, in stockholders' equity. Foreign currency transaction gains and losses are included in the results of operations in other income and expense.

Cash and Cash Equivalents

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

Fair Value of Financial Instruments

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, other assets, accounts payable, accrued expenses and other liabilities approximate fair value due to their short-term maturities. Our marketable securities are valued based upon pricing of securities with similar investment characteristics and holdings. Our derivative financial instruments are measured at fair value using observable market inputs such as forward rates, interest rates, our own credit risk and our counterparties' credit risks. Our debt obligations are carried at historical cost, which approximates fair value. Our contingent consideration liabilities related to our acquisitions are valued based on various estimates, including probability of success, estimated revenues, discount rates and amount of time until the conditions of the milestone payments are met.

Marketable Securities

We invest our excess cash balances in marketable securities of highly rated financial institutions and investment-grade debt instruments. We seek to diversify our investments and limit the amount of investment concentrations for individual institutions, maturities and investment types. We classify these marketable securities as available-for-sale and, accordingly, record such securities at fair value. We classify these marketable securities as current assets as these investments are intended to be available to the Company for use in funding current operations.

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

We sponsor a nonqualified deferred compensation plan which allows certain highly-compensated employees to elect to defer income to future periods. Participants in the plan earn a return on their deferrals based on several investments options, which mirror returns on underlying mutual fund investments. We choose to invest in the underlying mutual fund investments to offset the liability associated with our nonqualified deferred compensation plan. These securities are classified as trading securities and are carried at fair value with gains and losses included in investment income. The changes in the underlying liability to the employee are recorded in operating expenses.

Accounts Receivable

Our standard credit terms vary based on the country of sale and range from 30 to 120 days. Our consolidated average days' sales outstanding ranges from 60 to 70 days. We evaluate the creditworthiness of customers on a regular basis. In certain European countries, sales by us are subject to payment terms that are statutorily determined. This is primarily the case in countries where the payer is government-owned or government-funded, which we consider to be creditworthy. The length of time from sale to receipt of payment in certain countries exceeds our credit terms. In countries in which collections from customers extend beyond normal payment terms, we seek to collect interest. We record interest on customer receivables as interest income when collected. For non-interest bearing receivables with an estimated payment beyond one year, we discount the accounts receivable to present value at the date of sale, with a corresponding adjustment to revenue. Subsequent adjustments for further declines in credit rating are recorded as bad debt expense as a component of selling, general and administrative expense. We also use judgments as to our ability to collect outstanding receivables and provide allowances for the portion of receivables if and when collection becomes doubtful, and we also assess on an ongoing basis whether collectibility is reasonably assured at the time of sale.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk are limited to cash equivalents, marketable securities, accounts receivable and our foreign exchange derivative contracts. We invest our cash reserves in money market funds or high-quality marketable securities in accordance with our investment policy. The stated objectives of our investment policy is to preserve capital, provide liquidity consistent with forecasted cash flow requirements, maintain appropriate diversification and generate returns relative to these investment objectives and prevailing market conditions.

At December 31, 2014, four individual customers accounted for 58% of the accounts receivable balance, with individual customers ranging from 10% to 23% of the accounts receivable balance. At December 31, 2013, two individual customers accounted for 30% of the accounts receivable balance, with individual customers accounting for 10% and 20%. For the years ended December 31, 2014 and 2013, one customer accounted for 18% and 20%, respectively, of our product sales. No other customers accounted for more than 10% of net product sales or accounts receivable.

As a result of our foreign operations, we are exposed to changes in the general economic conditions in the countries in which we conduct business. Substantially all of our accounts receivable due from these countries are due from or backed by sovereign or local governments, and the amount of non-sovereign accounts receivable is not material. We continue to monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. The adverse credit and economic conditions in Italy and Spain, among other members of the European Union, have improved in recent periods and, although collection of our accounts receivables due from these countries may extend beyond our standard credit terms, we do not expect any such delays to have a material impact on our financial condition or results of operations.

Inventories

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

The components of inventory are as follows:

	December 31,	
	2014	2013
Raw materials	$ 14,570	$ 12,170
Work-in-process	107,170	62,192
Finished goods	54,701	28,240
	$ 176,441	$ 102,602

Capitalization of Inventory Costs

We capitalize inventory produced for commercial sale, which may include costs incurred for certain products awaiting regulatory approval. We capitalize inventory produced in preparation of product launches sufficient to support estimated initial market demand. Capitalization of such inventory begins when we have (i) obtained positive results in clinical trials that we believe are necessary to support regulatory approval, (ii) concluded that uncertainties regarding regulatory approval have been sufficiently reduced, and (iii) determined that the inventory has probable future economic benefit. In evaluating whether these conditions have been met, we consider clinical trial results for the underlying product candidate, results from meetings with regulatory authorities, and the compilation of the regulatory application. If we are aware of any material risks or contingencies outside of the standard regulatory review and approval process, or if there are any specific negative issues identified relating to the safety, efficacy, manufacturing, marketing or labeling of the product that would have a significant negative impact on its future economic benefits, the related inventory would not be capitalized. At December 31, 2014, we capitalized $22,005 of inventory produced for commercial sale for products awaiting regulatory approval. At December 31, 2013, we did not capitalize any inventory associated with such products.

Products that have been approved by the U.S. Food and Drug Administration (FDA) or other regulatory authorities, such as Soliris, are also used in clinical programs to assess the safety and efficacy of the products for usage in diseases that have not been approved by the FDA or other regulatory authorities. The form of Soliris utilized for both commercial and clinical programs is identical and, as a result, the inventory has an "alternative future use" as defined in authoritative guidance. Raw materials and purchased drug product associated with clinical development programs are included in inventory and charged to

research and development expense when the product enters the research and development process and no longer can be used for commercial purposes and, therefore, does not have an "alternative future use".

For products which are under development and have not yet been approved by regulatory authorities, purchased drug product is charged to research and development expense upon delivery. Delivery occurs when the inventory passes quality inspection and ownership transfers to us. Nonrefundable advance payments for research and development activities, including production of purchased drug product, are deferred and capitalized until the goods are delivered. We also recognize expense for raw materials purchased for developmental purposes when the raw materials pass quality inspection and we have an obligation to pay for the materials.

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 no longer meet quality specifications or may expire, which requires adjustments to our inventory values. We also apply judgment related to the results of quality tests that we perform throughout the production process, as well as our understanding of regulatory guidelines, to determine if it is probable that inventory will be saleable. These quality tests are performed throughout the pre-and post-production process, and we continually gather additional information regarding product quality for periods after the manufacture date. Soliris currently has a maximum estimated life of 48 months and, based on our sales forecasts, we expect to realize the carrying value of the Soliris inventory. In the future, reduced demand, quality issues or excess supply beyond those anticipated by management may result in a material adjustment to inventory levels, which would be recorded as an increase to cost of sales.

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. For inventories that are capitalized in preparation of product launch, we also consider the expected approval date in assessing realizability. To the extent that inventory is expected to expire prior to being sold, we will write down the value of inventory.

Derivative Instruments

We record the fair value of derivative instruments as either assets or liabilities on the balance sheet. The accounting for gains and losses resulting from changes in fair value is dependent on the use of the derivative and whether it is designated and qualifies for hedge accounting.

All qualifying hedging activities are documented at the inception of the hedge and must meet the definition of highly effective in offsetting changes to future cash. The effectiveness of the qualifying hedge contract is assessed quarterly. We record the fair value of the qualifying hedges in other current assets, other assets, other current liabilities and other liabilities. Gains or losses resulting from changes in the fair value of qualifying hedges are recorded in other comprehensive income (loss) until the forecasted transaction occurs. When the forecasted transaction occurs, this amount is reclassified into revenue. Any non-qualifying portion of the gains or losses resulting from changes in fair value, if any, is reported in other income and expense.

Property, Plant and Equipment

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

- Building and improvements—five to thirty years
- Machinery and laboratory equipment—three to ten years
- Computer hardware and software—three to five years
- Furniture and office equipment—three years

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

Construction-in-progress reflects amounts incurred for property, plant, or equipment construction or improvements that have not been placed in service.

Manufacturing Facilities

We capitalize costs incurred for the construction of facilities which support commercial manufacturing. We also capitalize costs related to validation activities which are directly attributable to preparing the facility for its intended use, including engineering runs and inventory production necessary to obtain approval of the facility from government regulators for the production of a commercially approved drug. When the facility is substantially complete and ready for its intended use and regulatory approval for commercial production has been received, we will place the asset in service.

The production of inventory for preparing the facility for its intended use requires two types of production: engineering runs which are used for testing purposes only and do not result in saleable inventory, and validation runs which are used for validating equipment and may result in saleable inventory. The costs associated with inventory produced during engineering runs and normal production losses during validation runs are capitalized to fixed assets and depreciated over the asset's useful life. Saleable inventory produced during the validation process is initially treated as a fixed asset; however, upon regulatory approval, this inventory is reclassified to inventory and expensed in cost of goods sold as product is sold, or in research and development expenses as product is utilized in R&D activities. Abnormal production costs incurred during the validation process are expensed as incurred.

Acquisitions

Business combinations are accounted for using the acquisition method of accounting. Under the acquisition method of accounting, the tangible and intangible assets acquired and the liabilities assumed are recorded as of the acquisition date at their respective fair values. We evaluate a business as an integrated set of activities and assets that is capable of being managed for the purpose of providing a return in the form of dividends, lower costs or other economic benefits and consists of inputs and processes that provide or have the ability to provide outputs. In an acquisition of a business, the excess of the fair value of the consideration transferred over the fair value of the net assets acquired is recorded as goodwill. In an acquisition of net assets that does not constitute a business, no goodwill is recognized.

Our consolidated financial statements include the results of operations of an acquired business after the completion of the acquisition.

Intangible Assets

Our intangible assets consist of licenses, patents, purchased technology and acquired in-process research and development (IPR&D). Intangible assets with definite lives are amortized over their estimated useful lives and reviewed periodically for impairment.

Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized based on their estimated useful lives at that point in time.

Goodwill

Goodwill represents the excess of purchase price over fair value of net assets acquired in a business combination and is not amortized. Goodwill is subject to impairment testing at least annually or when a triggering event occurs that could indicate a potential impairment. We are organized and operate as a single reporting unit and therefore the goodwill impairment test is performed using our overall market value, as determined by our traded share price, compared to our book value of net assets. We completed our annual impairment test as of December 31, 2014 and determined the carrying value of goodwill was not impaired.

Impairment of Long-Lived Assets

Our long-lived assets are primarily comprised of intangible assets and property, plant and equipment. We evaluate our finite-lived intangible assets and property, plant and equipment, for impairment whenever events or changes in circumstances indicate the carrying value of an asset or group of assets is not recoverable. If these circumstances exist, 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 asset 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.

In addition, indefinite-lived intangible assets, comprised of IPR&D, are reviewed for impairment annually and whenever events or changes in circumstances indicate that it is more likely than not that the asset is impaired by comparing the fair value to the carrying value of the asset.

We recognized impairment charges associated with early stage indefinite-lived intangible assets acquired in connection with the purchase of Taligen and Orphatec of $11,514 in 2014. We recognized impairment charges associated with an early stage indefinite-lived intangible asset and a purchased technology asset acquired in connection with the purchase of Taligen of $33,521 in 2013, and we recognized impairment charges associated with an early stage indefinite-lived intangible asset acquired in connection with the purchase of Taligen of $26,300 in 2012. We did not recognize any other impairment loss for long-lived assets during the years ended December 31, 2014, 2013 and 2012.

Contingent Consideration

We record contingent consideration resulting from a business combination at its fair value on the acquisition date. On a quarterly basis, we revalue these obligations and record increases or decreases in their fair value as an adjustment to operating earnings. Changes to contingent consideration obligations can result from adjustments to discount rates, accretion of the liability due to the passage of time, changes in our estimates of the likelihood or timing of achieving development or commercial milestones, changes in the probability of certain clinical events or changes in the assumed probability associated with regulatory approval.

Contingent Liabilities

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

Treasury Stock

Treasury stock is accounted for using the cost method, with the purchase price of the common stock recorded separately as a deduction from stockholders' equity.

Revenue Recognition

Our principal source of revenue is 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. Depending on these criteria, revenue is usually recorded upon receipt of the product by the end customer, which is typically a hospital, physician’s office, private or government pharmacy or other health care facility. On a regular basis, we review revenue arrangements, such as distributor relationships, to determine whether changes in these criteria have an impact on revenue recognition. Amounts collected from customers and remitted to governmental authorities, such as value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in our consolidated statements of operations and do not impact net product sales.

Our customers are primarily comprised of distributors, pharmacies, hospitals, hospital buying groups, and other health care providers. In some cases, we may also sell Soliris to governments and government agencies.

Because of factors such as the pricing of Soliris, the limited number of patients, the short period from product sale to patient infusion and the lack of contractual return rights, Soliris customers often carry limited inventory. We also monitor inventory within our sales channels to determine whether deferrals are appropriate based on factors such as inventory levels compared to demand, contractual terms and financial strength of distributors. In some cases, exact quantities of inventory in the channel are not precisely known, requiring us to estimate these amounts. If actual amounts of inventory differ from these estimates, these adjustments could have an impact in the period in which these estimates change.

In addition to sales in countries where Soliris is commercially available, we have also recorded revenue on sales for patients receiving Soliris treatment through named-patient programs. The relevant authorities or institutions in those countries

have agreed to reimburse for product sold on a named-patient basis where Soliris has not received final approval for commercial sale.

We record estimated rebates payable under governmental programs, including Medicaid in the United States and other programs outside the United States, as a reduction of revenue at the time of product sale. Our calculations related to these rebate accruals require analysis of historical claim patterns and estimates of customer mix to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period and record any necessary adjustments, which may have an impact on revenue in the period in which the adjustment is made. Generally, the length of time between product sale and the processing and reporting of the rebates is three to six months.

We have entered into volume-based arrangements with governments in certain countries in which reimbursement is limited to a contractual amount. Under this type of arrangement, amounts billed in excess of the contractual limitation are repaid to these governments as a rebate. We estimate incremental discounts resulting from these contractual limitations, based on estimated sales during the limitation period, and we apply the discount percentage to product shipments as a reduction of revenue. Our calculations related to these arrangements require estimation of sales during the limitation period, and adjustments in these estimates may have a material impact in the period in which these estimates change.

We record distribution and other fees paid to our customers as a reduction of revenue, unless we receive an identifiable and separate benefit for the consideration and we can reasonably estimate the fair value of the benefit received. If both conditions are met, we record the consideration paid to the customer as an operating expense. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

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

Research and Development Expenses

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

Share-Based Compensation

We have one share-based compensation plan known as the Amended and Restated 2004 Incentive Plan. Under this plan, restricted stock, restricted stock units, stock options and other stock-related awards may be granted to our directors, officers, employees and consultants or advisors of the Company or any subsidiary. To date, share-based compensation issued under the plan consists of incentive and non-qualified stock options, restricted stock and restricted stock units, including restricted stock units with market and non-market performance conditions.

Compensation expense for our share-based awards is recognized based on the estimated fair value of the awards on the grant date. Compensation expense reflects an estimate of the number of awards expected to vest and is primarily recognized on a straight-line basis over the requisite service period of the individual grants, which typically equals the vesting period. Compensation expense for awards with performance conditions is recognized using the graded-vesting method.

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 and the reduction in the expense from expected forfeitures. We currently use historical exercise and cancellation patterns as our best estimate of future estimated life.

For our non-market performance-based awards, we estimate the anticipated achievement of the performance targets, including forecasting the achievement of future financial targets. These estimates are revised periodically based on the probability of achieving the performance targets and adjustments are made throughout the performance period as necessary. We use payout simulation models to estimate the grant date fair value of market performance-based awards. The payout

simulation models assume volatility of our common stock and the common stock of a comparator group of companies, as well as correlations of returns of the price of our common stock and the common stock prices of the comparator group.

Earnings Per Common Share

Basic earnings per common share (EPS) are computed by dividing net income by the weighted-average number of shares of common stock outstanding. For purposes of calculating diluted EPS, the denominator reflects the potential dilution that could occur if stock options, unvested restricted stock, unvested restricted stock units or other contracts to issue common stock were exercised or converted into common stock, using the treasury stock method.

The following table summarizes the calculation of basic and diluted EPS for years ended December 31, 2014, 2013 and 2012:

	Year Ended December 31,		
	2014	2013	2012
Net income used for basic and diluted calculation	$ 656,912	$ 252,895	$ 254,822
Shares used in computing earnings per common share—basic	198,103	195,532	190,461
Weighted-average effect of dilutive securities:			
Shares issuable upon the assumed conversion of our 1.375% convertible senior notes	—	—	8
Stock awards	3,520	4,180	8,032
Dilutive potential common shares	3,520	4,180	8,040
Shares used in computing earnings per common share—diluted	201,623	199,712	198,501
Earnings per common share:			
Basic	$ 3.32	$ 1.29	$ 1.34
Diluted	$ 3.26	$ 1.27	$ 1.28

We exclude from EPS the weighted-average number of securities whose effect is anti-dilutive. Excluded from the calculation of EPS for the years ended December 31, 2014, 2013 and 2012 were 1,099, 2,243, and 1,899 shares of common stock, respectively, because their effect is anti-dilutive.

Income Taxes

We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax basis of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowance when it is more likely than not that deferred tax assets will not be realized.

We recognize the benefit of an uncertain tax position that has been taken or we expect to take on income tax returns if such tax position is more likely than not to be sustained. The tax benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of unrecognized tax benefits is adjusted, as appropriate, for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, or new information obtained during a tax examination or resolution of an examination. We also accrued for potential interest and penalties related to unrecognized tax benefits as a component of tax expense.

Comprehensive Income

Comprehensive income is comprised of net income and other comprehensive income (loss). Other comprehensive income (loss) includes changes in equity that are excluded from net income, such as changes in pension liabilities, unrealized gains and losses on marketable securities, unrealized gains and losses on hedge contracts and foreign currency translation adjustments. Certain of these changes in equity are reflected net of tax.

Other Investments

We invest in companies with securities that are not publicly traded and where fair value is not readily available. Other investments include an investment in the preferred stock of the non-public entity Moderna LLC. During 2014, we purchased $37,500 of preferred equity of Moderna LLC. We recorded our investment at cost within other assets in our condensed consolidated balance sheets. We regularly monitor these investments to evaluate whether there has been an other-than-temporary decline in its fair value, based on the implied value of recent company financings, public market prices of comparable companies, and general market conditions. The carrying value of these investments was not impaired as of December 31, 2014.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2016 and allows for adoption using a full retrospective method, or a modified retrospective method. We are currently assessing the method of adoption and the expected impact the new standard has on our financial position and results of operations.

2. Acquisitions

Acquisition of Enobia Pharma Corp.

In February 2012, we acquired Enobia Pharma Corp. (Enobia), a privately held clinical-stage biotechnology company based in Montreal, Canada and Cambridge, Massachusetts, in a transaction accounted for under the acquisition method of accounting for business combinations. Under the acquisition method of accounting, the assets acquired and liabilities assumed of Enobia were recorded as of the acquisition date at their respective fair values. The reported consolidated financial condition after completion of the acquisition reflects these fair values. Enobia's results of operations are included in the consolidated financial statements from the date of acquisition. The acquisition was intended to further our objective to develop and commercialize therapies for patients with severe, ultra-rare and life-threatening disorders. Enobia's lead product candidate, asfotase alfa, is a human recombinant targeted alkaline phosphatase enzyme-replacement therapy for patients suffering with hypophosphatasia (HPP), an ultra-rare, life-threatening, genetic metabolic disease for which there are no approved treatments.

We made an upfront cash payment of $623,876 for 100% of Enobia's capital stock. Additional contingent payments of up to an aggregate of $470,000 would be due upon reaching various regulatory and sales milestones. We financed the acquisition with existing cash and proceeds from our new credit facility.

A reconciliation of upfront payments in accordance with the purchase agreement to the total purchase price is presented below:

	Enobia
Base payment per agreement	$ 610,000
Cash acquired	18,141
Working capital adjustment	(4,265)
Upfront payment in accordance with agreement	623,876
Estimated fair value of contingent consideration	117,000
Total purchase price	**$ 740,876**

The initial estimate of fair value of contingent consideration was $117,000, which was recorded as a noncurrent liability. We determined the fair value of these obligations to pay additional milestone payments using various estimates, including probabilities of success, discount rates and amount of time until the conditions of the milestone payments are met. This fair value measurement is based on significant inputs not observable in the market, representing a Level 3 measurement within the fair value hierarchy. The resulting probability-weighted cash flows were discounted using a cost of debt rate of 5.2% for developmental milestones and a weighted average cost of capital rate of 13.0% for commercial milestones. These rates were

representative of market participant assumptions. The range of estimated milestone payments is from zero if no clinical milestones are achieved for any product to $470,000 if various regulatory and sales milestones are achieved.

Subsequent to the acquisition date, we have adjusted the contingent consideration to fair value with changes in fair value recognized in operating earnings. Changes in fair values reflect new information about the probability and timing of meeting the conditions of the milestone payments. In the absence of new information, changes in fair value will only reflect the interest component of contingent consideration related to the passage of time as development work progresses towards the achievement of the milestones. At December 31, 2014, the fair value of the contingent consideration for Enobia was $155,299. Changes in fair value of the consideration for Enobia were $22,286 and $8,602 for the years ended December 31, 2014 and 2013, respectively.

The following table summarizes the estimated fair values of assets acquired and liabilities assumed:

	Enobia
Cash and cash equivalents	$ 18,141
Current assets	5,536
In-process research and development	587,000
Other noncurrent assets	910
Assets acquired	**611,587**
Deferred tax liability	(31,471)
Other liabilities assumed	(13,674)
Liabilities assumed	**(45,145)**
Goodwill	**174,434**
Net assets acquired	**$ 740,876**

Asset categories acquired in the Enobia acquisition included working capital, fixed assets, deferred tax assets and IPR&D. The fair value of working capital was determined to approximate book values.

Intangible assets associated with IPR&D projects relate to Enobia's lead product candidate, asfotase alfa. The estimated fair value of $587,000 was determined using the multi-period excess earnings method, a variation of the income approach. The multi-period excess earnings method estimates the value of an intangible asset equal to the present value of the incremental after-tax cash flows attributable to that intangible asset. The fair value using the multi-period excess earnings method was dependent on an estimated weighted average cost of capital for Enobia of 13.0%, which represents a rate of return that a market participant would expect for these assets.

The excess of purchase price over the fair value amounts of the assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. We do not expect any portion of this goodwill to be deductible for tax purposes. The goodwill attributable to our acquisition of Enobia has been recorded as a noncurrent asset and is not amortized, but is subject to an annual review for impairment. The factors that contributed to the recognition of goodwill included the synergies that are specific to our business and not available to market participants, including our unique ability to commercialize therapies for rare diseases, our skills and relationships related to biologics manufacturing, our existing relationships with specialty physicians who can identify patients with HPP and a global distribution network to facilitate immediate drug delivery.

We recorded a net deferred tax liability of $31,471. This amount was primarily comprised of $78,527 related to IPR&D, offset by acquired net operating losses and research credit carryovers totaling $47,056.

For the year ended December 31, 2012, we recorded $6,794 of expenses associated with the operations of Enobia from February 7, 2012 through March 31, 2012 in our condensed consolidated statement of comprehensive income. Effective April 1, 2012, the operations of Enobia were integrated into our operations.

Pro forma financial information (unaudited)

The following unaudited pro forma information presents the combined results of operations for the years ended December 31, 2012, as if the acquisition of Enobia had been completed on January 1, 2012. The pro forma results do not reflect operating efficiencies or potential cost savings which may result from the consolidation of operations. The pro forma results have been adjusted to remove costs associated with changes in the fair value of Enobia's preferred stock. Included in the pro forma net income for the year ended December 31, 2012, are approximately $23,673 and $7,900 of Alexion and Enobia acquisition-related costs, respectively, which are not expected to have an ongoing impact.

	Year Ended December 31, 2012
Revenues	$ 1,134,114
Net income	236,407
Earnings per common share	
Basic	$ 1.24
Diluted	$ 1.19

Other Acquisitions

Orphatec Pharmaceuticals GmbH

In February 2011, we acquired certain patents and assets from Orphatec Pharmaceuticals GmbH (Orphatec) related to an investigational therapy for patients with molybdenum cofactor deficiency (MoCD) Type A, an ultra-rare genetic disorder characterized by severe brain damage and rapid death in newborns. We made initial payments of $3,050 in cash and may make additional future payments of up to $42,000 in contingent milestone payments upon various development, regulatory and commercial milestones. The range of estimated milestone payments is from zero if no products gain market approval to $42,000 if all indications for up to two products gain both U.S. and European marketing approval and reach applicable sales levels.

The initial estimate of fair value of contingent consideration was $5,086. Subsequent to the acquisition date, we have measured the contingent consideration arrangement at fair value with changes in fair value recognized in operating earnings. As of December 31, 2014 we made a milestone payment of $3,000 related to this acquisition. At December 31, 2014, the fair value of the contingent consideration for Orphatec was $5,936. Changes in fair value of the consideration for Orphatec were $232, $1,181 and $2,087 for the years ended December 31, 2014, 2013 and 2012, respectively.

Taligen Therapeutics, Inc.

In January 2011, we acquired all of the outstanding capital stock of Taligen Therapeutics, Inc. (Taligen) in a transaction accounted for under the acquisition method of accounting for business combinations. We made initial payments of $111,773 in cash and may make additional future payments of up to $367,000 in contingent milestone payments upon achievement of various development and commercial milestones. The range of estimated milestone payments is from zero if no clinical milestones are achieved for any product to $367,000 if six products gain both U.S. and European marketing approval.

The initial estimate of fair value of contingent consideration was $11,634. Subsequent to the acquisition date, we have adjusted the contingent consideration to fair value with changes in fair value recognized in operating earnings. At December 31, 2014, the fair value of the contingent consideration for Taligen was $1,736. Changes in fair value of the consideration for Taligen were $(2,223), $(5,777) and $(2,948) for the years ended December 31, 2014, 2013 and 2012, respectively. Included in the change in fair value for the years ended December 31, 2014 and 2013 is a benefit of $2,458 and $5,973, respectively, related to the decrease in the fair value of the contingent consideration related to this acquisition. The decrease in fair value was a result of a decreased likelihood of payments for contingent consideration due to a reassessment of scientific findings.

Acquisition-Related Costs

Acquisition-related costs associated with our business combinations for the years ended December 31, 2014, 2013 and 2012 include the following:

	Year Ended December 31,		
	2014	2013	2012
Separately-identifiable employee costs	$ —	$ 248	$ 3,669
Professional fees	—	775	12,593
Changes in fair value of contingent consideration	20,295	4,006	6,550
	$ 20,295	**$ 5,029**	**$ 22,812**

During the years ended December 31, 2014, 2013 and 2012, we incurred costs of approximately $22,286, $9,625 and $23,673, respectively, related to the Enobia acquisition, which are included in the amounts above.

3. Property, Plant and Equipment, Net

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

	December 31, 2014	December 31, 2013
Land	$ 9,130	$ 692
Buildings and improvements	170,355	154,996
Machinery and laboratory equipment	65,079	56,130
Computer hardware and software	59,927	41,704
Furniture and office equipment	11,371	10,119
Construction-in-progress	214,041	41,573
	529,903	305,214
Less: Accumulated depreciation and amortization	(137,655)	(104,105)
	$ 392,248	$ 201,109

Included in construction-in-progress at December 31, 2014 and 2013 was $126,566 and $32,230, respectively of costs associated with the construction of a new facility in New Haven, Connecticut. In November 2012, we entered into a lease agreement for office and laboratory space to be constructed in New Haven. Although we will not legally own the premises, we are deemed to be the owner of the building during the construction period based on applicable accounting guidance for build-to-suit leases due to our involvement during the construction period. Accordingly, the landlord's costs of constructing the facility are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our consolidated balance sheet. Construction of the new facility began in June 2013 and is expected to be completed in 2015.

Depreciation and amortization of property, plant and equipment was approximately $34,901, $19,084 and $15,192 for the years ended December 31, 2014, 2013 and 2012, respectively.

At December 31, 2014 and 2013, computer software costs included in property, plant and equipment were $16,292 and $9,691, respectively. Depreciation and amortization expense for capitalized computer software costs was $7,016, $4,503 and $4,228 for the years ended December 31, 2014, 2013 and 2012, respectively.

4. Intangible Assets and Goodwill

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

		December 31, 2014			December 31, 2013		
	Estimated Life (months)	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Licenses	72-96	$ 28,507	$ (28,461)	$ 46	$ 28,507	$ (18,719)	$ 9,788
Patents	84	10,517	(10,517)	—	10,517	(9,100)	1,417
Purchased technology	144	—	—	—	—	—	—
Acquired IPR&D	Indefinite	587,000	—	587,000	598,514	—	598,514
Total		$ 626,024	$ (38,978)	$ 587,046	$ 637,538	$ (27,819)	$ 609,719
Goodwill	Indefinite	$ 256,974	$ (2,901)	$ 254,073	$ 256,974	$ (2,901)	$ 254,073

Amortization of our intangible assets was approximately $11,159, $8,257 and $5,660 for the years ended December 31, 2014, 2013 and 2012, respectively. Assuming no changes in the gross cost basis of intangible assets, amortization of $46 will occur in 2015.

As of December 31, 2014, we have recorded indefinite-lived intangible assets of $587,000 of purchased IPR&D from prior business acquisitions. As of December 31, 2014, except as noted below, there have been no significant changes that would impact the carrying value of IPR&D since the date of acquisition.

During the fourth quarter 2014, we reviewed for impairment the value of the early stage, Phase II indefinite-lived intangible asset related to the Orphatec acquisition. We initiated such review as part of our annual impairment testing and increased costs associated with clinical trial studies. The estimated value that can be obtained from a market participant in an arm's length transaction was determined to be de minimis as of December 31, 2014. As a result, in the fourth quarter 2014, we

recognized an impairment charge of $8,050 to write-down these assets to fair value. In addition, during the first quarter of 2014, we reviewed for impairment the value of an early stage, Phase I indefinite-lived intangible asset related to our acquisition of Taligen Therapeutics, Inc. We initiated such review based on a reassessment of scientific findings associated with this acquired asset. As a result, we recognized an impairment of $3,464 for the year ended December 31, 2014 to adjust this asset to fair value, which was determined to be de minimis.

During 2013, we reviewed for impairment the value of an early stage, Phase I indefinite-lived intangible asset related to the Taligen acquisition. We initiated such review as part of our annual impairment testing and based our evaluation on preliminary scientific findings of a Phase I clinical trial which led us to reassess the development of this acquired asset. The fair value of this IPR&D asset was determined using the income approach, which used significant unobservable (Level 3) inputs. These unobservable inputs included, among other things, risk-adjusted forecast future cash flows to be generated by this asset, contributory asset charges for other assets employed in this IPR&D project and the determination of an appropriate discount rate based on a weighted average cost of capital of 21.5% to be applied in calculating the present value of future cash flows. Based on these factors, the estimated value that can be obtained from a market participant in an arm's length transaction of $3,464 was lower than the carrying amount. We also reviewed for impairment the value of purchased technology associated with the Taligen acquisition and determined the estimated value to be de minimis. As a result, we recognized an impairment charge of $33,521 to write-down these assets to fair value, which was recorded in operating expenses in our consolidated statement of operations for the year ended December 31, 2013.

During 2012, we reviewed for impairment the value of an early stage, preclinical indefinite-lived intangible asset related to the Taligen acquisition. We initiated such review based on our evaluation of negative scientific findings associated with our development of a different asset for the treatment of age-related macular degeneration, the likelihood of success for ophthalmic use and the value that can be obtained from a market participant in an arm's length transaction. These developments led us to deprioritize the development of this acquired asset. As a result, we recognized an impairment charge of $26,300 to write-down this asset to fair value, which was determined to be de minimis based on the value of the asset to a market participant in an arm's length transaction. The fair value of this IPR&D asset was determined using the income approach, which used significant unobservable (Level 3) inputs. These unobservable inputs included, among other things, risk-adjusted forecast future cash flows to be generated by this asset, contributory asset charges for other assets employed in this IPR&D project and the determination of an appropriate discount rate based on a weighted average cost of capital of 22.0% to be applied in calculating the present value of future cash flows. The impairment charge was recorded in operating expenses in our consolidated statement of operations for the year ended December 31, 2012.

The following table summarizes the changes in the carrying amount of goodwill:

Balance at December 31, 2012	$	253,645
Change in goodwill associated with prior acquisition		428
Balance at December 31, 2013 and 2014	$	254,073

5. Marketable Securities

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and estimated fair value of available-for-sale investments by type of security at December 31, 2014 and December 31, 2013 were as follows:

	December 31, 2014			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Commercial paper	$ 142,495	$ —	$ —	$ 142,495
Corporate bonds	494,032	415	(581)	493,866
Municipal bonds	174,759	132	(46)	174,845
Other government related obligations:				
U.S.	99,668	14	(71)	99,611
Foreign	193,439	100	(174)	193,365
Bank certificates of deposit	77,000	—	—	77,000
	$ 1,181,393	$ 661	$ (872)	$ 1,181,182

	December 31, 2013			
	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Commercial paper	$ 112,679	$ —	$ —	$ 112,679
Corporate bonds	476,459	487	(588)	476,358
Municipal bonds	202,396	47	(40)	202,403
Other government related obligations:				
U.S.	46,466	30	(7)	46,489
Foreign	156,974	54	(204)	156,824
Bank certificates of deposit	33,004	—	—	33,004
	$ 1,027,978	$ 618	$ (839)	$ 1,027,757

The aggregate fair value of available-for-sale securities in an unrealized loss position as of December 31, 2014 and December 31, 2013 was $472,241 and $461,634. Investments that have been in a continuous unrealized loss position for more than 12 months were not material. As of December 31, 2014 we believe that the cost basis of our available-for-sale investments is recoverable.

The fair values of available-for-sale securities by classification in the consolidated balance sheet were as follows:

	December 31, 2014	December 31, 2013
Cash and cash equivalents	$ 167,892	$ 43,780
Marketable securities	1,013,290	983,977
	$ 1,181,182	$ 1,027,757

The fair values of available-for-sale debt securities at December 31, 2014, by contractual maturity, are summarized as follows:

	December 31, 2014
Due in one year or less	$ 641,052
Due after one year through three years	540,130
Due after three years through five years	—
	$ 1,181,182

As of December 31, 2014 and December 31, 2013, the fair value of our trading securities was $4,277 and $1,017.

We utilize the specific identification method in computing realized gains and losses. Realized gains and losses on our available-for-sale and trading securities were not material for the year ended December 31, 2014 and 2013.

6. Derivative Instruments and Hedging Activities

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

We enter into foreign exchange forward contracts, with durations of up to 60 months, to hedge exposures resulting from portions of our forecasted revenues, including intercompany revenues, that are denominated in currencies other than the U.S. dollar. The purpose of the hedges of revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. These hedges are designated as cash flow hedges upon contract inception. At December 31, 2014, we had open contracts with notional amounts totaling $1,524,521 that qualified for hedge accounting.

The impact on accumulated other comprehensive income (AOCI) and earnings from foreign exchange contracts that qualified as cash flow hedges, for the years ended December 31, 2014 and 2013 were as follows:

	Year Ended December 31,	
	2014	2013
Gain (loss) recognized in AOCI, net of tax	$ 110,088	$ (1,000)
Gain reclassified from AOCI to net product sales (effective portion), net of tax	$ 16,514	$ 18,820
Gain (loss) reclassified from AOCI to other income and expense (ineffective portion), net of tax	$ 2,439	$ (837)

Assuming no change in foreign exchange rates from market rates at December 31, 2014, $74,142 of gains recognized in AOCI will be reclassified to revenue over the next 12 months.

We enter into foreign exchange forward contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results. Hedge accounting is not applied to these derivative instruments as gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. As of December 31, 2014, the notional amount of foreign exchange contracts where hedge accounting is not applied was $224,410.

We recognized a gain of $26,295, $8,306 and $3,518, in other income and expense, for the years ended December 31, 2014, 2013 and 2012, respectively, associated with the foreign exchange contracts not designated as hedging instruments. These amounts were largely offset by gains or losses in monetary assets and liabilities.

The following tables summarize the fair value of outstanding derivatives at December 31, 2014 and 2013:

	December 31, 2014			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	$ 77,348	Other current liabilities	$ 794
Foreign exchange forward contracts	Other non-current assets	58,698	Other non-current liabilities	86
Total fair value of derivative instruments		**$ 136,046**		**$ 880**

	December 31, 2013			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	$ 21,815	Other current liabilities	$ 20,228
Foreign exchange forward contracts	Other non-current assets	9,839	Other non-current liabilities	14,864
Total fair value of derivative instruments		**$ 31,654**		**$ 35,092**

The fair value of our foreign exchange forward contracts that are not designated as hedging instruments was zero as of December 31, 2014 and December 31, 2013.

Although we do not offset derivative assets and liabilities within our condensed consolidated balance sheets, our International Swap and Derivatives Association (ISDA) agreements provide for net settlement of transactions that are due to or from the same counterparty upon early termination of the agreement due to an event of default or other termination event. The following tables summarize the potential effect on our condensed consolidated balance sheets of offsetting our foreign exchange forward contracts subject to such provisions:

	December 31, 2014					
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/Liabilities Presented in the Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 136,046	$ —	$ 136,046	$ (880)	$ —	$ 135,166
Derivative liabilities	(880)	—	(880)	880	—	—

	December 31, 2013					
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/Liabilities Presented in the Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 31,654	$ —	$ 31,654	$ (27,256)	$ —	$ 4,398
Derivative liabilities	(35,092)	—	(35,092)	27,256	—	(7,836)

7. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2014	December 31, 2013
Royalties	$ 25,863	$ 40,945
Payroll and employee benefits	88,467	64,950
Taxes payable	94,823	108,907
Rebates payable	36,827	124,297
Clinical	30,123	17,818
Manufacturing	42,631	7,250
Other	76,498	38,177
	$ 395,232	$ 402,344

8. Debt

In February 2012, we entered into a credit agreement, as amended (the Credit Agreement) with a syndicate of banks, that provides for a $240,000 senior secured term loan facility payable in equal quarterly installments of $12,000 starting June 30, 2012 and a $200,000 senior secured revolving credit facility through February 7, 2017. In addition to borrowings upon prior notice, the revolving credit facility includes borrowing capacity in the form of letters of credit up to $60,000 and borrowings on same-day notice, referred to as swingline loans, of up to $10,000. Borrowings can be used for working capital requirements, acquisitions and other general corporate purposes. With the consent of the lenders and the administrative agent and subject to satisfaction of certain conditions, we may increase the term loan facility and/or the revolving credit facility by an aggregate amount not to exceed $150,000.

We may elect that the loans under the Credit Agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.25% to 2.00% depending on our consolidated leverage ratio (as calculated in accordance with the Credit Agreement), or (ii) in the case of loans denominated in U.S. dollars, a Base Rate equal to the higher of the (A) Prime Rate then in effect, (B) Federal Funds Rate then in effect plus 0.50%, and (C) Eurodollar Rate then in effect plus 1.00%, plus in each case of (A), (B) or (C), 0.25% to 1.00% depending on our consolidated leverage ratio (as calculated in accordance with the Credit 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 7, 2017, the maturity date. At December 31, 2014 and 2013, the interest rate on our outstanding loans under the Credit Agreement was 1.41%.

Our obligations under the credit facilities are unconditionally guaranteed, jointly and severally, by certain of our existing domestic subsidiaries and are required to be guaranteed by certain of our future domestic subsidiaries. The obligations of our non-U.S. subsidiaries under the credit facilities are unconditionally guaranteed, jointly and severally, by us, certain of our existing domestic subsidiaries, and certain of our foreign subsidiaries, and are required to be guaranteed by certain of our future subsidiaries. All obligations of each borrower under the credit facilities, and the guarantees of those obligations, are backed, subject to certain exceptions, by substantially all of each borrower's assets and the assets of certain guarantors, including the pledge of the equity interests of certain of our subsidiaries and real estate located in Smithfield, Rhode Island, but excluding intellectual property and assets of certain foreign subsidiaries.

The Credit Agreement requires us to comply with certain financial covenants on a quarterly basis. Further, the Credit Agreement includes negative covenants, subject to exceptions, restricting or limiting our ability and the ability of our subsidiaries to, among other things, incur additional indebtedness, grant liens, engage in certain investment, acquisition and disposition transactions, pay dividends, repurchase capital stock and enter into transactions with affiliates. The Credit 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.

For the years ended December 31, 2014, 2013 and 2012 we made payments of $55,500, $36,000, and $91,000, against the term loan, respectively. As of December 31, 2014, we had $57,500 outstanding on the term loan. As of December 31, 2014, we had open letters of credit of $10,284, and our borrowing availability under the revolving facility was $189,716.

The fair value of our long term debt, which is measured using Level 2 inputs, approximates book value.

The contractual maturities of our long-term debt obligations due subsequent to December 31, 2014 are $10,000 in 2015, $38,000 in 2016, and $9,500 in 2017. As of December 31, 2014, we recorded $48,000 due under our term loan in current liabilities based on our intent and ability to make payments in this amount during 2015. In January 2015, we made a payment of $12,000.

9. Commitments and Contingencies

Commitments

License Agreements

In December 2014, we entered into an agreement with X-Chem Pharmaceuticals (X-Chem) that allows us to identify novel drug candidates from X-Chem's proprietary drug discovery engine. Alexion will have the exclusive worldwide rights to develop and commercialize products arising from the collaboration in up to three program targets. Due to the early stage of these assets, we recorded expense for an upfront payment of $8,000. In addition, for each program target, for a maximum of three targets, we could be required to make additional payments upon the achievement of specified research, development and regulatory milestones up to $75,000, as well as royalties on commercial sales.

In January 2014, we entered into an agreement with Moderna Therapeutics, Inc. (Moderna) that allows us to purchase ten product options to develop and commercialize treatments for rare diseases with Moderna's messenger RNA (mRNA) therapeutics platform. Alexion will lead the discovery, development and commercialization of the treatments produced through this broad, long-term strategic agreement, while Moderna will retain responsibility for the design and manufacture of the messenger RNA against selected targets. Due to the early stage of these assets, we recorded expense for an upfront payment of $100,000. We will also be responsible for funding research activities under the program. In addition, for each drug target, up to a maximum of ten targets, we could be required to make an option exercise payment of $15,000 and to pay up to an additional $120,000 with respect to a rare disease product and $400,000 with respect to a non-rare disease product in development and sales milestones if the specific milestones are met over time as well as royalties on commercial sales.

In July 2013, we entered into a license and collaboration agreement with Ensemble Therapeutics Corporation for the identification, development and commercialization of therapeutic candidates based on specific drug targets. Due to the early stage of these assets, we recorded expense for an upfront payment of $11,500 during the third quarter of 2013. We will also be responsible for funding research activities under the program. In addition, for each drug target, up to a maximum of four targets, we could be required to pay up to an additional $90,750 in development milestones as the specific milestones are met over time. The agreement also provides for royalty payments on commercial sales of each product developed under the agreement.

In January 2013, we entered into a license agreement for a technology, which provides an exclusive research license and an option for an exclusive commercial license for specific targets and products to be developed. Due to the early stage of this asset, we recorded expense for an upfront payment of $3,000 during the first quarter of 2013. We will also be required to pay annual maintenance fees during the term of the arrangement. In addition, for each target up to a maximum of six targets we develop, we could be required to pay up to an additional $70,500 in license fees, development and sales milestones as the specific milestones are met over time.

Lonza Agreement

We rely on Lonza Group AG and its affiliates (Lonza), a third party manufacturer, to produce a portion of commercial and clinical quantities of Soliris and for clinical quantities of asfotase alfa, and we have contracted and expect to continue contracting for product finishing, filling and packaging through third parties. We have various agreements with Lonza, with remaining total non-cancellable future commitments of approximately $383,500. Our agreements with Lonza also include potential payments totaling up to $5,000 that will become payable if and when certain milestones are achieved. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at Alexion Rhode Island Manufacturing Facility (ARIMF) and a payment with respect to sales of Soliris manufactured at Lonza facilities.

Contingent Liabilities

We are currently involved in various claims, lawsuits and legal proceedings. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, we accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on our best estimates based on available

information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, we may reassess the potential liability related to these matters and may revise these estimates, which could result in a material adverse adjustment to our operating results.

We have in the past received, and may in the future receive, notices from third parties claiming that their patents may be infringed by the development, manufacture or sale of Soliris. Under the guidance of ASC 450, *Contingencies*, we record a royalty accrual based on our best estimate of the fair value percent of net sales of Soliris that we could be required to pay the owners of patents for technology used in the manufacture and sale of Soliris. A costly license, or inability to obtain a necessary license, could have a material adverse effect on our financial results.

In January 2011, Novartis Vaccines and Diagnostics, Inc. (Novartis) filed an action against us and other biopharmaceutical companies in the U.S. District Court for the District of Delaware claiming willful infringement by us of U.S. Patent No. 5,688,688 (688 Patent). During the third quarter of 2013, the parties engaged in discussions to resolve the matter. In October 2013, we and Novartis agreed to resolve all claims asserted by Novartis in the action. In October 2013, the parties entered into a settlement agreement and dismissal pursuant to which Novartis granted Alexion a non-exclusive, fully paid license to the 688 Patent for our products and dismissed its case with prejudice. As a result, we recorded expense of $9,181 in cost of sales in the third quarter 2013 related to this litigation settlement agreement.

As previously reported, in the third quarter of 2012 we reduced our estimate for probable contingent liabilities due to the execution of a settlement and non-exclusive license agreement in October 2012 with a third party related to the third party's intellectual property. We adjusted the liability to reflect the actual, negotiated royalty rate set forth in the agreement. This change in estimate resulted in a positive impact in cost of sales of $53,377 during the third quarter 2012.

In March 2013, we received a Warning Letter (Warning Letter) from the U.S. Food and Drug Administration (FDA) regarding compliance with current Good Manufacturing Practices (cGMP) at ARIMF. The Warning Letter followed an FDA inspection which concluded in August 2012. At the conclusion of that inspection, the FDA issued a Form 483 Inspectional Observations, to which we responded in August 2012 and provided additional information to the FDA in September and December 2012. The observations relate to commercial and clinical manufacture of Soliris at ARIMF. We responded to the Warning Letter in a letter to the FDA dated in April 2013. At the conclusion of another inspection of ARIMF in August 2014, the FDA issued a Form 483 with three inspectional observations, none of which was designated as a repeat observation to the Warning Letter. The observations are inspectional and do not represent a final FDA determination of compliance. We continue to manufacture products, including Soliris, at ARIMF. While the resolution of the issues raised in the Warning Letter is difficult to predict, we do not currently believe a loss related to this matter is probable or that the potential magnitude of such loss or range of loss, if any, can be reasonably estimated. To the extent that circumstances related to this matter change, the impact could have a material adverse effect on our financial operations.

Unrelated to the Warning Letter, we initiated voluntary recalls and replacements of certain lots of Soliris in 2013 and 2014 due to the presence of visible particles detected in a limited number of vials in these lots. These recalls did not interrupt the supply of Soliris to patients. Following investigation, we believe that we have identified the filling process step at our third party fill/finish provider that resulted in the presence of the visible particles and we have implemented the changes necessary to modify the process step. During the fourth quarter of 2013, we recorded expense of $14,277 in cost of sales resulting from the expected disposal of inventory in 2014. Expenses associated with recalls were not material in 2014.

Operating Leases

As of December 31, 2014, we lease our headquarters and primary research and development facilities in Cheshire, Connecticut. The leases are set to expire in 2016 and 2020. Monthly fixed rent started at approximately $315, increasing to approximately $324 over the term of this lease. We also lease space for our regional executive and sales offices in Lausanne, Switzerland, and our global supply chain and distribution headquarters in Dublin, Ireland, as well as in other U.S. locations and foreign countries to support our operations as a global organization.

Aggregate lease expense was $22,738, $19,094 and $16,758 for the years ended December 31, 2014, 2013 and 2012, respectively. Lease expense is being recorded on a straight-line basis over the applicable lease terms.

Aggregate future minimum annual rental payments, for the next five years and thereafter under non-cancellable operating leases (including facilities and equipment) as of December 31, 2014 are:

Year		
2015	$	21,481
2016		18,878
2017		12,074
2018		8,371
2019		5,497
Thereafter		6,260

In January 2015, we entered into a new lease agreement for office space in Zurich, Switzerland to support the relocation of the European headquarters. The new lease is estimated to commence in the second quarter of 2015 and will expire 10 years later, with a minimum renewal option of 5 years and a maximum renewal option of 10 years. The lease provides for annual payments of $2,600 over the term of the lease.

Facility Lease Obligation

In November 2012, we entered into a new lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. The term of the new lease will commence upon the landlord's substantial completion of the building and will expire 12 years later, with a minimum renewal option of 7 years and a maximum renewal option of 20 years, provided that we expand our lease to include all rentable space in the building. Although we will not legally own the premises, we are deemed to be the owner of the building during the construction period based on applicable accounting guidance for build-to-suit leases due to our involvement during the construction period. Accordingly, the landlord's costs of constructing the facility are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our consolidated balance sheet. As of December 31, 2014, we recorded a construction-in-process asset of $126,566, inclusive of the landlord's costs as well as costs incurred by Alexion, and an offsetting facility lease obligation of $107,099 associated with the new facility.

We also entered into an agreement with the State of Connecticut Department of Economic and Community Development which provides for a forgivable loan and grants totaling $26,000 and tax credits of up to $25,000 related to the lease agreement in New Haven, Connecticut. The program requires that we meet certain criteria in order to prevent forfeiture or repayment of the loan, grants and credits, which include (i) maintaining corporate headquarters in Connecticut for the next 10 years; and (ii) achieving and maintaining up to 668 full-time employment positions in the State of Connecticut over the next 6 years. Proceeds from the forgivable loan and grants will reduce our basis in the cost of the building. As of December 31, 2014, we have not received any grant funds or tax credits associated with our agreement with the State of Connecticut.

Aggregate future minimum non-cancellable commitments under this facility lease obligation, assuming a substantial completion date of November 2015, as of December 31, 2014 are as follows:

Year	
2015	1,941
2016	11,651
2017	11,651
2018	11,738
2019	12,177
Thereafter	100,371

License and Research and Development Agreements

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

License agreements generally provide for us to pay an initial fee followed by annual minimum royalty payments. Additionally, certain agreements call for future payments upon the attainment of agreed upon milestones, such as, but not

limited to, Investigational New Drug (IND) application or approval of Biologics License Application. These agreements require minimum royalty payments based on sales of products developed from the applicable technologies, if any.

Clinical and manufacturing development agreements generally provide for us to fund manufacturing development and on-going clinical trials. Clinical trial and development agreements include contract services and outside contractor services including contracted clinical site services related to patient enrollment 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.

The minimum fixed payments (assuming non-termination of the above agreements) as of December 31, 2014, for each of the next five years are as follows:

Year	License Agreements	Clinical and Manufacturing Development Agreements
2015	$ 8,964	$ 81,810
2016	2,214	95,730
2017	664	102,980
2018	3,164	102,980
2019	1,064	—

10. Income Taxes

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

	Year Ended December 31,		
	2014	2013	2012
U.S.	$ 222,088	$ 376,067	$ 294,794
Non-U.S.	650,019	150,202	102,772
	$ 872,107	$ 526,269	$ 397,566

The components of the income tax provision are as follows:

	Year Ended December 31,		
	2014	2013	2012
Domestic			
Current	$ 285,624	$ 141,051	$ (2,094)
Deferred	(111,890)	92,040	114,807
	173,734	233,091	112,713
Foreign			
Current	81,810	34,975	73,287
Deferred	(40,349)	5,308	(43,256)
	41,461	40,283	30,031
Total			
Current	367,434	176,026	71,193
Deferred	(152,239)	97,348	71,551
	$ 215,195	$ 273,374	$ 142,744

We continue to maintain a valuation allowance against certain deferred tax assets where realization is not certain.

We continue to pay cash taxes in U.S. Federal, various U.S. states, and foreign jurisdictions where we have operations and have utilized all of our net operating losses.

At December 31, 2014, we have federal and state net operating loss carryforwards of $7,718 and $12,377, respectively. Included in the NOL's are state NOL's of $6,593 attributable to excess tax benefits from the exercise of non-qualified stock options and vests of restricted stock. The tax benefits attributable to these NOL's will be credited directly to additional paid in capital when utilized to offset taxes payable. Our NOL's expire between 2022 and 2033. We also have federal and state income tax credit carryforwards of $117,109 and $2,609, respectively. These income tax credits expire between 2015 and 2034. All of these U.S. federal and state income tax credit carryforwards are attributable to excess tax benefits from the exercise of non-qualified stock options and vests of restricted stock.

Certain stock option exercises and restricted stock vestings resulted in tax deductions in excess of previously recorded benefits based on the value at the time of grant. Although these additional tax benefits or "windfalls" are reflected in U.S. state net operating loss carryforwards and U.S. federal and state income tax credit carryforwards, pursuant to authoritative guidance, the additional tax benefit associated with the windfall is not recognized until the deduction reduces taxes payable. Accordingly, since the tax benefit does not reduce our current taxes payable due to net operating loss carryforwards and credit carryforwards, these "windfall" tax benefits are not reflected in our net operating losses and credit carryforwards in deferred tax assets for all periods presented.

We were granted an incentive tax holiday in the Canton of Vaud in Switzerland effective January 1, 2010. This tax holiday had exempted us from most local corporate income taxes in Switzerland through the end of 2014 and was renewable for an additional 5 years with final expiration in 2019. During 2013, we undertook a restructuring which significantly changed our business model in Switzerland and we converted from a principal company to a distribution and service company. As a result of the significant change to our business activities in Switzerland, the Canton of Vaud in Switzerland provided final notification to us in December 2014 that our structure no longer complied with the conditions of the incentive tax holiday. In the fourth quarter of 2014, we made a payment of $22,817 in satisfaction of the clawback of previously exempted cantonal income taxes for tax years 2010 through 2013. This amount was fully accrued on our balance sheet as of December 31, 2013. Prospectively, our federal and cantonal tax will be based on the current enacted tax rates in Switzerland.

The Tax Reform Act of 1986 contains certain provisions that can limit a taxpayer's ability to utilize net operating loss and tax credit carryforwards in any given year resulting from cumulative changes in ownership interests in excess of 50% over a three-year period. We have determined that these limiting provisions were triggered during a prior year. However, we believe that such limitations are not expected to result in the expiration or loss of any significant amount of our federal NOL's and income tax credit carryforwards.

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

	Year Ended December 31,		
	2014	2013	2012
U.S. federal statutory tax rate	35.0 %	35.0 %	35.0 %
State and local income taxes	0.9 %	3.3 %	1.7 %
Foreign income tax rate differential	(19.7)%	(14.1)%	(6.7)%
Income tax credits	(3.7)%	(3.5)%	(0.3)%
Foreign income tax credits	(4.8)%	(20.5)%	(0.1)%
Foreign income subject to U.S. taxation	15.8 %	10.2 %	0.2 %
Stock option compensation	0.1 %	1.1 %	0.7 %
State tax incentives	— %	— %	(1.1)%
Structuring related costs	— %	— %	4.8 %
Non-deductible acquisition related costs	— %	— %	0.3 %
U.S. deferred taxes on foreign earnings	— %	27.2 %	— %
Other nondeductible and permanent differences	1.1 %	13.2 %	1.8 %
Provision (benefit) attributable to valuation allowances	— %	— %	(0.4)%
Effective income tax rate	24.7 %	51.9 %	35.9 %

The U.S. Federal tax credit for research and experimentation expenses expired December 31, 2013. In connection with this expiration, our 2014 tax expense, for the first three quarters of the year, did not include any benefit from the U.S. Federal

tax credit for research and experimentation. In December 2014, the Tax Increase Prevention Act of 2014, which retroactively extended the tax credit for research and experimentation back to January 1, 2014 through the end of 2014, was signed into law. The effects of a change in tax law is recognized in the period that includes the date of enactment and, therefore, our tax benefit attributable to the 2014 U.S. Federal tax credit of $3,222 for research and experimentation was recorded in the fourth quarter of 2014.

The U.S. Federal tax credit for research and experimentation expenses had previously expired December 31, 2011. In connection with this expiration, our 2012 tax expense did not include any benefit from the U.S. Federal tax credit for research and experimentation. In January 2013, the American Taxpayer Relief Act of 2012, which retroactively extended the tax credit for research and experimentation back to January 1, 2012 through the end of 2013, was signed into law. The effects of a change in tax law is recognized in the period that includes the date of enactment and, therefore, our tax benefit attributable to the 2012 U.S. Federal tax credit of $2,719 for research and experimentation was recorded in the first quarter of 2013.

In 2012, as a result of structuring the Enobia business, we recorded income tax expense of $21,812 in our income statement. The structuring also required us to make a cash payment of $47,200 in early 2013, and this amount was fully accrued on our balance sheet as of December 31, 2012.

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

	December 31, 2014	December 31, 2013
Deferred tax assets:		
Net operating losses	$ 3,401	$ 5,398
Income tax credits	1,706	4,863
Stock compensation	49,090	33,539
Accruals and allowances	29,072	26,092
Research and development expenses	129,995	3,418
Accrued royalties	41,201	14,346
	254,465	87,656
Valuation allowance	(1,117)	(1,934)
Total deferred tax assets	253,348	85,722
Deferred tax liabilities:		
Depreciable assets	(40,648)	(41,281)
Unrealized gains	(45,191)	(134)
Investment in foreign partnership	(116,359)	(100,746)
Total deferred tax liabilities	(202,198)	(142,161)
Net deferred tax asset (liability)	$ 51,150	$ (56,439)

We follow authoritative guidance regarding accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosures, and transition.

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

	2014	2013	2012
Beginning of period balance	$ 46,389	$ 12,393	$ 9,773
Increases for tax positions taken during a prior period	899	2,571	99
Decreases for tax positions taken during a prior period	(2,468)	(812)	(1,931)
Increases for tax positions taken during the current period	9,063	33,056	4,651
Decreases for tax positions related to settlements	(24,812)	(419)	(199)
Decreases for tax positions related to lapse of statute	(396)	(400)	—
	$ 28,675	$ 46,389	$ 12,393

The total amount of accrued interest and penalties was not significant as of December 31, 2014. The total amount of tax benefit recorded during 2014 which related to unrecognized tax benefits was $17,012. Expense recognized during 2013 was $7,897 and 2012 was not material. Unless related to excess tax benefits from stock options, all of our unrecognized tax benefits, if recognized, would have a favorable impact on the effective tax rate.

We expect none of our total unrecognized tax benefits to reverse within the next twelve months. We file federal and state income tax returns in the U.S. and in numerous foreign jurisdictions. The U.S. and foreign jurisdictions have statute of limitations ranging from 3 to 5 years. However, the statute of limitations could be extended due to our NOL carryforward position in a number of our jurisdictions. The tax authorities generally have the ability to review income tax returns for periods where the statute of limitation has previously expired and can subsequently adjust the NOL carryforward or tax credit amounts. Accordingly, we do not expect to reverse any significant portion of the unrecognized tax benefits.

The Internal Revenue Service (IRS) commenced an examination of our U.S. income tax returns for 2008 and 2009 during the second quarter 2011. This examination was completed during the fourth quarter of 2013. As a result of this audit, there was not a material change in the liability for unrecognized tax benefits.

We do not record U.S. tax expense on the undistributed earnings of our controlled foreign corporation (CFC) subsidiaries as these earnings are intended to be permanently reinvested offshore. At December 31, 2014, the cumulative amount of these earnings was approximately $359,000. During the fourth quarter of 2013, in connection with the centralization of our global supply chain and technical operations in Ireland, our U.S. parent company became a direct partner in a captive foreign partnership. To the extent that our U.S. parent company receives its allocation of partnership income, the amounts will be taxable in the U.S. each year and therefore the permanent reinvestment assertion will no longer apply to such earnings. The recognition of deferred tax liabilities associated with the aforementioned partnership resulted in tax expense of approximately $95,800 during the fourth quarter of 2013. We also distributed the majority of earnings and profits of our non U.S. subsidiaries via a dividend in the amount of $152,000 during the fourth quarter of 2013. This dividend did not give rise to any U.S. cash tax liability. This resulted in repatriation of a significant portion of our remitted earnings at December 31, 2013.

We do not have any present or anticipated future need for cash held by our CFCs, as cash generated in the U.S., as well as borrowings, are expected to be sufficient to meet U.S. liquidity needs for the foreseeable future.

It is not practicable to estimate the amount of additional taxes which might be payable on our CFCs' undistributed earnings due to a variety of factors, including the timing, extent and nature of any repatriation. While our expectation is that all foreign undistributed earnings, other than our U.S. parent company's share of the foreign partnership profits, are permanently invested, there could be certain unforeseen future events that could impact our permanent reinvestment assertion. Such events include acquisitions, corporate restructuring or tax law changes not currently contemplated.

11. Share-based Compensation

At December 31, 2014, we have one stock option plan, the Amended and Restated 2004 Incentive Plan ("2004 Plan"). Under the 2004 Plan, restricted stock and restricted stock units (collectively referred to as Restricted Stock), incentive and non-qualified stock options, and other stock-related awards, may be granted for up to a maximum of 47,874 shares to our directors, officers, key employees and consultants. Stock options granted under the 2004 Plan 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. Restricted stock awards also generally vest over four years, with performance-based restricted stock units having a three-year vesting period.

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

	Year Ended December 31,		
	2014	2013	2012
Cost of sales	$ 4,174	$ 3,214	$ 2,815
Research and development	36,203	23,905	13,839
Selling, general and administrative	74,084	49,084	37,359
Total share-based compensation expense	114,461	76,203	54,013
Income tax effect	(42,082)	(28,652)	(20,188)
Total share-based compensation expense, net of tax	$ 72,379	$ 47,551	$ 33,825

Share-based compensation expense capitalized to inventory during the years ended December 31, 2014, 2013 and 2012 was $10,211, $3,978, and $2,838, respectively.

As of December 31, 2014, there was $249,511 of total unrecognized share-based compensation expense related to non-vested share-based compensation arrangements granted under the Plan. The expense is expected to be recognized over a weighted-average period of 2.70 years.

Stock Options

A summary of the status of our stock option plans at December 31, 2014, and changes during the year 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, 2013	8,619	$ 50.69		
Granted	1,472	173.04		
Exercised	(3,408)	33.64		
Forfeited and canceled	(263)	102.99		
Outstanding at December 31, 2014	6,420	$ 85.65	6.98	$ 638,145
Vested and unvested expected to vest at December 31, 2014	6,320	$ 84.85	6.96	$ 633,345
Exercisable at December 31, 2014	3,440	$ 48.59	5.72	$ 469,383

Total intrinsic value of stock options exercised during the years ended December 31, 2014, 2013 and 2012 was $459,940, $204,470 and $308,009, respectively. We primarily utilize newly issued shares to satisfy the exercise of stock options. The total fair value of options vested during the years ended December 31, 2014, 2013 and 2012 was $35,859, $32,249 and $27,301, respectively.

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

	December 31, 2014	December 31, 2013	December 31, 2012
Expected life in years	3.64 - 5.30	3.30 - 5.37	3.30 - 4.19
Interest rate	.97% - 1.74%	0.30% - 1.21%	0.45% - 0.78%
Volatility	32.15% - 34.87%	29.81% - 36.93%	29.82% - 38.57%
Dividend yield	—	—	—

The expected stock price volatility rates are based on historical volatilities of our common stock. The risk-free interest rates are based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. The average expected life represents the weighted average period of time that options granted are expected to be

outstanding. We have evaluated three distinct employee groups in determining the expected life assumptions, and we estimate the expected life of stock options based on historical experience of exercises, cancellations and forfeitures of our stock options.

The weighted average fair value at the date of grant for options granted during the years ended December 31, 2014, 2013 and 2012 was $51.22, $23.99 and $24.04 per option, respectively.

Restricted Stock

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

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested Restricted Stock at December 31, 2013	1,789	$ 78.63
Shares granted	855	174.22
Shares forfeited	(186)	99.88
Shares vested	(650)	63.53
Nonvested Restricted Stock at December 31, 2014	1,808	$ 127.08

Restricted stock awards granted in 2014 and 2013 include 129 and 81 restricted stock units granted to senior management, which have both non-market performance-based and service-based vesting conditions. The weighted average grant date fair value of these awards granted in 2014 and 2013 was $176.04 and $97.07 respectively. The number of non-market performance-based restricted stock units granted represents the number of shares earned during the performance period, which ended on December 31, 2014 and 2013, respectively, based on specific pre-established performance goals. These awards will vest over a three year period, subject to the employees' continued employment with the Company.

The fair value of restricted stock at the date of grant is based on the fair market value of the shares of common stock underlying the awards on the date of grant. The weighted average fair value at the date of grant for restricted stock awards granted during the years ended December 31, 2014, 2013 and 2012, including restricted stock units with non-market performance conditions, was $174.22, $95.06 and $82.13 per share, respectively. The total fair value of restricted stock vested during the years ended December 31, 2014, 2013 and 2012 was $41,304, $26,679 and $18,573, respectively.

During 2014, we granted market-based performance awards to senior management which provides the recipient the right to receive restricted stock at the end of a three year performance period, based on pre-established market-based performance goals. We used payout simulation models to estimate the grant date fair value of the awards and recognized expense of $301 during 2014.

12. Stockholders' Equity

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 hundredth of a share of a new series of preferred stock at an exercise price of $75.00, subject to adjustment (see below). The rights may be exercised only after a public announcement that a party acquired 20% or more of our common stock or after commencement or public announcement to make a tender offer for 20% or more of our common stock. The rights, which do not have voting rights, expire on March 6, 2017, and may be redeemed by us at a price of $0.01 per right at any time prior to their expiration or the acquisition of 20% or more of our stock. The preferred stock purchasable upon exercise of the rights will have a minimum preferential dividend of $10.00 per year, but will be entitled to receive, in the aggregate, a dividend of 100 times the dividend declared on a share of Common Stock. In the event of liquidation, the holders of the shares of preferred stock will be entitled to receive a minimum liquidation payment of $100 per share, but will be entitled to receive an aggregate liquidation payment equal to 100 times the payment to be made per share of Common Stock.

On February 23, 2007, our Board of Directors amended the purchase price under the preferred stock purchase rights. Further, as a result of the two-for-one stock split of the Company's outstanding shares of common stock effected on August 22, 2008, the number of shares of preferred stock purchasable upon proper exercise of each preferred stock purchase right automatically adjusted from one hundredth of a share of preferred stock to two hundredths of a share of preferred stock. Therefore, the purchase price, for each two hundredths of a share of preferred stock to be issued upon the exercise of each

preferred stock purchase right is $300.00. Except for the increase in the purchase price, the terms and conditions of the rights remain unchanged.

In the event that we are acquired in a merger, other business combination transaction, or 50% 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.

Common Stock

In May 2012, in conjunction with our addition into the S&P 500 Index, we completed the sale of 5,000 shares of our common stock in a public offering. The net proceeds from the sale of shares in the offering were $462,212.

Share Repurchases

In November 2012, we announced that our Board of Directors authorized the repurchase of up to $400,000 of our common stock. In December 2014, our Board of Directors authorized the repurchase of up to an additional $500,000 of our common stock. The repurchase program does not have an expiration date and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at the Company's discretion. Under the program, we repurchased 1,903 and 758 shares of our common stock at a cost of $302,599 and $66,136 during the years ended December 31, 2014 and 2013, respectively. At December 31, 2014, there is a total of $519,712 remaining for repurchases under these repurchase program.

13. Other Comprehensive Income and Accumulated Other Comprehensive Income

The following table summarizes the changes in AOCI, by component, for the years ended December 31, 2014, 2013 and 2012:

	Defined Benefit Pension Plans	Unrealized Gains (Losses) from Marketable Securities	Unrealized Gains (Losses) from Hedging Activities	Foreign Currency Translation Adjustment	Total Accumulated Other Comprehensive Income (Loss)
Balances, December 31, 2011	$ (4,183)	$ —	$ 11,321	$ (2,959)	$ 4,179
Other comprehensive income before reclassifications	(1,807)	—	14,856	150	13,199
Amounts reclassified from other comprehensive income	278	—	(11,021)	—	(10,743)
Net other comprehensive income (loss)	(1,529)	—	3,835	150	2,456
Balances, December 31, 2012	$ (5,712)	$ —	$ 15,156	$ (2,809)	$ 6,635
Other comprehensive income before reclassifications	(6,175)	(197)	(1,000)	(4,573)	(11,945)
Amounts reclassified from other comprehensive income	385	51	(17,983)	—	(17,547)
Net other comprehensive income (loss)	(5,790)	(146)	(18,983)	(4,573)	(29,492)
Balances, December 31, 2013	$ (11,502)	$ (146)	$ (3,827)	$ (7,382)	$ (22,857)
Other comprehensive income before reclassifications	(5,732)	(63)	110,088	(6,337)	97,956
Amounts reclassified from other comprehensive income	664	(25)	(18,953)	—	(18,314)
Net other comprehensive income (loss)	(5,068)	(88)	91,135	(6,337)	79,642
Balances, December 31, 2014	$ (16,570)	$ (234)	$ 87,308	$ (13,719)	$ 56,785

The table below provides details regarding significant reclassifications from AOCI during the years ended December 31, 2014, 2013 and 2012:

Details about Accumulated Other Comprehensive Income Components	Amount Reclassified From Accumulated Other Comprehensive Income during the year ended December 31, 2014	2013	2012	Affected Line Item in the Consolidated Statements of Operations
Unrealized Gains (Losses) on Hedging Activity				
Effective portion of foreign exchange contracts	$ 18,874	$ 20,569	$ 12,869	Net product sales
Ineffective portion of foreign exchange contracts	2,787	(915)	(824)	Foreign currency loss
	21,661	19,654	12,045	
	(2,708)	(1,671)	(1,024)	Income tax provision
	$ 18,953	$ 17,983	$ 11,021	
Unrealized Gains (Losses) from Marketable Securities				
Realized gains (losses) on sale of securities	$ 40	$ (81)	$ —	Investment income
	40	(81)	—	
	(15)	30	—	Income tax provision
	$ 25	$ (51)	$ —	
Defined Benefit Pension Items				
Amortization of prior service costs and actuarial losses	$ (865)	$ (421)	$ (304)	(a)
	(865)	(421)	(304)	
	201	36	26	Income tax provision
	$ (664)	$ (385)	$ (278)	

(a) This AOCI component is included in the computation of net periodic pension benefit cost (see Note 15 for additional details).

14. Fair Value Measurement

Authoritative guidance establishes a valuation hierarchy for disclosure of the inputs to the valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value.

The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2014 and 2013, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

		Fair Value Measurement at December 31, 2014			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$ 176,331	$ —	$ 176,331	$ —
Cash equivalents	Commercial paper	$ 117,529	$ —	$ 117,529	$ —
Cash equivalents	Corporate bonds	$ 9,315	$ —	$ 9,315	$ —
Cash equivalents	Municipal bonds	$ 12,050	$ —	$ 12,050	$ —
Cash equivalents	Other government-related obligations	$ 23,998	$ —	$ 23,998	$ —
Cash equivalents	Bank certificates of deposit	$ 5,000	$ —	$ 5,000	$ —
Marketable securities	Mutual funds	$ 4,277	$ 4,277	$ —	$ —
Marketable securities	Commercial paper	$ 24,966	$ —	$ 24,966	$ —
Marketable securities	Corporate bonds	$ 484,551	$ —	$ 484,551	$ —
Marketable securities	Municipal bonds	$ 162,795	$ —	$ 162,795	$ —
Marketable securities	Other government-related obligations	$ 268,978	$ —	$ 268,978	$ —
Marketable securities	Bank certificates of deposit	$ 72,000	$ —	$ 72,000	$ —
Other current assets	Foreign exchange forward contracts	$ 77,348	$ —	$ 77,348	$ —
Other assets	Foreign exchange forward contracts	$ 58,698	$ —	$ 58,698	$ —
Other current liabilities	Foreign exchange forward contracts	$ 794	$ —	$ 794	$ —
Other liabilities	Foreign exchange forward contracts	$ 86	$ —	$ 86	$ —
Other current liabilities	Acquisition-related contingent consideration	$ 46,546	$ —	$ —	$ 46,546
Contingent consideration	Acquisition-related contingent consideration	$ 116,425	$ —	$ —	$ 116,425

		Fair Value Measurement at December 31, 2013			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$ 234,212	$ —	$ 234,212	$ —
Cash equivalents	Commercial paper	$ 6,298	$ —	$ 6,298	$ —
Cash equivalents	Corporate bonds	$ 15,255	$ —	$ 15,255	$ —
Cash equivalents	Municipal bonds	$ 2,225	$ —	$ 2,225	$ —
Cash equivalents	Bank certificates of deposit	$ 20,003	$ —	$ 20,003	$ —
Marketable securities	Mutual funds	$ 1,017	$ 1,017	$ —	$ —
Marketable securities	Commercial paper	$ 106,381	$ —	$ 106,381	$ —
Marketable securities	Corporate bonds	$ 461,103	$ —	$ 461,103	$ —
Marketable securities	Municipal bonds	$ 200,178	$ —	$ 200,178	$ —
Marketable securities	Other government-related obligations	$ 203,313	$ —	$ 203,313	$ —
Marketable securities	Bank certificates of deposit	$ 13,001	$ —	$ 13,001	$ —
Other current assets	Foreign exchange forward contracts	$ 21,815	$ —	$ 21,815	$ —
Other assets	Foreign exchange forward contracts	$ 9,839	$ —	$ 9,839	$ —
Other current liabilities	Foreign exchange forward contracts	$ 20,228	$ —	$ 20,228	$ —
Other liabilities	Foreign exchange forward contracts	$ 14,864	$ —	$ 14,864	$ —
Other current liabilities	Acquisition-related contingent consideration	$ 35,932	$ —	$ —	$ 35,932
Contingent consideration	Acquisition-related contingent consideration	$ 106,744	$ —	$ —	$ 106,744

There were no securities transferred between Level 1, 2 and 3 for the year ended December 31, 2014.

Valuation Techniques

We classify mutual fund investments, which are valued based on quoted market prices in active markets with no valuation adjustment, as Level 1 assets within the fair value hierarchy.

Cash equivalents and marketable securities classified as Level 2 within the valuation hierarchy consist of institutional money market funds, commercial paper, municipal bonds, U.S. and foreign government-related debt, corporate debt securities and certificates of deposit. We estimate the fair values of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include market pricing based on real-time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs. We validate the prices provided by our third-party pricing sources by understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances.

Our derivative assets and liabilities include foreign exchange derivatives that are measured at fair value using observable market inputs such as forward rates, interest rates, our own credit risk as well as an evaluation of our counterparties' credit risks. Based on these inputs, the derivative assets and liabilities are classified within Level 2 of the valuation hierarchy.

Contingent consideration liabilities related to acquisitions are classified as Level 3 within the valuation hierarchy and are valued based on various estimates, including probability of success, discount rates and amount of time until the conditions of the milestone payments are met.

As of December 31, 2014, there has not been any impact to the fair value of our derivative liabilities due to our own credit risk. Similarly, there has not been any significant adverse impact to our derivative assets based on our evaluation of our counterparties' credit risks.

Contingent Consideration

In connection with prior acquisitions, we may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approval or sales-based milestone events. We determine the fair value of these obligations on the acquisition date using various estimates that are not observable in the market and represent a Level 3 measurement within the fair value hierarchy. The resulting probability-weighted cash flows were discounted using a cost of debt of 4.8% for developmental milestones and a weighted average cost of capital ranging from 12% to 21% for sales-based milestones.

Each reporting period, we adjust the contingent consideration to fair value with changes in fair value recognized in operating earnings. Changes in fair values reflect new information about the probability and timing of meeting the conditions of the milestone payments. In the absence of new information, changes in fair value will only reflect the interest component of contingent consideration related to the passage of time as development work progresses towards the achievement of the milestones.

Estimated future contingent milestone payments related to prior business combinations range from zero if no milestone events are achieved, to a maximum of $876,000 if all development, regulatory and sales-based milestones are reached. As of December 31, 2014, the fair value of acquisition-related contingent consideration was $162,971. The following table represents a roll-forward of our acquisition-related contingent consideration:

	December 31, 2014
Balance at beginning of period	$ (142,676)
Change in fair value	(20,295)
Balance at end of period	$ (162,971)

15. Employee Benefit Plans

Defined Contribution Plan

We have one 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 equal to $1.00 for each dollar contributed up to the first 6% of an individual's base salary and incentive cash bonus up to the annual IRS maximum. For the years ended December 31, 2014, 2013 and 2012, we recorded matching contributions of approximately $8,782, $6,360, and $3,700 respectively.

Defined Benefit Plans

We maintain defined benefit plans for employees in certain countries outside the United States, including retirement benefit plans required by applicable local law. The plans are valued by independent actuaries using the projected unit credit method. The liabilities correspond to the projected benefit obligations of which the discounted net present value is calculated based on years of employment, expected salary increases, and pension adjustments.

The following table sets forth the funded status and the amounts recognized for defined benefit plans:

	December 31,	
	2014	2013
Change in benefit obligation:		
Projected benefit obligation, beginning of year	$ 38,166	$ 24,484
Prior service cost	—	—
Service cost	8,136	5,413
Interest cost	780	504
Change in assumptions	5,571	2,643
Recognized actuarial net loss	1,350	3,701
Foreign currency exchange rate changes	(3,055)	573
Net transfers (from) to plan	(247)	848
Projected benefit obligation, end of year	$ 50,701	$ 38,166
Accumulated benefit obligation, end of year	$ 43,141	$ 30,655

	December 31,	
	2014	2013
Change in plan assets:		
Fair value of plan assets, beginning of year	$ 23,327	$ 16,006
Return on plan assets	393	244
Employer contributions	4,417	3,811
Plan participants' contributions	1,741	1,523
Foreign currency exchange rate changes	(2,855)	895
Net transfers (from) to plan	(247)	848
Fair value of plan assets, end of year	$ 26,776	$ 23,327
Funded status at end of year	$ (23,925)	$ (14,839)

The Company measures the fair value of plan assets based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The following table presents total plan assets by investment category as of December 31, 2014 and the classification of each investment category within the fair value hierarchy with respect to the inputs used to measure fair value:

	December 31, 2014		December 31, 2013	
	Fair Value (Level 2)	as % of total plan assets	Fair Value (Level 2)	as % of total plan assets
Cash and cash equivalents	$ 1,794	7%	$ 1,470	6%
Equity security funds	10,791	40%	9,237	40%
Debt security funds	11,246	42%	9,704	42%
Real estate funds	2,945	11%	2,916	12%
	$ 26,776	**100%**	**$ 23,327**	**100%**

All plan asset investments are classified as Level 2 within the fair value hierarchy and are valued utilizing observable prices for similar instruments and quoted prices for identical or similar instruments in markets that are not active. The investment objective is to maximize the overall return from investment income and capital appreciation consistent with the preservation of capital considering investment strategies and asset allocation limits as determined by pension law. The targeted allocation for these funds (if any) is as follows:

	Target Allocation Ranges in %
Cash and notes receivable issued by banks or insurance companies	0-10%
Equity securities	30-60%
Debt securities	16-45%
Real estate	10-20%
Other	0-12%

At December 31, 2014, we have recorded a liability of $23,925 in other non-current liabilities and a charge to accumulated other comprehensive income, net of tax, of $16,570 related to an additional minimum liability.

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

	December 31,	
	2014	2013
Weighted average assumptions - Net Periodic Benefit Cost:		
Discount rate	2.0%	2.0%
Long term rate of return on assets	4.0%	4.0%
Rate of compensation increase	1.6%	1.6%
Weighted average assumptions - Projected Benefit Obligation:		
Discount Rate	1.4%	2.1%
Rate of compensation increase	1.6%	1.6%

The discount rates used to determine the net periodic benefit cost and projected benefit obligation represent the yield on high quality AA-rated corporate bonds for periods that match the duration of the benefit obligations.

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

The components of net periodic benefit cost are as follows:

	Year Ended December 31,		
	2014	2013	2012
Service cost	$ 8,136	$ 5,413	$ 4,733
Interest cost	780	504	464
Expected return on plan assets	(900)	(633)	(515)
Employee contributions	(1,741)	(1,523)	(1,163)
Amortization of prior service costs	9	9	9
Amortization and deferral of actuarial gain	846	410	217
Total net periodic benefit cost	$ 7,130	$ 4,180	$ 3,745

Other changes in plan assets and benefit obligations recognized in AOCI are as follows:

Amount included in AOCI - December 31, 2012	**$**	**(5,712)**
Prior service cost		9
Net loss arising during the period		(3,710)
Change in assumptions		(2,657)
Amortization of net gain		412
Plan assets losses		(391)
Taxes		547
Amount included in AOCI - December 31, 2013	**$**	**(11,502)**
Prior service cost		9
Net loss arising during the period		(1,354)
Change in assumptions		(5,640)
Amortization of net gain		856
Plan assets losses		(513)
Taxes		1,574
Amount included in AOCI - December 31, 2014	**$**	**(16,570)**

The amount in accumulated other comprehensive income as of December 31, 2014 that is expected to be recognized as a component of the net periodic pension costs in 2015 is $1,216.

We estimate that we will pay employer contributions of approximately $4,238 in 2014. The expected future cash flows to be paid in respect of the pension plans as of December 31, 2014 were as follows:

Year	
2015	1,985
2016	1,511
2017	1,450
2018	1,247
2019	1,227
2020 to 2024	4,922

16. Restructuring

In the fourth quarter 2014, we announced plans to move the European headquarters from Lausanne to Zurich, Switzerland. The relocation of the European headquarters will support our growing operational needs based on current business forecasts. The activities at our Lausanne site will be relocated to our Zurich, Cheshire, Connecticut, and Dublin, Ireland locations. As a result of this action, we recorded restructuring expenses of $15,365 related to employee costs in the fourth quarter of 2014. We expect to incur approximately $10,000 to $15,000 of additional restructuring related charges in 2015 related to contract termination and additional employee costs. We expect to pay all accrued amounts related to this restructuring activity by the end of fiscal year 2015. The restructuring reserve of $15,365 is included within accrued expenses liabilities on the Company's consolidated balance sheet as of December 31, 2014.

17. Segment Information

We operate as one business segment, which is the innovation, development and commercialization of life-transforming therapeutic products. Therefore, our chief operating decision-maker manages our operations as a single operating segment.

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

	Year Ended December 31,		
Revenues:	**2014**	**2013**	**2012**
United States	$ 730,089	$ 561,405	$ 400,483
Europe (1)	836,134	514,987	418,321
Asia Pacific	244,059	203,538	161,480
Other	423,451	271,416	153,830
	$ 2,233,733	$ 1,551,346	$ 1,134,114

(1) As described in Note 19 "Quarterly Financial Information (unaudited)", included within the Europe revenues for 2014 is a reimbursement of $87,830 for shipments made in years prior to January 1, 2014 as a result of an agreement with the French government.

	December 31,	
Long-lived assets (2):	**2014**	**2013**
United States	$ 298,122	$ 190,791
Europe	88,543	5,413
Other	5,583	4,905
	$ 392,248	$ 201,109

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

18. Subsequent Events

In January 2015, we entered into a license agreement with a third party to obtain certain intellectual property rights and technology related to specific therapeutic compounds. The agreement provides an exclusive research, development and commercial license for products to be developed using such compounds. Pursuant to the terms of the agreement, we made an upfront payment of $50,000 during the first quarter 2015. We could be required to pay up to an additional $213,000 in development and regulatory milestones related to a product developed under the agreement for a single disease indication. An additional $437,000 in milestone payments could be due if certain development and regulatory milestones are achieved for additional disease indications. The agreement also provides for royalty payments and potential milestone payments of up to $180,000 on commercial sales of products developed under the agreement.

In January 2015, we entered into a new lease agreement for approximately 44,000 square feet of office space in Zurich, Switzerland to support the relocation of the European headquarters. The lease is estimated to commence in the second quarter of 2015 and will expire 10 years later, with a minimum renewal option of 5 years and a maximum renewal option of 10 years. The lease provides for annual payments of $2,600 over the term of the lease.

19. Quarterly Financial Information (unaudited)

The following condensed quarterly financial information is for the years ended December 31, 2014 and 2013:

	March 31	June 30	September 30	December 31
2014:				
Revenues	$ 566,616 (1)	$ 512,495	$ 555,146	$ 599,476
Cost of sales	32,939 (1)	39,626	51,858	49,439
Operating expenses	324,174	254,020	266,629	346,342 (2)
Operating income	209,503	218,849	236,659	203,695
Net income (loss)	$ 159,354	$ 166,495	$ 177,731	$ 153,332
Earnings (loss) per common share				
Basic	$ 0.81	$ 0.84	$ 0.90	$ 0.77
Diluted	$ 0.79	$ 0.83	$ 0.88	$ 0.76

	March 31	June 30	September 30	December 31
2013:				
Revenues	$ 338,941	$ 370,091	$ 400,405	$ 441,909
Cost of sales	35,269	39,377	51,358	51,552
Operating expenses	186,700	193,023	213,772	252,285 (3)
Operating income	116,972	137,691	135,275	138,072
Net income	$ 82,217	$ 95,885	$ 93,785	$ (18,992)
Earnings per common share				
Basic	$ 0.42	$ 0.49	$ 0.48	$ (0.10)
Diluted	$ 0.41	$ 0.48	$ 0.47	$ (0.10)

(1) Included within revenues for the first quarter of 2014 is a reimbursement for shipments made in years prior to January 1, 2014 as a result of an agreement with the French government which positively impacted reimbursement for Soliris. As a result of the agreement, in the first quarter of 2014, we recognized $87,830 of net product sales from Soliris in France relating to years prior to January 1, 2014. Also, included within cost of sales for the first quarter of 2014 is the incremental impact in cost of sales of $2,055 for additional royalties related to the $87,830 of net product sales from prior year shipments.

(2) Included within operating expenses for the fourth quarter of 2014 is $15,365 for restructuring expenses recognized in connection with the relocation of the European headquarters.

(3) Included within operating expenses for the fourth quarter of 2013 is an impairment charge of $33,521 to write-down the value of an early stage, Phase I indefinite-lived intangible asset and purchased technology asset related to the Taligen acquisition.

Exhibit 10.16

MASTER MANUFACTURING AND SUPPLY AGREEMENT

Between

ALEXION PHARMA INTERNATIONAL TRADING

&

ALEXION PHARMACEUTICALS, INC.

And

LONZA GROUP AG

&

LONZA BIOLOGICS TUAS PTE LTD

&

LONZA SALES AG

Dated 16th December, 2014

* Omitted information is the subject of a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934 and has been filed separately with the Securities and Exchange Commission.

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* Omitted information is the subject of a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934 and has been filed separately with the Securities and Exchange Commission.

MASTER MANUFACTURING AND SUPPLY AGREEMENT

THIS MASTER MANUFACTURING AND SUPPLY AGREEMENT ("**Agreement**") is dated as of 16th December, 2014 (the "**Effective Date**"), by and between Lonza Biologics Tuas Pte Ltd, a company incorporated in Singapore with a principal place of business at 35 Tuas South Avenue 6, Singapore 637377 ("**Lonza Singapore**"), Lonza Sales AG, a company incorporated in Switzerland with a principal place of business at Muenchensteinerstrasse 38 CH-4002 Basel, Switzerland ("**Lonza Sales**"), Lonza Group AG., a Swiss company having its principal place of business at Muenchensteinerstrasse. 38, 4002, Basel, Switzerland ("**Lonza Group AG**"), and Alexion Pharma International Trading, an Irish corporation having its principal place of business at Block 10a, Beckett Way, Park West Business Park, Nangor Road, Dublin, Ireland ("**Alexion**"), and Alexion Pharmaceuticals Inc., a Delaware corporation with offices at 352 Knotter Drive, Cheshire, CT 06410, USA ("**Alexion Inc**").

BACKGROUND

Alexion develops, markets and sells certain proprietary biopharmaceutical products. Alexion desires to obtain additional supply of commercial quantities of certain Product substances. Lonza has the experience and expertise necessary to perform the manufacturing and related services needed to supply the applicable Products, and Lonza has agreed to provide manufacturing capacity at certain facilities that will be suitable for production of commercial quantities of the Products.

Alexion desires to contract with Lonza as a manufacturer of commercial quantities of the applicable Product substances of certain proprietary biopharmaceutical products of Alexion and purchase commercial quantities of such Products from Lonza, and Lonza desires to perform such services and sell commercial quantities of such Products to Alexion, all on the terms and conditions set forth in this Agreement.

In accordance with each applicable PSA (as defined below), no later than sixty (60) days after the execution of the PSA or such other date set forth in the PSA, Lonza and Alexion shall enter into a TTA and Quality Agreement (each as defined below) for the purpose of further effectuating the intent of the Parties hereunder.

AGREEMENT

NOW, THEREFORE, IN CONSIDERATION OF the mutual covenants set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the Parties agree as follows:

ARTICLE 1.
DEFINITIONS

The following terms, whether used in the singular or plural, shall have the meanings assigned to them below for purposes of this Agreement.

1.1 "**Acquisition Cost**" means the actual invoiced price paid by Lonza to any Third Party for acquiring any raw materials, packaging components and intermediates used exclusively in

* Omitted information is the subject of a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934 and has been filed separately with the Securities and Exchange Commission.

the manufacture of the Product under a PSA and this Agreement, including direct out-of-pocket shipping and handling costs and customs duties incurred and paid by Lonza in connection with the acquisition of such materials, packaging components and intermediates.

1.2 "**Affiliate**" means any corporation, partnership, limited liability company or other entity, which directly or indirectly controls, is controlled by or is under common control with the relevant Party to this Agreement, and "control" and its correlates means the ownership of more than fifty percent (50%) of the issued voting shares, or the legal power to direct or cause the direction of the general management and policies, of the Party in question.

1.3 "**Alexion**" means Alexion and, solely in respect of Section 21.7 and Exhibit B, Alexion Inc.

1.4 "**Alexion Confidential Information**" means all technical and other information known to, controlled or owned by Alexion or its Affiliates at any time during the Term, and not known to and at the free disposal of Lonza prior to its disclosure by Alexion or its Affiliates to Lonza and not in the public domain, including, without limitation, Alexion Materials, Alexion LSP, Alexion Tests and the Cell Line.

1.5 "**Alexion Process**" means that part of the Process which consists of know-how and improvements invented by or specifically for Alexion or any of its Affiliates.

1.6 "**Alexion Materials**" means Alexion New Material and Alexion Original Material.

1.7 "**Alexion New Material**" means all information, documents and materials relating to the Product that will be generated by Lonza, any Approved Subcontractor and/or Alexion under this Agreement, including without limitation, manufacturing and quality control instructions or requirements under any quality control agreements between the parties (including the QA Agreement), and specifications necessary to manufacture, label, package, store, handle, stability test, quality control test and release the Product, all in accordance with this Agreement, including without limitation the Product and partially-Processed Product. Alexion New Material does not include any Lonza Confidential Information.

1.8 "**Alexion Original Material**" means all information, documents and materials that will be or have been provided by Alexion to Lonza under this Agreement, including without limitation, Confidential Information.

1.9 "**Alexion Patent Rights**" means all Patent Rights that are controlled by Alexion and are necessary or useful in the performance of the Services by Lonza as contemplated hereby. The Alexion Patent Rights are listed on Exhibit C and attached hereto.

1.10 "**Alexion Tests**" means the tests to be carried out on the Product following receipt by Alexion, as specified in the relevant PSA, as modified from time to time by written agreement between the Parties.

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1.11 "**Approved Subcontractors**" means any Affiliate of Lonza and/or other Third Party subcontracted by Lonza after prior written approval of Alexion to perform part of its obligations hereunder, all as listed in the QA Agreement.

1.12 "**ARIMF**" means Alexion Rhode Island Manufacturing Facility.

1.13 "**Background Intellectual Property**" means any Intellectual Property either (i) owned or controlled by a Party prior to the Effective Date or (ii) developed or acquired by a Party independently from the performance of this Agreement.

1.14 "**Batch**" means the quantity of bulk form of the Product produced from a single operation of the Process, at the [*]L or [*]L scale, as the context requires, and refers to an Engineering Batch, a Process Validation Batch, and/or a Commercial Batch, as the context requires.

1.15 "**BLA**" means a Biologics License Application and amendments thereto for a Product filed pursuant to the requirements of the FDA, as defined in 21 C.F.R. §600 et seq., for FDA approval of a Product, and "sBLA" means a supplemental BLA.

1.16 "**cGMP**" means the regulatory requirements for current good manufacturing practices promulgated by the FDA under the FD&C Act, 21 C.F.R. §§ 210, 211 and 600 et *seq.* and under the PHS Act, 21 C.F.R. §§ 600-610 and specified by the EU/PIC guidelines, as such regulatory requirements may be amended from time to time, and the corresponding or similar national laws, rules and regulations of those jurisdictions in which the Product is manufactured. As used herein, the "FD&C Act" means the United States Federal Food, Drug and Cosmetic Act, as the same may be amended from time to time.

1.17 "**Campaign**" means any series of Batches for a Product at a particular Facility.

1.18 "**Cell Line**" means a proprietary Alexion cell line that expresses the Product.

1.19 "**Certificate of Analysis**" means, as further specified in the applicable Quality Agreement, with respect to each Batch subject thereto, a document prepared by Lonza certifying that the final bulk product has met all Specifications.

1.20 **"Certificate of Compliance"** means, as further specified in the applicable Quality Agreement, with respect to each Batch subject thereto, a document prepared by Lonza that incorporates the Certificate of Analysis and which also certifies that the final bulk product was manufactured according to cGMP.

1.21 **"Commence**" or "**Commencement**" means, with respect to the commencement of a Batch, the removal of the first ampoule of the Cell Line from the relevant cell bank stocks with the intent that such cells shall be used in accordance with this Agreement.

1.22 "**Commercial Batch**" means a Batch produced for the purposes of commercial use by Alexion.

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1.23 “**Components**” means for example Raw Materials, [*].

1.24 "**Confidential Information**" means Alexion Confidential Information and/or Lonza Confidential Information, as the context requires.

1.25 “**Critical Components**” means Components that are critical for the Services as defined in the Quality Agreement.

1.26 “**Critical Decision**” means a decision on any matter that will or would be reasonably likely to have a material impact on an operational, financial, quality and/or compliance basis, on a Product and/or any of the Services.

1.27 “**Delivery**” has the meaning set forth in Section 5.4.1.

1.28 “**EMA**” means the European Medicines Agency, or any successor agency thereto.

1.29 "**Engineering Batch**" means a Batch used for process demonstration and confirmation of some or all of the Process steps, and is described in Section 4.6.1 hereof.

1.30 “**Executive Steering Committee**” or “**ESC”** is defined in Section 3.2.1.

1.31 "**Facility**" means, as applicable, Lonza's commercial manufacturing facilities located at:

1.31.1 [*] (the “[*] **Facility**”);

1.31.2 [*] (the “[*] **Facility**”) and/or;

1.31.3 [*] (the “[*] **Facility**”),

including any additional Lonza facility which is agreed in writing by the Parties to be added as a Facility hereunder, each as set forth with respect to a Product in the applicable PSA.

1.32 "**FDA**" means the United States Food and Drug Administration, or any successor agency thereto.

1.33 “**FD&C Act**” is defined in Section 1.16.

1.34 “**Force Majeure Event**” is defined in Section 20.1.

1.35 “**Forecast**” is defined in Section 5.2.1(a).

1.36 “**Intellectual Property**” means (i) inventions (whether or not patentable), patents, ideas, discoveries, trade secrets, copyrights, trademarks, trade names and domain names, rights in compositions of matter, rights in processes, rights in formulations, rights in articles of manufacture, rights in designs, rights in computer software, database rights, rights in confidential information (including know-how) and any other intellectual property rights,

in each case whether registered or unregistered, (ii) all applications (or rights to apply) for, and renewals or extensions of, any of the rights described in the foregoing clause (i), and (iii) all rights and applications that are similar or equivalent to the rights and application described in the foregoing clauses (i) and (ii), which exist now, or which come to exist in the future, in any part of the world.

1.37 **"Knowledge**" An individual shall be deemed to have "Knowledge" of a particular fact or other matter if: (i) such individual is actually aware of such fact or other matter or (ii) (except when Knowledge is stated to be "actual Knowledge") a prudent individual could be expected to discover or otherwise become aware of such fact or other matter in the course of conducting a reasonably comprehensive investigation concerning the truth or existence of such fact or other matter. Each of Lonza and Alexion shall be deemed to have "Knowledge" of a particular fact or other matter if any of their respective directors, officers or employees with the authority to establish policy for the company has actual knowledge of such fact or other matter after due and diligent inquiry.

1.38 "**License Agreement**" has the meaning ascribed to it by Exhibit B.

1.39 "**Liabilities**" is defined in Section 15.1.1.

1.40 "**Lonza**", except where otherwise indicated, means:

1.40.1 Lonza Singapore in respect of all activities performed at the [*] Facility;

1.40.2 Lonza Sales in respect of all activities performed at either the [*] Facility or the [*] Facility; and

1.40.3 Lonza Group AG in respect of Section 21.8.

1.41 "**Lonza Confidential Information**" means all technical and other information known to, owned or controlled by Lonza or its Affiliates from time to time, and not known to and at the free disposal of Alexion prior to its disclosure by Lonza or its Affiliates to Alexion and not in the public domain, including, without limitation, the Lonza Media Formulations and the Lonza Process.

1.42 "**Lonza Media Formulations**" means Lonza's proprietary formulations of cell growth medium and cell growth supplements used in the Process.

1.43 "**Lonza Process**" means that part of the Process which was originally invented by or for Lonza, plus any generic improvements or know-how which were invented by or for Lonza. Notwithstanding the foregoing, the Lonza Process specifically excludes any Alexion Process.

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1.44 "**Materials of Environmental Concern**" means any hazardous substance as is identified by any Regulatory Authority.

1.45 "**Minimum Order**" is defined in Section 5.2.2.

1.46 "**Net Sales**" means all monies received by or on behalf of Alexion or its Affiliates in respect of the worldwide sale of Product (eculizumab) less the following items to the extent that they are paid or allowed and included in the invoice price for the Product (eculizumab):

- normal discounts actually granted;
- credits granted for Product (eculizumab) or other goods returned or not accepted by customers;
- packaging, transportation and prepaid insurance charges on shipments or deliveries to customers;
- Customs duties, surcharges and other governmental charges;
- taxes actually incurred by Alexion or its Affiliates (for example, VAT) in connection with the sale or delivery of Product (eculizumab) or other goods to customers; and
- rebates or charge backs actually paid or credited.

Upon any sale or other disposal of Product (eculizumab) by or on behalf of Alexion or its Affiliates other than a bona fide arm's length transaction exclusively for money or upon any use of the Product (eculizumab) for purposes which do not result in a disposal of such Product (eculizumab) in consideration of sales revenue customary in the country of use such sale, other disposal or use shall be deemed to constitute a sale at the then current maximum selling price in the country in which such sale, other disposal, or use occurs. For the avoidance of doubt, the supply of Product (eculizumab) free of charge (including without limitation provision of product free of charge for compassionate purposes), commercial samples, or for use in clinical studies or to third parties for evaluation purposes shall not be included in this provision.

1.47 "**Non-Conforming Batch**" means a Batch that fails to conform to the Specifications as set forth in Section 9.1 hereof.

1.48 "**Out of Freeze Date**" means the date of removal of the vial of cells from frozen storage for the production of a Batch.

1.49 "**Party**" or "**Parties**" means Alexion and/or Lonza, as the context requires.

1.50 "**PAI**" has the meaning set forth in Section 10.2.

1.51 "**PIP**" has the meaning set forth in Section 10.2.

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1.52 "**PHS Act**" means the Public Health Service Act, Biological Products, as amended.

1.53 "**Post-Release Deviation**" means a deviation raised by either Alexion or Lonza post-release of the Certificate of Compliance by Lonza regardless of when Alexion or Lonza become aware of or are informed of such deviation.

1.54 "**Process**" and "**Processing**" means any and all operations, including packaging for shipment, carried out for the manufacture of the Product under this Agreement, as summarily described under each PSA and in the applicable Quality Agreement and the applicable TTA, as such process may be changed from time to time in accordance with this Agreement.

1.55 "**Process Validation**" means those activities necessary to validate the Process at the relevant Facility, including a process validation master plan, a process specification cleaning validation, and a process performance qualification study.

1.56 **"Process Validation Batches"** means Batches that are produced to confirm reproducibility of the Process and are required to complete consistency studies, all to the extent necessary to support an approvable supplemental regulatory filing as determined by the applicable Regulatory Authorities.

1.57 "**Product**" means such proprietary biopharmaceutical product of Alexion or an Affiliate of Alexion as is set forth in an applicable PSA as a Product under this Agreement, and includes Product (eculizumab) and Product (Asfotase alfa) as well as any other product set forth in a PSA or a TTA.

1.58 "**PSA**" or "**Product Specific Appendix**" is defined in Section 2.3.

1.59 "**Purchase Order**" has the meaning set forth in Section 5.2.4.

1.60 "**Quality Agreement**" or "**QA Agreement**" means each Quality Agreement to be entered into, with respect to a Product, by and between the Parties no later than sixty (60) days after the execution of the PSA or such other date set forth in the applicable PSA for such Product, as the same may be amended from time to time by mutual written agreement of the Parties.

1.61 "**Quality Assurance**" or "QA" means the sum total of the organised quality assurance arrangements made with the purpose of ensuring that a Product meets the Specifications and shall specifically include all activities as set forth in the QA Agreement.

1.62 "**Raw Materials**" means ingredients, additives, disposables including filters and bags, and reagents, which are purchased or used by Lonza in the performance of the Services.

1.63 "**Regulatory Authority**" means any governmental authority in Switzerland, Singapore, US, EMEA, and/or any other country competent to grant Registrations for the Processing and/or marketing of pharmaceutical products and/or the Product and/or finished product comprised of the Product. For the avoidance of doubt, in the event that the regulations of

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two such countries contain different standards for the Product, the stricter (more demanding) requirement shall adhere.

1.64 [*].

1.65 "**Services**" means the services to be provided by Lonza which are the subject of this Agreement, including the services under each PSA and the provision of personnel and operation of relevant plant and equipment at the Facilities.

1.66 "**SHE**" means safety, security, health and environmental protection.

1.67 "**Specifications**" means the specifications for the relevant Product, as agreed by the Parties and set forth in the Quality Agreement, as may be modified from time to time by the written agreement of the Parties.

1.1 "**Tech Transfer Agreement**" or "**TTA**" is defined in Section 4.5.

1.2 "**Term**" is defined in Section 18.1.

1.3 "**Third Party**" means any party other than Alexion, Lonza and their respective Affiliates.

ARTICLE 2.
AGREEMENT STRUCTURE

2.1 **Entire Agreement**. This Agreement (including all Exhibits, the Quality Agreements, purchase orders, PSAs and TTAs) constitutes the entire understanding between the Parties with respect to the subject matter hereof and supersedes all prior agreements, negotiations, understandings, representations, statements and writings relating thereto, including but not limited to the Large-Scale Product Supply Agreement (Singapore) dated 19th October 2011, the Exclusive Manufacturing and Supply Agreement dated 23 December 2010 and the Manufacturing Services Agreement dated 5th November 2009, which three agreements were assigned to Alexion with an effective date of 1st January 2014. Except as otherwise expressly provided, this Section 2.1 will not affect any rights and obligations which, from the context thereof, are intended to survive termination or expiration of such prior agreements, nor shall it prejudice any other remedies that the Parties may have under such agreements. In addition, the License Agreement shall continue in force in accordance with its terms as modified by Exhibit B hereto,

2.2 **Integration**. To the extent any terms set forth in a PSA, TTA, Purchase Order and/or any Quality Agreement conflict with the terms set forth in this Agreement, the terms within this Agreement shall control unless otherwise expressly agreed by the Parties in writing in such PSA, TTA, Quality Agreement and/or Purchase Order.

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2.3 **Product Specific Appendix/PSA**. In conjunction with entering into this Agreement, the Parties may agree certain activities, the description of which shall be contained in an individual product specific appendix to this Agreement (the "**PSA**", a form of which is attached hereto as **Exhibit A**), executed by a duly authorized officer of each Party.

2.3.1 The Parties have agreed the following PSAs:

(a) The manufacture of Product (eculizumab) in [*];

(b) The manufacture of Product (eculizumab) in [*];

(c) The manufacture of Product (Asfotase alfa) in [*];

(d) The manufacture of Product (Asfotase alfa) in [*]; and

(e) The manufacture of cell banks at [*].

2.3.2 It is understood and agreed that one or more Affiliates may be performing one or more activities by or on behalf of a Party under this Agreement and/or a PSA, provided that any Lonza Affiliate may perform the Processing, filling, packaging, storage, testing, shipping or receiving of Products only at the Facility specified in the applicable PSA for each Product. Each Party (including its Affiliates) may execute PSAs under this Agreement, provided, however, that the Parties hereto shall each remain liable and be responsible for the performance of each PSA and this Agreement and the obligations of their respective Affiliates under each PSA and otherwise under this Agreement.

2.3.3 Each PSA shall be subject to and deemed a part of this Agreement. No PSA, or any modification thereto, shall be attached to or made a part of this Agreement without first being executed by the Parties hereto in a writing which specifically references this Agreement.

2.4 **Quality Agreements**. In conjunction with entering into this Agreement, the Parties shall negotiate in good faith, execute and deliver a Quality Agreement for each Facility at which Lonza carries out Services under this Agreement that governs the responsibilities related to quality systems and quality requirements for Product at such Facility, including quality control, testing and release thereof. The parties shall negotiate and execute a Quality Agreement for each Facility (or revise as appropriate an existing Quality Agreement) within sixty (60) days of execution of the PSA relating to such Facility. Each Quality Agreement (including any revised existing Quality Agreement) is incorporated herein by reference and shall be subject to this Agreement.

2.5 **TTA**. In conjunction with entering into this Agreement, with respect to each Product to be manufactured under a specific PSA under this Agreement (with the exception of the manufacture of Product (eculizumab) in [*] and Product (Asfotase alfa) in [*]), the Parties

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shall jointly develop the applicable TTA in accordance with the requirements of this Agreement, which TTA shall establish the scope, process, key deliverables, and timeline for the modifications to the relevant Facility and licensing transfer from Alexion to Lonza for manufacturing such Product at the Facility. Each TTA (including any revised existing TTA) is hereby incorporated herein by reference and shall be subject to this Agreement.

ARTICLE 3.
GOVERNANCE STRUCTURE

3.1 **Committees and Teams Generally**. Each Party will be responsible for its internal decision making process and for informing the other Party of decisions made materially or adversely affecting the manufacturing and/or supply of the Product in a regular and timely manner. Without limiting the foregoing, the Parties will establish a Governance Structure comprised of an Executive Steering Committee, a Joint Steering Committee and Joint Project Teams to oversee the performance of this Agreement.

3.2 **Executive Steering Committee**.

3.2.4 **Formation**. Within thirty (30) days after the Effective Date, the Parties will establish an executive steering committee ("**Executive Steering Committee**" or "**ESC**") to oversee manufacture at each applicable Facility and the performance of this Agreement and the PSAs hereunder. The Executive Steering Committee will be composed of an equal number of senior representatives (not to exceed four from each Party) appointed by each of Alexion and Lonza. Either Party may replace any or all of its representatives at any time upon prior written notice to the other Party.

3.2.5 **Responsibilities**. The Executive Steering Committee shall perform the following functions:

(a) review the business relationship between the Parties including on-going business, future new business opportunities and long term strategies.

(b) settle disputes or disagreements that are unresolved by a Joint Steering Committee unless otherwise indicated in this Agreement; and

(c) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties.

3.2.3 **Composition**. The Executive Steering Committee shall be comprised of the following representatives from each Party:

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(a) The Chief Global Operations Officer of Alexion and the Chief Operating Officer of Lonza

(b) SVP, Global Manufacturing Operations of Alexion and the Senior Vice-President, Global Operations of Lonza

(c) CMO, Business Management of Alexion and the Global Head of Sales for Lonza.

(d) The Head of Quality of both parties; and

(e) Additional representatives as identified and agreed by the ESC.

3.3 **Joint Steering Committee**

3.3.1 **Formation**. Within thirty (30) after the Effective Date, the Parties will establish a Joint Steering Committee **("Joint Steering Committee" or "JSC",** which shall consist of Monthly JSC and Quarterly JSC components as further described in Section 3.5.2 and each reference to "**Joint Steering Committee**" or "**JSC**" in this Agreement shall mean either component as the case may be unless otherwise specified in this Agreement**)** to oversee and manage the activities to be conducted under this Agreement and each PSA and the Facilities included herein. The JSC will consist of such equal number of representatives of each Party as are reasonably necessary to accomplish the goals of this Agreement. Each Party will promptly notify the other Party of its initial appointees to each JSC. Each Party may replace any or all of its JSC representatives effective upon written notice to the other Party.

3.3.2 **Responsibilities**. The Joint Steering Committee shall have the following responsibilities:

(a) High level oversight of all Facilities involved in manufacture of Product under this Agreement including, but not limited to, determining the overall strategy at each applicable Facility in the manner contemplated by this Agreement

(b) Establishment and review of key performance indicators for all Facilities involved in manufacture of Product under this Agreement

(c) Resolution of issues escalated from the JPT's

(d) Escalation of unresolved issues to the ESC.

3.3.3 **Composition**. The Joint Steering Committee shall be comprised of, for Alexion, the VP, Technical Operations, Senior Director, Technical Services,

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Executive Director, External Quality Assurance and Senior Director, CMO, Business Management, and for Lonza, the regional Vice Presidents of Operations, Contract Manager, Sales representative, a global Quality Assurance representative and, in respect of the relevant Facility, the Head of Site, Quality Assurance Director, Operations Director and Project Manager.

3.4 **Joint Project Team**

3.4.1 **Formation**. Within thirty (30) days after the Effective Date the Parties will establish a Joint Project Team ("Joint Project Team" or "JPT") for each separate Facility to oversee and manage the activities to be conducted under this Agreement and each PSA herein at such Facility. Each JPT will headed up by a Lonza site Project Manager and an Alexion CMO Business Manager (each a "Project Manager"). Each Project Manager will have day-to-day operational responsibility for such Party's responsibilities hereunder with respect to all related activities at the Facility.

3.4.2 **Responsibilities**. The Joint Project Team shall have the following responsibilities:

(a) Execution and completion of project activities and deliverables

(b) Oversight of commercial manufacturing campaigns including all pre-campaign preparation and post-campaign activities.

(c) Resolution of all operational issues that may arise from time to time associated with the manufacture of Product.

(d) Escalation of unresolved issues to the JSC

3.4.3 **Composition**. Each JPT shall be headed up by a Lonza Project Manager and an Alexion CMO Business Manager as appointed by the Parties. The JPT shall be composed of appropriate Technical, Quality and/or Operational representatives from the Parties as is necessary to execute the responsibilities of the JPT.

3.5 **Meetings**.

3.5.1 **ESC**. The ESC will meet at least quarterly, and as agreed by the ESC to make determinations as required of it, provided the first ESC meeting shall be within ninety (90) days of the Effective Date. The Parties will attempt to ensure that at least three of such meetings in each calendar year shall be face-to-face and shall alternate at each of the Party's offices unless otherwise decided by the ESC. The Parties shall determine at each ESC meeting whether to generate minutes for such ESC meeting. Where minutes are generated, the Parties shall issue final minutes no

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later than sixty (60) days after such ESC meeting unless otherwise agreed in writing between the Parties.

3.5.2 **JSC**. The JSC will meet via telecon for each Facility to include the relevant Facility-based Lonza JSC members and Contract Manager at least monthly during the term of this Agreement unless the Parties otherwise agree in writing. On a quarterly basis in place of the Monthly JSC meetings, a single JSC meeting shall be held to also include the regional Vice Presidents of Operations, Sales representative and global Quality Assurance representative and this meeting shall be used to consider activities at all the Facilities, including forecasts and scheduling and key performance indicators. Meetings may be called on a more frequent basis by the JSC especially during the early stages of the collaboration or if necessary to resolve issues escalated from a JPT. These meetings may be held via teleconference or videoconference but the Quarterly JSCs shall be held face to face at least two times per year alternately at the Parties' facilities or at such locations as the Parties may otherwise agree. Minutes will be generated and issued within 1 (one) week of each JSC meeting showing the following:

(d) Attendance

(e) Summary of topics discussed

(f) Decisions made

(g) Actions assigned.

Decisions.

(a) The JSC may make Critical Decisions only if a quorum exists, which means the meeting is attended by, for Alexion, representatives from External Quality Assurance, Technical Operations and CMO, Business Management at Director level or above, and for Lonza, the relevant Facility Site Head or regional Vice President of Operations, a relevant Facility or global Quality Assurance representative at Associate Director level or above, and either the Contract Manager or Sales representative, or in each case a delegate from each such function pursuant to Section 3.5.4.

(b) If the JSC is unable, despite the good faith efforts of all members, to resolve a disputed issue that is within the purview of the JSC, the disputed issue shall be referred immediately by the JSC to the ESC. If the dispute cannot be resolved by the ESC, the matter will be handled in accordance with Article 19 hereof.

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3.5.3 **JPT** A JPT shall meet as frequently as agreed but at least once per week during campaign preparation (defined as 90 days prior to the first out of freeze date of a Campaign), campaign execution and post campaign activities. Outside of these times, a JPT may meet less frequently but not less than once per calendar month. Any exceptions to meeting frequency shall be mutually agreed by the Project Managers. These meetings may be held via teleconference, videoconference or face-to-face as agreed by the JPT. Minutes will be generated and issued within 2 working days of each JSC meeting showing the following:

(a) Attendance

(b) Summary of topics discussed

(c) Decisions made

(d) Actions assigned

Decisions.

(a) Where a JPT is unable, despite good faith efforts of all members, to resolve a disputed issue that is within the purview of the JPT, the disputed issue shall be referred by agreement of the JPT, to the JSC for resolution.

(b) The JPT may not make a Critical Decision, which shall be escalated to the JSC for decision.

Pre-and Post-Campaign Review Meetings. In addition to the above, Lonza and Alexion shall carry out pre- and post-Campaign meetings at each Facility and each Party shall have the right to invite representatives to such meetings it chooses in its reasonable discretion. The duration of each meeting shall be determined jointly by the JPT to adequately accommodate the meeting agenda, but in no event shall be longer than two (2) days, unless jointly agreed by the JPT. The agenda for each pre-campaign meeting shall be proposed by Alexion and agreed by Lonza, Lonza not to unreasonably disagree with any agenda item proposed by Alexion. Lonza shall have the opportunity to suggest additional topics, not to be unreasonably refused by Alexion. Post campaign review meetings shall follow Lonza's standard agenda for these meetings, with additional topics suggested by Alexion, not to be unreasonably refused by Lonza.

3.5.4 **Generally**. Unless otherwise specified in this Agreement, all meetings of the operating committees hereunder, upon the determination of the applicable operating committee, may be conducted by conference telephone or videoconference. Telephonic and videoconference meetings shall be effective only if at least two (2) representative of each Party are in attendance or participating in

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the meeting. Meetings shall be attended by the members provided that if a member may not attend, s/he may send a delegate.

ARTICLE 4.
LICENSING TRANSFER AND PROCESS IMPLEMENTATION

4.1 **Supply of Alexion Materials**. Pursuant to the agreements identified in Section 2.1, Lonza has possession of, or Alexion shall supply, sufficient Alexion Materials, including sufficient purified reference standard for the Product and sufficient ampoules of the Cell Line from an appropriate cell bank for Lonza to provide the Services.

4.2 **Rights in Alexion Confidential Information, Alexion Patent Rights and Alexion Materials, Rights to the Processes and Biosimilar Restriction.**

4.2.1 Alexion hereby grants Lonza the non-exclusive right to use the Alexion Confidential Information, the Alexion Patent Rights, and the Alexion Materials solely for the purpose of Lonza performing Services for Alexion under this Agreement. Lonza and its Affiliates will not use the Alexion Confidential Information, Alexion Patent Rights or Alexion Materials (or any part thereof) for any other purpose without Alexion's prior written consent either during or after the term of this Agreement. Except as set forth in this Section 4.2, no licenses are granted to Lonza to use the Alexion Materials, the Alexion Patent Rights or the Alexion Confidential Information, and no licenses shall arise or be deemed to have arisen by default, estoppel or otherwise. Without limitation of any other clauses herein related to survival, the provisions of this Section 4.2 shall survive the termination of this Agreement.

4.2.2 Lonza confirms that the Cell Line and all other cell lines and material generated by Lonza or any of its Affiliates pursuant to this Agreement are owned by Alexion (subject to Lonza's retained rights in the Lonza Patent Rights and Lonza Confidential Information), and are included in the Alexion Material. Lonza hereby grants and agrees to grant to Alexion an exclusive, perpetual, royalty-free, worldwide license to utilize the Lonza Process for manufacture, use and sale of [*] (regardless of whether such patents have terminated or expired, or later terminate, or expires for any reason). Except with respect to the performance of the Services under this Agreement, such license is exclusive even as to Lonza and its Affiliates. Except as specifically set forth above, Lonza retains the exclusive ownership and right to use the Lonza Process (but not the Alexion Process) in connection with the manufacture, use and sale of all other products, including without limitation [*].

4.2.3 Lonza further agrees that neither Lonza nor its Affiliates will manufacture for itself, its Affiliates, and/or for any third party [*] (using the Lonza Process or any other

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process) while Lonza is manufacturing [*] of each Product. The Parties agree at such time as they add any other Product to this Agreement, [*]which discussions will be considered on a case-by-case basis, and the [*] minimum above shall not necessarily be considered as the minimum requirement for the biosimilar restriction to apply to such additional Products which minimum may be more, less or the same depending on the particular case including the potential market of such new Products. For the purposes of this section 4.2.3, [*].

4.3 **Lonza Obligations Regarding Alexion Materials.** At all times, Lonza shall use reasonable best efforts to keep the Alexion Materials secure and safe from loss, damage, theft, misuse and unauthorized access in such manner as Lonza stores its own materials of similar nature; not part with possession of the Alexion Materials or the Product save for the purpose of tests at the Testing Laboratories or as directed by Alexion; and cause all Testing Laboratories to be subject to confidentiality and non-use obligations no less onerous than those confidentiality and non-use obligations imposed on Lonza under this Agreement.

4.4 **No Other License.** Without prejudice to Lonza's right to receive payment hereunder or to Lonza's own proprietary rights in the Lonza Process, the Lonza Information and the Lonza Patent Rights, Lonza agrees that, except as expressly provided in Section 4.2 above, Lonza shall not by virtue of this Agreement acquire any right, license or title in, or to, the Alexion Patent Rights, the Alexion Confidential Information, the Alexion Materials or the Product.

4.5 **TTA**. By no later than sixty (60) days after the execution of a PSA, which PSA covers the manufacture of a Product (with the exception of the manufacture of Product (eculizumab) in [*] and Product (Asfotase alfa) in [*],), the Parties shall jointly develop and enter into a technology transfer agreement, which shall set forth the specific responsibilities of the Parties in connection with the modification of the applicable Facility and implementation of the Process at such Facility (each a "**TTA**"). Each TTA may be amended from time to time by mutual agreement of Lonza and Alexion. Each TTA will also incorporate by reference more detailed functional plans as needed.

4.6 **Initial Batches**.

4.6.1 **Engineering Batches**. Lonza shall manufacture Engineering Batches in compliance with the requirements of cGMP, including applicable Batch records as well as any documentation, processes and procedures referred to in such Batch records, and use commercially reasonable efforts to ensure such Batches conform to the applicable Specifications. A minimum number of Engineering Batches are required before moving to Process Validation. The PSA shall set forth the minimum number of Engineering Batches to be manufactured by Lonza as well as any other requirements with respect to such Engineering Batches. At Alexion's election, Alexion may make whatever further use of such Engineering Batches as it shall determine, or direct Lonza to dispose of such Engineering Batches.

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4.6.2 **Process Validation**. Once the Process applicable to a PSA is implemented at the applicable Facility, Lonza shall use reasonable best efforts to perform all required process validations (as described in the PSA for such Product) and shall produce the number of Process Validation Batches, each as specified in the applicable PSA, sufficient to document the operability and reproducibility of the Process and permit the Parties to complete and file the necessary regulatory documents.

4.7 **Raw Materials**.

4.7.1 **Raw Materials**. Alexion shall pay Lonza the [*] of all Raw Materials and [*], together with the following handling fees, expressed as percentages of such [*]:

	Soliris [*]	**Soliris** [*]	**Asfotase Alfa** [*]	**Asfotase Alfa** [*]
Raw Materials	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]

provided however that with regard to the manufacture of Product (eculizumab) in [*], (a) the [*] in the Batch price and will not be invoiced separately, (b) the [*] in the Batch price and will be invoiced separately; and provided further that Alexion may decide at any time to purchase for any Facility any such [*] directly from an outside party by informing Lonza thereof in which case no payment shall be made by Alexion to Lonza for such [*] and [*]; and provided further where Lonza invoices Alexion separately for Raw Materials and/or [*] under this Section 4.7.1, Lonza shall use reasonable best efforts to obtain the lowest possible pricing for such Raw Materials and [*]. Where Alexion so purchases any [*] directly from an outside party, these must be delivered to the relevant Facility in accordance with the requirements of the applicable manufacturing schedule, and where a Batch cannot be manufactured solely due to such [*] not being made available on time then (a) Alexion shall pay a cancellation charge equal to [*]% of the Batch price and [*]% of any handling fee for Raw Materials for such Batch (except where Lonza is able to resell the cancelled Batch slots by a new order of greater or equal value not under purchase order with Lonza by another client at the time of such cancellation) and (b) Lonza shall have no liability to Alexion for such Batch not being manufactured.

4.7.2 **Raw Materials Management and Safety Stock.** For each production Campaign, Lonza shall, at a minimum, procure safety stock of Raw

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Materials equivalent to [*] worth of Raw Materials for a Campaign containing up to [*] and [*] worth of Raw Materials for a Campaign containing [*] batches. Prior to each Campaign, Lonza and Alexion shall discuss and agree if the safety stock level of Raw Materials shall be increased to a maximum of [*] worth of Raw Materials for a Campaign of up to [*]. Alexion and Lonza will discuss and agree safety stock strategy for Campaigns over [*], but at a minimum shall be equivalent to [*] worth of Raw Materials. Lonza and Alexion shall meet yearly to perform a joint review and risk assessment of Raw Materials to agree any changes or exceptions to the strategy. Lonza shall provide to Alexion on a quarterly basis an inventory report of Alexion-owned Raw Materials.

4.7.3 **Critical Components**. Lonza shall not change the supplier of any Critical Component without the prior written consent of Alexion.

4.7.4 **Media**. For the avoidance of doubt, the Parties acknowledge that they have agreed that (a) it is not intended to use [*]-manufactured media at the [*] Facility or [*] Facility, but if it so used, no additional payment equivalent to the US [*] per liter in (b) below will be charged by Lonza, but (b) in the event that APIT or any of its Affiliates uses [*]-manufactured media at any other facility for the manufacture of Product, Alexion will pay Lonza US [*] per liter therefor. The obligation of subparagraph (b) shall not be applicable in the event that Lonza cannot or will not supply Lonza-manufactured media.

ARTICLE 5.
PRODUCTION AND SUPPLY

5.1 **Commitment to Manufacture; Purchase**. Subject to the terms and conditions set forth in this Agreement, during the Term, Alexion shall retain Lonza, in accordance with the individual PSAs executed by the Parties, as a non-exclusive manufacturer of the Product (eculizumab), and as a non-exclusive manufacturer of Product (Asfotase alfa).

5.2 **Production and Supply**.

5.2.3 **Forecasts and Manufacturing Schedule**

(h) **Forecast.** In respect of the calendar year 2015 and thereafter, Alexion shall provide to Lonza a [*] forecast, with the first such forecast to be provided to Lonza no later than [*] days after the Effective Date and thereafter updated in [*] of each year ("**Forecast**"). The Forecast shall set forth, for the lesser of [*] or the remainder of the Term, on a Facility-by-Facility and Product-by-Product basis, the number of Batches requested to be manufactured, with: (i) the first [*] of each Forecast to be provided in line with the relevant Lonza Manufacturing Schedule; and (ii) the [*] to be

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provided on an annual basis, which, in the case of clause (ii) shall be non-binding in respect to the number of Batches Forecast above the Minimum Order. In addition, Alexion shall use its commercially reasonable efforts to provide a Forecast that would permit Lonza to plan Alexion's annual production in no more than one Campaign in any given year.

(i) **Manufacturing Schedule.** Within [*] of the receipt of each Forecast, Lonza shall provide to Alexion a Manufacturing Schedule (which Manufacturing Schedule shall detail, at a minimum, the estimated Out of Freeze and Delivery dates for each Batch) for no less than the Minimum Order set forth in such Forecast. The Delivery date of the last Batch in such Manufacturing Schedule must be within the calendar year in which the Batch was Forecast. In order to allow a level of flexibility at the Facility, Lonza can adjust the estimated Out Of Freeze date (and as a result, the target Delivery date) as follows:

(i) [*] or more prior to the Out of Freeze Date, the Out of Freeze Date can be adjusted by plus or minus [*];

(ii) between [*] and [*] prior to the Out of Freeze Date, the Out of Freeze Date can be adjusted by plus or minus [*]; and

(iii) less than [*] prior to the Out of Freeze Date, the Out of Freeze Date can be adjusted by plus or minus [*].

provided, however, that (x) a single Out of Freeze Date may not be adjusted by more than a cumulative total of [*], (y) any such adjustment by Lonza shall not cause Alexion to be in breach of its obligations in Section 4.7.1 concerning timely delivery of Raw Materials and (z) Lonza shall use commercially reasonable efforts to start and complete Campaigns in the same calendar year but if Lonza fails to start and complete a Campaign in the same calendar year, the portion of the Campaign completed in the following year shall be counted in the prior year for purposes of satisfying Minimum Order requirements unless otherwise requested in writing by Alexion.

(c) **Capacity Notice**. Lonza shall make good faith efforts to notify Alexion at such time as Lonza receives firm orders that would prevent Lonza having the capacity to fulfill one or more Batches set forth in the [*] of any Forecast.

5.2.4 **Minimum Order.** In respect of the calendar years to and including [*], Alexion shall place with Lonza the following minimum Purchase Orders for Batches, based on starts in the Manufacturing Schedules provided by Lonza for each relevant calendar year ("Minimum Order"):

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(e) **Soliris** [*]**:** In respect of Product (eculizumab) manufactured in [*], a minimum of [*] as set forth in the PSA, a minimum of [*] or as many as agreed in the PSA, and a minimum of [*].

(f) **Soliris** [*]**:** In respect of Product (eculizumab) manufactured in [*], a minimum of [*].

(g) **Asfotase Alfa** [*]: In respect of Product (Asfotase Alfa) manufactured in [*].

(h) **Asfotase Alfa** [*]**:** In respect of Product (Asfotase Alfa) manufactured in [*].

(i) In respect of the calendar years [*], Alexion commits to the non-product-specific capacity commitment below, which Lonza commits to reserve for supply on a Product-by-Product basis from any of the Facilities then under a PSA for such Product, as follows:

- [*] for one or two products in no more than [*]), and
- [*].
- In each of the foregoing cases, Lonza can supply from any of its Facilities provided that the total price for the Batches, including the fee for Raw Materials, supplied from the alternative Facility(ies) shall not be greater than if they had been supplied from the original Facility(ies) (by way of example, if the change is from the original Facility supplying on [*]L scale to an alternative Facility supplying on a [*]L scale, the total price for [*]supplied from the alternative Facility shall be no greater than the (i) the total price of [*] supplied from the original Facility plus (ii) the fee for the Raw Materials from the original Facility).
- Any movement of a Product to a Facility that is not at such time under a PSA requires the prior written agreement of both Parties to a new PSA for such Facility and the Parties shall work together in good faith to agree such PSA.

Where the cycle time is greater than the above assumptions, the Batch price and number of Commencements would have to be reviewed. Both Parties shall use commercially reasonable efforts to work together to reduce cycle times.

5.2.5 **Demand above the Minimum Order**. Where Alexion Forecasts demand subject to section 5.2.1 which is above the Minimum Order, the following shall apply:

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(a) **Soliris** [*]**:**[*] but where a Purchase Order for additional demand above the Minimum Order is accepted by Lonza, it shall be binding on both Parties.

(b) **Soliris** [*]:[*] and beyond is subject to whether or not Lonza has freely available capacity, but where a Purchase Order for additional demand is accepted by Lonza it shall be binding on both Parties.

(c) **Asfotase alfa** [*]: Additional demand is subject to whether or not Lonza has freely available capacity. [*]Where a Purchase Order for additional demand is accepted by Lonza it shall be binding on both Parties.

(d) **Asfotase alfa** [*]: Additional demand is subject to whether or not Lonza has freely available capacity, but where a Purchase Order for additional demand is accepted by Lonza it shall be binding on both Parties.

5.2.6 **Purchase Orders**. Alexion shall issue to Lonza, at least [*] prior to Commencement of the first Batch in a Campaign, a written purchase order, consistent with the agreed Manufacturing Schedule, ("**Purchase Order**"). To the extent such Purchase Order conforms to the Manufacturing Schedule for such Product in terms of amount and timing of delivery, Alexion and Lonza both shall be bound thereby, and Lonza shall be obligated to confirm in writing, within [*] [*] of the date of such Purchase Order, their acceptance of such Purchase Order. Lonza shall use its commercially reasonable efforts to accommodate any reasonable changes to a Purchase Order that Alexion may request. The Parties agree that there shall be one Purchase Order issued for each separate Batch. However, in respect of the period from the Effective Date until [*], Alexion shall place, and Lonza shall accept, within [*] of the Effective Date, Purchase Orders in respect of the Batches set out in section 5.2.2 above provided such Purchase Orders are consistent with the Manufacturing Schedules provided by Lonza. In the case a Party terminates this Agreement in accordance with Section 18.2.2 or 18.2.3 (as the case may be), Lonza shall not be obliged to manufacture, and Alexion shall not be obliged to pay for, any Batch having a Commencement after the Notice Period. During the Notice Period, both Parties' obligations under this Agreement shall continue in respect of Minimum Orders and Purchase Orders.

5.3 **Cancellation Fee**. The Minimum Order cannot be canceled either by Alexion or Lonza. Any demand above the Minimum Order for which Purchase Orders have been agreed by the Parties in accordance with Section 5.2.4 are binding on both Parties and cannot be cancelled by Alexion or Lonza. Any Minimum Order or demand above the Minimum Order that is binding that Alexion requests to be cancelled will be subject to payment of a cancellation charge equal to [*] of the Batch price and [*] of any handling fee for Raw Materials in accordance with section 4.7 above. If Lonza is able to resell the cancelled Batch

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slots by a new order of greater or equal value not under purchase order with Lonza by another client at the time of such cancellation, then Lonza shall waive this cancellation charge. Notwithstanding the above, no cancellation fee shall be imposed in the case of a Batch having a Commencement after the Notice Period in accordance with Section 5.2.4.

5.4 **Provision of Batches**.

5.4.1 **Delivery.** Except as provided in Section 6.5 below, the date on which Lonza issues to Alexion a Certificate of Compliance in a form reasonably acceptable to Alexion with respect to such Batch shall constitute Delivery ("Deliver", or 'Delivered", as appropriate). Both parties shall use good faith efforts to reduce the time period between bulk fill and Delivery.

5.4.2 **Title**: For the avoidance of doubt, without prejudice to Section 7, title to and responsibility for the Product shall pass to Alexion on the date of Delivery.

5.4.3 **Supply Deficiencies**. If Lonza fails to produce a Batch specified in the relevant Purchase Order, then this shall constitute a "**Supply Deficiency**" for purposes of this Agreement. It shall not be a Supply Deficiency where a Batch fails to meet the [*] element of the Specification, provided such failure was not caused by Lonza's operational deviations. In such a case, Alexion shall pay for the Batch and Raw Materials, even although no Certificate of Compliance is Delivered in accordance with Section 5.4.1.

5.4.4 **Procedure to Cure Supply Deficiencies**. If there is a Supply Deficiency, Lonza shall increase the then current Campaign for the relevant Product (or if no longer current, then the next succeeding Campaign for such Product if not remedied beforehand) to remedy the Supply Deficiency and/or take one or more of the following steps to remedy any remaining Supply Deficiency, as determined by the Joint Steering Committee:

(a) Utilize any capacity of any other approved Facility which is not then committed to the performance of the Services or to performance of services for third party customers;

(b) Utilize suitable production capacity (i.e., fully validated for production of Batches of the Product in accordance with this Agreement) of Lonza or its Affiliates not then committed to third party customers; and

(c) Co-ordinate and co-operate with Alexion, through the Joint Steering Committee, to re-schedule Batches of Product ordered hereunder in order to maximize Lonza's ability to rectify the Supply Deficiency while minimizing the disruption to any Purchase Orders then in force and any commitments to third party customers.

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5.4.5 **Supply Failure**. If a Supply Deficiency arises such that Lonza is unable (or the Parties agree that there is no reasonable likelihood that Lonza will be able) to Deliver at least [*] of Purchase Orders in any twelve (12) month period, then such event shall constitute a "Supply Failure".

(a) Supply Failure shall entitle Alexion to elect within a [*] day period from the Supply Failure to: (a) treat the Supply Failure as a Supply Deficiency; or (b) terminate the relevant PSA.

(b) In the event Alexion elects to treat the Supply Failure as a Supply Deficiency, the provisions of Section 5.4.4 shall apply.

(c) Notwithstanding anything to the contrary in the foregoing, in the event that Lonza becomes unable to manufacture any Product for the foreseeable future (i.e., longer than [*] from the Supply Failure) due to Force Majeure, Lonza shall have the right to elect within a [*] day period from the Supply Failure to terminate the relevant PSA upon written notice to Alexion and the provisions of Section 18.3 shall apply.

5.4.6 **Exclusive Remedy**. Except as provided in this Section 5, Alexion shall not be entitled to cancel any unfulfilled part of the Services or to refuse to accept the Services on grounds of late performance or late delivery. The provisions of this Section 5 shall be the sole liability of Lonza and sole remedy of Alexion with respect to any Supply Deficiency or Supply Failure.

5.5 **Excess Capacity**.

5.5.3 **Request by Alexion**. Alexion may notify Lonza in writing if it wishes Lonza to initiate discussions with Lonza's third party customers regarding the opportunity for such third party customers to purchase services to be provided form any fermentation capacity of a Facility which has been reserved for Alexion pursuant to a Purchase Order, or which Alexion is obligated to reserve pursuant to this Agreement, in which case Lonza shall use commercially reasonable efforts to sell such capacity upon commercially reasonable terms.

5.5.2 **Price Adjustment**. Alexion's obligation to utilize or pay for such excess capacity will be waived to the extent that Lonza sells such excess capacity at a price, net of its reasonable personnel and associated costs in selling such excess capacity, that is equal to or greater than Alexon would have paid had it utilized such capacity. If Lonza is able to sell the excess capacity only at a price that will yield Lonza revenues, net of Lonza's reasonable personnel and associated costs in selling such excess capacity, that are less than Alexion would have paid had it utilized such capacity, it will only agree to such terms with Alexion's consent and Alexion shall then be responsible for reimbursing Lonza for such lost revenues (i.e., the difference from

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what Alexion would have been required to pay for such excess capacity). Alexion may request verification from Lonza's accountants, based on a review of Lonza's records, of the amount received by and such costs incurred by Lonza.

ARTICLE 6.

COLLECTION AND SHIPMENT OF PRODUCT

6.1 **Collection and Shipment**. Alexion and Lonza will work together in good faith to determine estimated collection dates for Product under this Agreement and Lonza shall make Product available for collection on an [*] basis the relevant Facility (as defined by Incoterms 2010).

6.2 **Title**: Without prejudice to Section 7, title to and responsibility for the Product shall pass to Alexion on the date of Delivery.

6.3 **Packaging and Labeling**. Unless otherwise agreed, Lonza will package and label Product in accordance with its standard operating procedures. Alexion will inform Lonza in writing in advance of any special packaging and labeling requirements for the Product. All additional costs and expenses incurred by Lonza in complying with such special requirements shall be charged to Alexion in addition to the Price.

6.4 **Transportation and Insurance**. Alexion agrees that it shall arrange collection of the Product within [*] days after the date of Delivery. Alexion shall be responsible for insuring each Batch (at Alexion's own cost) from the date of Delivery; Lonza shall be responsible for the costs to insure each Batch prior to the date of Delivery. The insurance value shall be equal to the replacement value of the Product ([*]). Lonza specifically acknowledges its obligation to provide validated cold storage (at the storage temperatures applicable at the Effective Date) for Product (eculizumab) and Product (Asfotase alfa), at all times prior to Alexion's pickup. At Alexion's request, Lonza will (acting as an independent agent for Alexion) arrange for the transportation of Product to a facility designated by Alexion together with insurance for the then applicable Price for the number of Batches transported. All additional costs and expenses incurred by Lonza in arranging transportation and insurance shall be charged to Alexion in addition to the Price provided Lonza invoices Alexion for such costs and expenses within the calendar quarter following shipment of the Batch. Transportation of the Product, whether or not under any arrangements made by Lonza on behalf of Alexion, shall be made at the sole risk and expense of Alexion. In cases where Alexion has not requested Lonza to arrange for transportation of Product, Lonza will provide reasonable co-operation with Alexion's transportation agents in coordinating the collection of Product from the Facility.

6.5 **Quarantine of Product**. With the agreement of both parties, Lonza will Deliver Product Batches in quarantine prior to delivery of the Certificate of Compliance. Such request shall be accompanied by Alexion's written acknowledgement that the Batch has been Delivered

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without the transmittal to Alexion of a Certificate of Compliance, that accordingly the Batch cannot be administered to humans until transmittal of the Certificate of Compliance, and that Alexion nevertheless accepts full risk of loss, title and ownership of the Batch. The Delivery of a Batch in quarantine shall be subject to such testing requirements as Lonza may reasonably require, and the [*] day period referred to in Section 6.7 shall run from Delivery in quarantine to Alexion of the relevant Batches.

6.6 **Inspection of Product**. Where Lonza has made arrangements for the transportation of Product under Section 6.4, Lonza shall use its reasonable endeavors to notify Alexion of shipment by facsimile or e-mail (return receipt requested) on the date of dispatch. Alexion shall diligently examine the Product as soon as practicable after receipt. Notice of all claims arising out of:

6.6.1 Damage to or total or partial loss of Product in transit shall be given in writing to Lonza and the carrier within [*] business days of receipt; or

6.6.2 Failure of a shipment of Product to arrive shall be given in writing within [*] business days of the date on which the shipment was made, as stated in Lonza's notice of shipment provided on the date of dispatch to Alexion.

Alexion shall make damaged Product available for inspection and shall comply with the requirements of any insurance policy covering the Product. Lonza shall offer Alexion all reasonable assistance, at Alexion’s cost, in pursuing any claims arising out of the transportation of Product, but Lonza's responsibility shall otherwise be limited by the [*] shipping term (Incoterms 2010).

6.7 **Tests**. Promptly following Delivery of a Batch of Product, or any sample intended to be representative thereof, Alexion shall carry out the Alexion Tests. If the Alexion Tests show that the Product fails to meet the applicable Specifications, then Alexion shall give Lonza written notice thereof within [*] days from the date of Delivery of the Batch and shall, unless otherwise directed by Lonza, return the Batch for further testing. In the absence of such written notice, the Batch shall be deemed to have been accepted by Alexion as meeting Specifications. If Lonza agrees, or it is determined pursuant to Section 6.8, that the returned Batch fails to meet Specifications and, to the extent that such failure is not due (in whole or in part) to acts or omissions of Alexion or any third party after Delivery of such Batch, the Batch in question shall be regarded as not having been Delivered and shall constitute or contribute towards a Supply Deficiency and entitle Alexion to the rights set forth in Section 5.4 (including Supply Deficiency) as well as this section 6.7, including a refund for the Batch Price and, for Product (eculizumab), an adjustment in respect of [*] in the case of a lost cycle and/or lost Batch in accordance with the relevant PSA.

6.8 **Disputes**. If there is any dispute concerning whether a Batch meets the applicable Specifications and/or the reasons therefor, such dispute shall be referred for decision to

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an independent expert (acting as an expert and not as an arbitrator) to be appointed by agreement between Lonza and Alexion or, in the absence of agreement by operation of the provisions of Section 19.2. The costs of such independent expert shall be borne equally between Lonza and Alexion. The decision of such independent expert shall be in writing and, save for manifest error on the face of the decision and subject to the rights of the Parties under Section 19.2, shall be binding on both Lonza and Alexion.

ARTICLE 7.
PAYMENTS

7.1 Milestone Payments

7.1.1 **Soliris** [*]: In respect of the manufacture of Soliris at the [*]Facility pursuant to this Agreement, Alexion shall pay Lonza the following non-refundable and non-creditable milestone payments, payable as follows:

(a) [*] payable on the Effective Date; and

(a) [*] payable on completion of modifications to the [*] Facility ready for tech transfer of Soliris to the [*] Facility, provided the modifications to the Facility are sufficient to allow manufacture of Soliris to take place. The Parties shall use reasonable best efforts to complete tech transfer activities no later than 31 December 2014 in accordance with a timeline to be agreed between the parties.

(b) All capital equipment required to be purchased will be purchased, owned, and installed by Lonza. Lonza will bear all costs of delivery, installation, validation, and maintenance of all such equipment. [*].

(c) A facility adaptation fee equal to [*] payable no later than 31 December 2014.

7.1.2 **Soliris** [*]: In respect of the manufacture of Soliris at the [*] Facility pursuant to this Agreement, Alexion shall pay Lonza on the Effective Date a non-refundable and non-creditable milestone payment in the amount of the US dollar equivalent of [*] using the exchange rate prevailing on the Effective Date as published by Thomson Reuters. In addition, the Parties shall use good faith efforts in evaluating (a) the capital equipment needed and (b) the necessary adaptations required to the [*] Facility and the payments due by Alexion to Lonza as a result.

7.1.3 **Asfotase Alfa** [*]: In respect of the manufacture of Asfotase Alfa at the [*] Facility pursuant to this Agreement, Alexion shall pay Lonza the following non-refundable and non-creditable milestone payments, payable as follows:

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(a) [*], payable on the date after all of the following have been completed: the TTA has been agreed, the tech transfer teams for both Parties have been fully established and the first meeting between the tech transfer teams from both Parties has taken place; provided that Lonza may invoice this milestone payment if the TTA has been agreed and the tech transfer teams have been so established even if Alexion is unable to accommodate a requested first meeting in December 2014; and

(b) All capital equipment required to be purchased will be purchased, owned and installed by Lonza. Lonza will bear all costs of delivery, installation, validation, of all such equipment. Lonza will bear all costs of maintenance of all such equipment. Where suitable capital equipment can be provided by Alexion, Lonza shall purchase such equipment from Alexion. A set-up fee equal to [*].

(c) A facility adaptation fee equal to [*] payable by Alexion no later than 31 December 2015.

(d) A fee in respect of Process Validation, estimated to be [*], payable as set out in the relevant PSA. Lonza shall obtain Alexion's prior written consent before incurring any of these Process Validation costs.

7.2 **Batch Pricing**

7.2.1 **Engineering Batches in** [*]. For each Engineering Batch of Product (Asfotase alfa) and of Product (eculizumab) manufactured in [*] in compliance with this Agreement, Alexion shall pay Lonza an amount equal to [*] per Batch.

7.2.2 **Process Validation Batches in** [*]. For each Process Validation Batch of Product (Asfotase alfa) and Product (eculizumab) manufactured in [*] in compliance with this Agreement, Alexion shall pay Lonza an amount equal to [*] per Batch.

7.2.3 **Commercial Batches**. For each Commercial Batch that is manufactured in compliance with this Agreement, Alexion shall pay Lonza the following amounts:

(a) For each Commercial Batch of Product (eculizumab) manufactured in [*] in a Campaign of between [*] Batches, an amount equal to [*].

(b) For each Commercial Batch of Product (eculizumab) manufactured in [*] in a Campaign of [*] or more Batches, an amount equal to [*].

(c) For each Commercial Batch of Product (eculizumab) manufactured in [*], an amount equal to [*].

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(d) For each Commercial Batch of Product (Asfotase Alfa) manufactured in [*], an amount equal to [*].

(e) For each Commercial Batch of Product (Asfotase Alfa) manufactured in [*] in a campaign size of between [*] Batches, an amount equal to [*].

(f) For each Commercial Batch of Product (Asfotase Alfa) manufactured in [*] in a campaign size of [*] or more Batches, an amount equal to [*].

(g) If, at the end of any calendar year, Alexion has ordered less than its Minimum Order for such year in accordance with Section 5.2.2 or has canceled Purchase Orders or Batches as provided in Section 5.3 then Alexion shall pay Lonza an amount equal to [*], subject to the last sentence of Section 5.3 Cancellation Fee.

7.2.4 **Price Adjustment**. Notwithstanding the foregoing, starting as noted below, the price of a Commercial Batch for Batches produced at a Facility shall be adjusted annually by the lesser of (x) [*] and (y) the year-over-year change to the index appropriate to each Facility (such year-over-year change to the index to take include all monthly changes over the twelve-month period, including decreases, and in the case the year-over-year change is negative, no adjustment shall be made), namely:

(a) [*] Facility: HICP Pharmaceuticals Index [*], provided the first price adjustment for a Product shall not be before [*].

(b) [*] Facility: Producer Price Index for Pharmaceutical Prescription Preparations, Prescription ("PPI" Series ID [*]), as reported by the Bureau of Labor Statistics of the U.S. Department of Labor, provided the first price adjustment for a Product shall not be before [*]; and

(c) [*] Facility: The [*] sub-index of the [*], provided the first price adjustment for a Product shall not be before [*].

In each case above, if such index is no longer available, the index by which it is replaced by the relevant agency or any successor agency issuing such indices shall be used. If such index is discontinued and there is no direct successor index, the Executive Steering Committee shall designate an appropriate index that approximates as closely as possible the PPI. In the event of any exceptional increase in the price of utilities such as gas, water, electricity, the Parties shall hold good faith negotiations to agree an equitable allocation of such increased costs, any such allocation to be agreed in writing between the Parties. Alexion shall have the right

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to carry out an audit, either itself or through a third party selected by Alexion in its discretion, as part of the discussions relating to any such price increase.

7.3 **Other Rights of Inspection**

7.3.1 **Alexion's Right of Inspection**. Lonza will ensure that Alexion and/or its Affiliates will have the right to audit the Facilities, the equipment used in the Processing, packaging, storage, testing, shipping or receiving of Products and Components in accordance with Article 10. Such audits may include (i) initial GMP-baseline Audits, (ii) for cause/event audits and/or (iii) audits for special cases in which Alexion's representatives may be present during the Processing of the Product. Alexion shall have the right to request that reasonable quantities of samples of the Components and Products be taken by Lonza for examination by Alexion purposes to verify Lonza's compliance with the Specifications and its obligations under this Agreement. Representatives of Alexion will have access during audits to all documents, records, reports, data, procedures, facilities, regulatory submissions, and all other information required to be maintained by the EMA, FDA and/or Regulatory Authorities by law or regulation. Alexion may audit Lonza's reports and records relating to the Processing (including Lonza's audits of any Approved Subcontractor) pursuant to this Agreement during normal business hours and with reasonable advance written notice and a Lonza representative may be present during any such inspection. The exact timelines for audits, including without limitation, the intervals and the number of days for the prior written notice, will be set forth in the QA Agreement.

7.3.2 **Regulatory Authorities' Right of Inspection**. Lonza shall permit, and cause to be permitted at its Approved Subcontractors, authorized officials of any Regulatory Authorities or other competent governmental agencies to inspect the Facility, including the equipment, used for the Processing, filling, packaging, storage, testing, shipping or receiving of Products and/or Components, as required or necessary for the granting or maintaining of any registration with a Regulatory Authority. Lonza shall provide written notice to Alexion of any such inspection, as well as any inspection of any other part of the Facility that would be reasonably likely to impact the Services or the Product, promptly and where possible prior to any such inspection.

7.3.3 **Survival**. The rights under this Section 7.3 shall survive in accordance with a post-termination quality agreement to be entered into by the Parties during the Notice Period in the case of termination under Section 18.2.2 or 18.2.3, or, following any other termination or expiration of this Agreement.

7.4 **Invoicing for Batches**: For amounts owed under or related to Section 7.2, an invoice for [*] of the applicable Batch price may be issued for each Batch in a Campaign, on or after

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the Commencement date for each Batch in such Campaign, and an invoice for the remaining [*] of such Batch price may be issued on or after the date of Delivery of the applicable Batch, provided however that where an Engineering Batch has not met Specification but has been manufactured in compliance with the requirements of cGMP, including applicable Batch records as well as any documentation, processes and procedures referred to in such Batch records then Alexion shall pay for the remaining [*] of such Batch even although a Certificate of Compliance will not be provided by Lonza. Each invoice shall be due and payable within thirty (30) days after receipt. Each invoice must clearly state the corresponding Alexion Purchase Order number and details of the Batch and stage being invoiced e.g. Commencement or Completion. If Alexion fails to dispute an invoice within such thirty (30) day period, then Alexion shall be obligated to pay such invoice and Alexion's rights with respect to any rejected Batch covered by such invoice shall be solely as set forth in this Agreement.

7.4.1 Where an invoice has been issued by Lonza for a Batch of Product and the Batch is terminated or rejected prior to the invoice being paid, then Lonza will issue Alexion [*].

7.4.2 Where an invoice has been issued by Lonza for a Batch of Product and the Batch is terminated or rejected after the invoice has been paid, then Lonza will return the payment or payments made on such invoice(s) for the terminated/rejected Batch in full within [*] days of the termination or rejection date of the Batch.

7.5 **Invoicing for Raw Materials** [*]**.** In accordance with section 4.7.1, Lonza shall invoice Alexion for Raw Materials upon Delivery of the corresponding Batch, and for safety stock of Raw Materials, Lonza shall invoice Alexion upon expiry of such Raw Materials. For any [*] (including safety stock for these items) ordered by Lonza for use in the manufacture of a Product, upon receipt of the invoice from the vendor, Lonza shall forward such invoice promptly to Alexion. Alexion shall pay Lonza in accordance with the thirty (30) day period referred to in section 7.4 above.

7.6 **Payments in Lieu of Royalty**. In respect of Product (eculizumab) only, whether manufactured in the [*] Facility or the [*] Facility (or such other Facility as the Parties may agree), Alexion shall make certain payments in lieu of royalty in accordance with Exhibit B.

7.7 **Payment Method**. All payments due hereunder shall be made by wire transfer in immediately available funds to a ba1nk designated by the Party to receive payment under the applicable PSA. Past due amounts shall bear interest at two percent (2.0%) per annum over the base rate from time to time of Bank of America, interest to accrue on a day to day basis.

7.8 **Taxes**. Each Party shall comply with its applicable taxation guidelines regarding filing and reporting for tax purposes. Neither Party shall treat their relationship under this Agreement

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as a partnership or as a pass-through entity for tax purposes. All payments and fees required to be paid pursuant to this Agreement are exclusive of all sales tax, use tax, value-added tax, tariffs, duties or other similar tax (which shall be borne and paid by Alexion) where applicable and shall be paid with deduction therefrom solely for income tax, or withholding tax in lieu of income tax, applicable to a payee that is required, pursuant to applicable law, to be deducted or withheld therefrom.

ARTICLE 8.
PROCESS CHANGES

8.1 **Process**. Lonza shall not unreasonably refuse any written request from Alexion to make changes to the Process (for example, changes to the Process which are required by an applicable regulatory authority or applicable laws) but no change to the Process shall be made except by an agreement in writing signed by the authorized representatives of the Parties.

8.2 **Specifications.** Lonza shall not unreasonably refuse any written request from Alexion to make changes to the Specifications (for example, changes to the Specifications that are required by an applicable regulatory authority or applicable laws), but no change to the Specifications shall be made except by an agreement in writing signed by the authorized representatives of the Parties.

8.3 **Adjustments resulting from Process and Specification Changes.** Any changes to a Process (such as column re-packing) or to the Specifications shall be implemented on terms and conditions to be agreed, which may include, but not be limited to, additional development services (to be performed on terms to be agreed), and reasonable adjustments to the Batch price.

ARTICLE 9.
REPLACEMENT

9.1 **Non-Conforming Batch**. Promptly following Delivery of a Batch of Product, or any sample intended to be representative thereof, Alexion shall carry out the Alexion Tests. If the Alexion Tests show that the Product fails to meet the applicable Specifications, then Alexion shall give Lonza written notice thereof within [*] days from the date of Delivery of the Batch and shall, unless otherwise directed by Lonza, return the Batch for further testing. In the absence of such written notice, the Batch shall be deemed to have been accepted by Alexion as meeting Specifications. If Lonza agrees, or it is determined pursuant to Section 6.8, that the returned Batch fails to meet Specifications and, to the extent that such failure is not due (in whole or in part) to acts or omissions of Alexion or any Third Party after Delivery of such Batch, the Batch in question shall be regarded as not having been Delivered and shall constitute or contribute towards a Supply Deficiency

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and entitle Alexion to the rights set forth in Section 5.4, including those associated with a Supply Deficiency, including a refund for the Batch price and, in the case of Product (eculizumab), [*]. This Section 9.1 shall also apply in the case of a Post-Release Deviation except that the [*] day period for providing notice shall commence on the date Alexion becomes aware of the Post-Release Deviation. Lonza agrees to reimburse Alexion for reasonable documented expenses in connection with [*], whether incurred by Alexion or which Alexion has to pay to a third party, as a result of a Post-Release Deviation resulting in a Batch failure provided this sentence shall not apply to expenses incurred after Alexion releases the Product for clinical or commercial use, which shall be subject to Article 11.

9.2 **No Lonza Liability**. If it is determined by agreement of the Parties (or in the absence of such agreement, by a mutually acceptable qualified independent Third Party whose fees shall be paid by the non-prevailing Party), or it is determined pursuant to Section 6.8 that either (i) such Batch is not a Non-Conforming Batch, or (ii) such Batch is a Non-Conforming Batch but the nonconformity was not caused by Lonza (or its agents or, as set forth in Section 9.4, suppliers), then in either such case Alexion shall pay to Lonza the price of such Batch and Lonza shall have no liability to Alexion with respect thereto.

9.3 **Lonza Liability; Replacement of Product**. If it is determined by agreement of the Parties (or in the absence of such agreement, by a mutually acceptable qualified independent Third Party whose fees shall be paid by the non-prevailing Party) that the nonconformity was caused by Lonza (or its agents or, as set forth in Section 9.4, suppliers), at Alexion's written request, Lonza shall, in accordance with section 5.4, replace such Non-Conforming Batch with conforming Product, at no additional cost to Alexion except for payment of the price of the replacement conforming Product, to the extent that Alexion has not previously paid the price therefor. In such case, the last sentence of Section 5.4.3(II) and 5.4.5 shall also apply.

9.4 **Batch Failures**. If it is determined by agreement of the Parties (or in the absence of such agreement, by a mutually acceptable qualified independent Third Party whose fees shall be paid by the non-prevailing Party) that a Batch fails to meet Specifications due to:

9.4.1 Raw Materials procured by Lonza where,

(a) Such failure is solely caused by such defect in the Raw Materials; and

(b) The relevant Raw Material was supplied by a Third Party (such that if the relevant Raw Material was supplied by Lonza or one of its Affiliates then Alexion shall not be liable to pay any amount to Lonza under this section 9.4.1); and

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(c) Such failure is due to no fault of Lonza and Lonza has audited the relevant supplier and the Raw Materials met any incoming specification; (such that if such failure is due to the fault of Lonza, Lonza has not audited the relevant supplier or the Raw Material has not met an incoming specification, then Alexion shall not be liable to pay any amount to Lonza under this section 9.4.1);

then [*].

or

9.4.2 the Process, [*].

ARTICLE 10.
REGULATORY SUPPORT AND INSPECTIONS

10.1 **Regulatory Support and Audits.** Lonza shall provide regulatory support to Alexion, including annual updates to any drug master files, biologics licenses and other manufacturing or marketing applications and approvals applicable to each Product held by Lonza or Alexion and the preparation for and hosting of inspections by the U.S. FDA (or other Regulatory Authorities) or Alexion (in the case of Alexion's inspections, at mutually convenient times). Alexion shall be entitled to conduct, and the price has been calculated to include Lonza regulatory support for, one (1) audit per Product for each Facility (at such times set forth in the applicable Quality Agreement) by Alexion personnel of up to [*] days each prior to commencement of the Services at each Facility and, thereafter, one audit (at such time set forth in the applicable Quality Agreement) by Alexion personnel of up to [*] days each per Product at each Facility in any one twelve month period, as well as for cause/event audits.

10.2 **Additional Support**. In addition, Lonza shall allow, and the price has been further calculated to include: a) two representatives of Alexion or one of its Affiliates located at the each Facility (i.e., a person-in-plant, or, "PIP") for a period of up to [*] months prior to Commencement of each Batch, to no longer than [*] past final release by Lonza for each Batch manufactured; b) Batch record audits of each Batch shall be permitted and copies of documentation can be provided upon request without additional cost to Alexion; and c) those costs incurred by Lonza in completion of any Pre-Approval Inspection ("PAI") for the Product from [*].

10.3 **Regulatory Submissions**. Alexion shall advise Lonza of any regulatory submissions regarding the Product which may require responses from Lonza to questions from the Regulatory Authorities in a timely fashion, taking account of the amount of information Lonza is required to provide. Lonza specifically acknowledges and agrees that no

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regulatory submissions relating to the Product shall be made to any governmental authority without express, prior, written approval of Alexion.

10.4 **Amendments**. If Lonza is required to amend the way it manufactures or tests the Product as a result of a change in any statutory or regulatory requirement after the Effective Date, it shall use all reasonable efforts to comply with such requirement. In this event the Parties shall negotiate in good faith any appropriate revision to the Price to reflect additional costs incurred by Lonza and any appropriate revision to the time schedules for providing the Product. Lonza shall not be required or entitled to amend the Services in any way unless and until the Parties have reached such agreement.

10.5 **Follow-Up Audits**. If Alexion conducts an audit of a Facility pursuant to its rights under Section 10.1 and, as a result of default on the part of Lonza, Alexion has just cause to conduct further audits in order to satisfy itself as to the matters of default in question, Alexion shall be entitled, without additional payment to Lonza, to conduct [*] per Product per facility (at such times set forth in the applicable Quality Agreement) in order to satisfy itself of the matters in question unless Alexion determines during such additional audit that the default is continuing in which case Alexion may conduct an additional follow-up audit(s) until the default is resolved. Any further audits beyond this number shall be performed on reasonable terms and conditions and at a price to be agreed, based on Lonza's standard rates.

10.6 **Assignment of Shared BLA**. Within [*] days following termination or expiration of this Agreement, Lonza shall assign to Alexion or Alexion’s designee Lonza's interest in any shared regulatory filing or license that relates exclusively to the Product and shall provide written notice thereof to Alexion.

ARTICLE 11.
RECALLS

11.1 **Assistance of Lonza.** If Alexion recalls any Product (voluntarily or by order of a Regulatory Authority) or is required to respond to inquiries of any Regulatory Authority relating to the Services hereunder, Lonza agrees to provide reasonable assistance to Alexion at Alexion’s sole expense. Any assistance to be provided by Lonza in response to inquiries of Regulatory Authorities shall be provided on terms to be agreed at Lonza's standard rates for providing such assistance.

11.2 **Reimbursement by Lonza**. Subject to the limitations of Lonza's liability to Alexion set out in this Agreement, Lonza agrees to reimburse Alexion for [*] incurred by Alexion as a result of recall of a Product mandated by law or by an applicable regulatory body, but only to the extent Lonza's negligence or willful misconduct in performing the Services has caused such recall to be required and such recall could not have reasonably have been

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expected to have been prevented by Alexion's application of the Alexion Tests or other product testing required by law to be undertaken by Alexion.

ARTICLE 12.
QUALITY ASSURANCE

12.1 **Responsibility for Quality Assurance and Quality Control**. The Parties shall negotiate in good faith to enter into a Quality Agreement, with respect to each Facility, no later than [*] days after the execution of the first PSA (or such other date set forth in such PSA) for such Facility. Responsibility for Quality Assurance obligations and quality control of each Product shall be allocated between Alexion and Lonza as set forth in each Quality Agreement and in standard operating procedures agreed upon in writing by Alexion and Lonza from time to time.

ARTICLE 13.
INTELLECTUAL PROPERTY

13.1 **Background IP**. Except as expressly otherwise provided herein, neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Background Intellectual Property of the other Party.

13.2 **New Alexion IP**. Subject to section 13.3, Alexion shall own all right, title, and interest in and to any and all Intellectual Property that Lonza and its Affiliates or other contractors or agents of Lonza develop, conceive, invent, first reduces to practice or makes, solely or jointly with Alexion or others, that (a) directly relates to the use of, (b) is solely a direct derivative of or (c) is an improvement to either (i) Alexion Confidential Information, (ii) and Alexion Background Intellectual Property or (iii) materials, processes or composition of matter that are owned or controlled by Alexion (collectively, the "New Alexion Intellectual Property"). For avoidance of doubt, "New Alexion Intellectual Property" shall include any material, processes, compositions of matter, articles of manufacture or other items that solely embody, or that are claimed or covered by, any of the foregoing Intellectual Property, but excluding any New General Application Intellectual Property.

13.3 **New Lonza IP**. Subject to the license granted in section 13.5, Lonza shall own all right, title and interest in Intellectual Property that Lonza and its Affiliates, the External Laboratories or other contractors or agents of Lonza, solely or jointly with Alexion, develops, conceives, invents, or first reduces to practice or makes in the course of performance of this Agreement that (i) is generally applicable to the development or manufacture of chemical or biological products or product components other than Intellectual Property that specifically relates to Products or (ii) is an improvement of, or direct derivative of, any Lonza Background Intellectual Property ("New General Application Intellectual Property"). For avoidance of doubt, "New General Application

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Intellectual Property" shall include any material, processes or other items that embody, or that are claimed or covered by, any of the foregoing Intellectual Property.

13.4 **Assignment**. Lonza hereby assigns to Alexion all of its right, title and interest in any New Alexion Intellectual Property. Lonza shall execute, and shall require its personnel as well as its Affiliates, or other contractors or agents and their personnel involved in the performance of this Agreement to execute, any documents reasonably required to confirm Alexion's ownership of the New Alexion Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New Alexion Intellectual Property.

13.5 **Licence to Alexion**. Subject to the terms and conditions set forth herein, Lonza hereby grants to Alexion a non-exclusive, world-wide, fully paid-up, irrevocable, transferable license, including the right to grant sublicenses, under the New General Application Intellectual Property, to make, use, sell, offer for sale and import Product manufactured under this Agreement.

13.6 **Licence to Lonza**. Alexion hereby grants Lonza the non-exclusive right to use the Alexion Confidential Information, Alexion Background Intellectual Property and New Alexion Intellectual Property during the Term solely for the purpose of fulfilling its obligations under this Agreement.

ARTICLE 1.
REPRESENTATIONS AND WARRANTIES; LIMITATIONS

1.4 **Alexion**. Alexion represents warrants and covenants to Lonza that:

1.4.1 Alexion has the corporate power and authority to enter into this Agreement;

1.4.2 Alexion has, and subject to Section 14.1.5 below, shall at all times throughout the term of this Agreement have, the right to supply the Cell Line, the other Alexion Materials and the Alexion Confidential Information to Lonza;

1.4.3 Any of the Cell Line, the other Alexion Materials, Alexion Confidential Information and Alexion Patent Rights not owned by Alexion are licensed to Alexion under a license which will permit their use by Lonza under this Agreement;

1.4.4 To the best of Alexion's Knowledge, the use by Lonza of the Cell Line, other Alexion Materials, Alexion Confidential Information and Alexion Patent

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Rights under this Agreement will not infringe any rights (including without limitation any intellectual or industrial property rights) vested in any third party;

1.4.5 Alexion will promptly notify Lonza in writing if it receives a claim or allegation from a third party that the Cell Line, other Alexion Materials, Alexion Confidential Information or the Alexion Patents, or that the use by Lonza of any of the foregoing for the performance of this Agreement, infringes any intellectual property rights of such third party.

THESE REPRESENTATIONS AND WARRANTIES ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND ALEXION HEREBY EXPRESSLY DISCLAIMS AND NEGATES, ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF TITLE AND NON-INFRINGEMENT.

1.5 **Lonza**. Lonza represents warrants and covenants to Alexion that:

1.5.1 Lonza has the corporate power and authority to enter into this Agreement;

1.5.2 The Product delivered to Alexion pursuant to this Agreement (including, without limitation, Process Validation Batches) shall be manufactured pursuant to cGMP and shall meet Specifications when delivered;

1.5.3 The Services shall be performed in accordance with all applicable laws and this Agreement;

1.5.4 Unencumbered title to all Product will be conveyed to Alexion upon the Delivery;

1.5.5 As of the Effective Date the Lonza Information, the Lonza Process, and the Lonza Patent Rights are owned by Lonza or Lonza is otherwise entitled to use them for the purposes of performing this Agreement and during the term of this Agreement Lonza shall not do or cause anything to be done which would adversely affect their ownership or entitlement to use the same for those purposes;

1.5.6 To the best of Lonza's Knowledge, the use by Lonza of the Lonza Process and Lonza Patent Rights and Lonza Information for the performance of this Agreement will not infringe any rights (including without limitation any intellectual or industrial property rights) vested in any third party;

1.5.7 Lonza will promptly notify Alexion in writing if it receives a claim or allegation from a third party that the use by Lonza of the Lonza Process and/or the Lonza Information and/or the Lonza Patents Rights for Services infringes any intellectual property rights vested in such third party; and

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1.5.8 Lonza has and shall maintain, during the term of this Agreement, all government permits, including but not limited to health, safety and environmental permits, necessary for the performance of this Agreement.

14.2.9 Lonza maintains has at all times and shall during the term of this Agreement shall maintain each Facility in accordance with cGMP requirements, including all cGMP certificates necessary and/or required, and all legal and regulatory requirements.

THESE REPRESENTATIONS AND WARRANTIES ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND LONZA HEREBY EXPRESSLY DISCLAIMS AND NEGATES, ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE (EVEN IF THAT PURPOSE IS KNOWN TO LONZA), TITLE AND NON-INFRINGEMENT.

1.6 **Limitation of Liability**. Subject to the exceptions set forth in this Section 14.3 below, each Party's liability under this Agreement shall not exceed the greater of (a) the total amount paid by Alexion to Lonza under this Agreement (and not just a single PSA) during the [*] preceding the date the allegedly liable Party received notice from the other Party alleging the liability and (b) [*]. Notwithstanding the foregoing, a Party's liability for any of the following shall not be limited or capped:

(a) death or personal injury arising from the acts or omissions of the liable Party;

(b) any fraud by the liable Party;

(c) gross negligence or intentional wrongdoing by the liable Party;

(d) breach of any provision of Article 16 (Confidentiality);

(e) any liability of the liable Party that, by law, statute or regulation, cannot be limited or excluded.

(f) in the case of liability of Lonza, the limitations set forth in this Section 14.3 shall not apply if and to the extent such liability arises out of Lonza's breach of Section 4.2 or 4.3 or out of third party claims, demands, or actions for which (i) Lonza is required to indemnify Alexion for a breach of the representation set forth in Section 14.2.4 in which instance Lonza's liability shall be no greater than the dollar amount of any such encumbrance, (ii) Lonza is required to pay a third party as a result of a breach of the representation set forth in Section 14.2.8 (subject to Section 14.2.3); (iii) Lonza is required to indemnify Alexion under Section 15.1.2

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(c); (iv) Lonza is required to indemnify Alexion under Section 15.1.2(d) (subject to Section 15.4); (v) Lonza is required to indemnify Alexion under Section 15.1.2(e); (vi) Lonza is required to indemnify Alexion under Section 15.1.2(f) (subject to Section 15.3).

(g) In the case of liability of Alexion, the limitations set forth in this Section 14.3 shall not apply if and to the extent such liability arises out of third party claims, demands, or actions for which Alexion is required to indemnify Lonza under Section 15.1.1.

1.7 **Disclaimer of Consequential Damages**. EXCEPT FOR CLAIMS ARISING FROM THE MISUSE OR MISAPPROPRIATION OF THE OTHER PARTY'S CONFIDENTIAL INFORMATION OR INTELLECTUAL PROPERTY, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING FROM OR RELATED TO BREACH OF THIS AGREEMENT, INCLUDING, WITHOUT LIMITATION, ANY CLAIMS FOR DAMAGES BASED UPON LOST PROFITS FOR SALES TO THIRD PARTIES. THE FOREGOING DISCLAIMER SHALL BE EFFECTIVE TO THE EXTENT PERMITTED BY APPLICABLE LAW.

ARTICLE 2.
INDEMNIFICATION

2.6 **Indemnification**.

2.6.4 **Indemnification by Alexion**. Subject to and except to the extent of any indemnification from Lonza pursuant to Section 15.1.2 below, Alexion shall indemnify, defend and hold Lonza, its Affiliates, and their respective directors, officers, and employees harmless from and against all losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' fees and expenses), (collectively, the "**Liabilities**") to the extent such Liabilities arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of (a) any negligence or fraudulent act or omission or willful misconduct of Alexion in relation to the use, processing, storage or sale of Product, the application of the APIS Tests or the marketing of the pharmaceutical product in which the Product is used, unless such liability arose from a failure of the Product to meet the warranties in Section 14.2.2; (b) any breach of the representations and warranties made by Alexion under this Agreement; (c) infringement of any intellectual property of a third party by the manufacture, use and sale of the Product (except to the extent Lonza has indemnified Alexion under Section 15.1.2(d)); (d) any claims alleging Lonza's use of the Alexion Confidential Information infringes or is alleged to infringe any rights (including without limitation any intellectual property rights) of a third party or misappropriates or is alleged to misappropriate

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the trade secrets of a third party; (e) any product liability (including death, personal injuries or economic losses) in respect of the Product, except to the extent that Lonza has indemnified Alexion under Section 15.1.2(f); and (f) any claims by employees, agents or vendors of Alexion unless such claim is caused by the gross negligence or willful misconduct of Lonza.

2.6.5 **Indemnification by Lonza**. Lonza shall indemnify, defend and hold Alexion, and its Affiliates, and their respective directors, officers, and employees harmless from and against all Liabilities to the extent such Liabilities arise out of or result from (a) Lonza's breach of the representations and warranties made by Lonza under this Agreement or any breach of any of the covenants made by Lonza under this Agreement, (b) Lonza's negligent acts or omissions or willful misconduct, or (c) the release by Lonza of any Materials of Environmental Concern into the ambient environment from any Facility in connection with the performance of this Agreement in violation of applicable environmental law unless such violation is caused by a misrepresentation of Alexion hereunder, or Lonza's violation of any applicable environmental law in connection with the performance of this Agreement unless such violation is caused by a misrepresentation of Alexion hereunder, (d) any clams alleging that the Lonza Process or the Lonza Media Formulations, the Lonza Information or the Lonza Patent Rights infringe any intellectual property of a third party or misappropriate any trade secret of a third party, (e) any claims by employees, agents or vendors of Lonza, unless such claim is caused by the gross negligence or wilful misconduct of Alexion; or (f) any product liability (including death, personal injuries or economic losses) suffered by a third party solely as a result of a defect in the Product Delivered by Lonza which defect arose from the negligent or fraudulent act or omission, or willful misconduct of Lonza in the performance of the Services and such product defect could not have reasonably been expected to be detected by the Alexion Tests or by other product testing required by law to be undertaken by Alexion.

2.7 **Indemnification Procedures**.

2.7.5 **Identification of Indemnitor and Indemnitee**. An "**Indemnitor**" means Alexion with respect to Section 15.1.1 hereof, and Lonza with respect to Section 15.1.2 hereof. An "**Indemnitee**" means any of Lonza, its Affiliates, and their respective directors, officers, and employees with respect to Section 15.1.1 hereof, and any of Alexion, and its respective Affiliates, directors, officers and employees with respect to Section 15.1.2 hereof.

2.7.6 **Indemnification Procedures**. An Indemnitee which intends to claim indemnification under Section 15.1.1 or 15.1.2 hereof shall promptly notify the Indemnitor in writing of any claim, lawsuit or other action in respect of which the Indemnitee, its Affiliates, or any of their respective directors, officers, and employees

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intend to claim such indemnification; provided, however, that any failure or delay in giving such notice shall only excuse the Indemnitor from its indemnity obligations hereunder to the extent that the Indemnitor is prejudiced thereby. The Indemnitee shall permit, and shall cause its Affiliates and their respective directors, officers, and employees to permit, the Indemnitor, at its discretion, to defend and/or settle any such claim, lawsuit or other action, at the Indemnitor's sole expense, and agrees to the complete control of such defense or settlement by the Indemnitor; provided, however, such settlement does not adversely affect the Indemnitee's rights under this Agreement or impose any obligations on the Indemnitee in addition to those set forth herein in order for the Indemnitor to exercise such rights. No such claim, lawsuit or other action shall be settled without the prior written consent of the Indemnitor, not to be unreasonably withheld, and the Indemnitor shall not be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnitee, its Affiliates and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification, all at the reasonable expense of the Indemnitor. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.

2.8 **Procedure for Product Liability Claims**. Notwithstanding anything to the contrary in Section 15.2.2, in the event Alexion seeks indemnification from Lonza under Section 15.1.2(f), then the Parties, each at its own expense, shall cooperate in the defense and settlement of such claims, provided, however that in the event that it is determined that such product liability was not the result of an action of Lonza for which Lonza has indemnified Alexion pursuant to Section 15.1.2(f), then Alexion shall reimburse Lonza for all reasonable fees and expenses incurred by Lonza (including without limitation attorneys' fees) in the defense and settlement of such claim and provided further in the event that it is determined that such product liability was the result of an action of Lonza for which Lonza has indemnified Alexion pursuant to Section 15.1.2(f) then Lonza shall reimburse Alexion for all reasonable fees and expenses (including without limitation attorneys' fees) incurred by Alexion in the defense and settlement of such claim. Notwithstanding the foregoing, in the event that it is determined that such product liability was only partially the result of an action of Lonza for which Lonza has indemnified Alexion pursuant to Section 15.1.2(f), any payments and reasonable attorney fees incurred in connection with such claims are to be apportioned between the Parties in accordance with the degree of cause attributable to each Party.

2.9 **Abatement**. Notwithstanding anything to the contrary in this Agreement, in the event that the use of the Lonza Process or the Lonza Media Formulations is held in a suit or proceeding to infringe any intellectual property rights of a third party (or to constitute the misappropriation of a trade secret of a third party), and the use of the Lonza Process and/or the Lonza Media Formulations is enjoined, or Lonza has an objective basis (confirmed by an opinion of its legal counsel) for believing that it is likely to be found to infringe or constitute a misappropriation, or is likely to be enjoined, then Lonza shall, at its sole cost

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and expense, and at its option, either (i) procure the right to continue the use of the Lonza Process and/or Lonza Media Formulations or (ii) modify the Lonza Process and/or Lonza Media Formulations so that it becomes non-infringing or no longer constitutes a misappropriation, provided that such modification has no adverse effect on Alexion hereunder; provided however that if (i) and (ii) are not reasonably practicable then either Party shall have the right, in its sole discretion, to terminate this Agreement by giving the other [*] prior written notice upon which notice the provisions of Section 18.3 shall apply.

2.10 **Insurance**. Lonza shall obtain and maintain insurance coverage of the types and in the amounts customary and consistent with the chemical industry standards. Without limiting the foregoing, Lonza shall obtain and maintain third party liability insurance and shall name Alexion and its Affiliates as named insureds on that policy. Alexion shall obtain and maintain insurance coverage which is customary and consistent with pharmaceutical industry standards, naming Lonza and its Affiliates as named insureds and providing that Lonza shall be notified at least thirty (30) days in advance of termination of such coverage.

2.11 **Survival of Indemnification Obligations**. The provisions of this Article 15 shall survive the termination or expiration of this Agreement.

ARTICLE 3.
CONFIDENTIALITY

3.6 **Confidentiality Obligations**.

3.6.7 **Lonza Confidentiality Obligations**. Lonza shall keep confidential and shall not publish or otherwise disclose Alexion Confidential Information to any Third Party other than:

(a) its employees who are bound by similar obligations of confidentiality and nonuse and who have a need to know such information in order to perform their duties in carrying out Lonza's obligations under this Agreement or an applicable PSA, TTA or Quality Agreement,

(b) contractors who are bound by similar obligations of confidentiality and nonuse and who have a need to know such information in order to provide direction to Lonza or Alexion regarding their respective rights and obligations under this Agreement or an applicable PSA, TTA or Quality Agreement, or

(c) Regulatory Authorities, for example the FDA, that require such information in order to review a BLA or sBLA for a Product or another regulatory filing.

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3.6.8 **Alexion Confidentiality Obligations**. Alexion shall keep confidential and shall not publish or otherwise disclose any Lonza Confidential Information to any Third Party other than:

(a) employees, consultants, agents, contractors, collaborators or licensees of Alexion or Alexion's Affiliates who are bound by similar obligations of confidentiality and nonuse and who have a need to know such information in order to perform their duties in carrying out Alexion's obligations or exercising Alexion's rights under this Agreement or an applicable PSA, TTA or Quality Agreement, or in order to provide direction to Alexion regarding the subject matter of this Agreement, including, but not limited to, production, testing, storage or quality of Product or regulatory or compliance issues related to Product, or

(b) Regulatory Authorities, for example the FDA, that require such information in order to review a BLA or sBLA for the Product or other regulatory filing.

3.7 **Exclusions**. The obligations of confidentiality and nonuse applicable hereunder to Lonza with respect to Alexion Confidential Information and to Alexion with respect to Lonza Confidential Information shall not apply to any information which the recipient demonstrates:

(d) at the time of disclosure, is known publicly or thereafter becomes known publicly through no fault of the recipient, its Affiliates or agents;

(e) becomes available to the recipient from a Third Party which is not legally prohibited from disclosing such information, provided such information was not acquired directly or indirectly from the disclosing Party;

(f) was developed by the recipient independently of information obtained from the disclosing Party as evidenced by written records;

(g) was already known to the recipient before receipt from the disclosing Party, as shown by its prior written records, provided that such information was not acquired directly or indirectly from the disclosing Party; or

(h) is released with the prior written consent of the Party that had originally disclosed such information to the other Party hereunder.

In determining whether or not the disclosing Party's Confidential Information has entered the public domain, the obligations of confidentiality shall no longer apply to only that portion of said Confidential Information that has become public, and portions remaining confidential shall retain their status as Confidential Information.

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3.8 **Notification of Mandatory Disclosure**.

3.8.1 **Notification and Consultation**. In the event that a Party (in such case, the "**Notifying Party**") believes it is required by applicable statute or regulation (including the rules and regulations of any national stock exchange on which such Party's securities are traded), or by judicial or administrative process to disclose any part of the other Party's (in such case, the "**Notified Party**") Confidential Information which is disclosed to it under this Agreement, the Notifying Party shall (i) promptly notify the Notified Party of each such requirement and identify the documents so required thereby, so that the Notified Party may seek an appropriate protective order or other remedy and/or waive compliance by the Notifying Party with the provisions of this Agreement, and (ii) consult with the Notified Party on the advisability of taking legally available steps to resist or narrow the scope of such requirement.

3.8.2 **Limited Disclosure**. If, in the absence of such a protective order or such a waiver by the Notified Party of the provisions of this Agreement, the Notifying Party is nonetheless required by mandatory applicable law to disclose any part of the Notified Party's Confidential Information which is disclosed to it under this Agreement, the Notifying Party may disclose such Confidential Information without liability under this Agreement, except that the Notifying Party shall furnish only that portion of the Confidential Information which is legally required.

3.9 **No Licenses; Maintenance of Confidentiality; Non-use Obligations**.

3.9.3 **No Licenses**. Except as expressly provided in Article 13 hereof, no right or license, either express or implied, under any intellectual property right is granted under this Agreement, any applicable PSA, TTA or Quality Agreement, by virtue of the disclosure of Confidential Information under this Agreement, any applicable PSA, TTA or Quality Agreement, or otherwise.

3.9.4 **Maintenance of Confidentiality**. Each Party shall use reasonable and customary precautions to safeguard the other Party's Confidential Information, which precautions shall be at least as protective as those used to protect its own Confidential Information, including ensuring that all employees, consultants, agents or contractors who are provided access to such Confidential Information are informed of the confidential and proprietary nature of such Confidential Information and have contractual confidentiality and nonuse obligations that are at least as restrictive as those contained in this Agreement.

3.9.5 **Equitable Relief**. Each Party agrees that the other Party and their respective Affiliates would be irreparably injured by a material breach of the confidentiality and nonuse provisions of this Agreement by the breaching Party or by its employees or the employees of its Affiliates, consultants, agents or contractors, that monetary remedies would be inadequate to protect the other Party against any

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actual or threatened material breach of the provisions of this Article 16 by the breaching Party or by its employees or the employees of its Affiliates, consultants, agents or contractors, and, without prejudice to any other rights and remedies otherwise available to the other Party, the breaching Party agrees, upon proof of any such actual or threatened material breach, to the granting of equitable relief, including injunctive relief and specific performance, in the other Party's favor without proof of actual damages.

3.10 **Survival of Confidentiality Obligations**. The provisions of this Article 16 shall survive the termination or expiration of this Agreement.

3.11 **Information Under Certain Prior Agreements**. The Parties agree that all Confidential Information exchanged between the Parties or their Affiliates under previous confidentiality agreements still in effect shall be deemed Confidential Information under this Agreement (either Alexion Confidential Information or Lonza Confidential Information, as the context requires) and shall be subject to the terms of this Agreement.

ARTICLE 4.
PRESS RELEASES; USE OF NAMES

4.8 **Press Releases**. No press release, publicity or other form of public written disclosure related to this Agreement, including the existence thereof, shall be permitted by either Party unless the other Party has indicated its consent to the form of the release in writing. This Section shall not apply to any disclosure as is deemed necessary, in the reasonable judgment of the responsible Party, to comply with regional, national, federal or state or local laws or regulations (including the rules and regulations of any national stock exchange on which such Party's securities are traded), or in connection with any proceedings under Section 19, provided, that each Party will take reasonable best efforts to have this Agreement and any reference to the provisions hereof filed under seal or otherwise kept confidential in any such proceeding.

4.9 **Use of Names**. Subject to the final sentence of Section 17.1, no Party shall use the name of the other Party in any advertising or promotional material, or otherwise, in connection with this Agreement or any related agreements, without the prior written consent of such other Party.

ARTICLE 5.
TERM; TERMINATION

5.6 **Term**. Unless sooner terminated pursuant to the terms of this Agreement or extended by mutual agreement of the Parties, the term of this Agreement (the "**Term**") shall commence on the Effective Date and shall remain in effect until [*].

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5.7 **Termination**.

5.7.6 **Termination With Cause**. Each Party shall be entitled to terminate this Agreement by serving written notice to the other Party (a) in the event of material breach hereof by the other Party and (in the case of a breach capable of remedy) such breach is not remedied within [*] days of receipt by the other of notice identifying the breach and requiring its remedy or, if such breach is incapable of remedy within [*] days, the other Party fails to commence actions within such [*] days to remedy such breach pursuant to a plan reasonably acceptable to the complaining Party; (b) in the event of the insolvency or bankruptcy of the other Party; and/or (c) as otherwise explicitly set forth in this Agreement, all subject to the consequences set forth in Section 18.3. Such written notice shall take effect in accordance with Section 21.11.

5.7.7 **Alexion Permissive Termination**. Alexion shall be entitled to terminate this Agreement and/or an individual PSA at any time without cause by [*] notice in writing, subject to Section 18.3.

5.7.8 **Lonza Permissive Termination**. Lonza shall be entitled to terminate this Agreement and/or an individual PSA at any time without cause by [*] notice in writing, subject to Section 18.3 (each of the [*] period in Section 18.2.2 and the [*] period in Section 18.2.3, a "**Notice Period**").

5.7.9 **Force Majeure**. With respect to a Force Majeure Event, in accordance with Section 20.3.

5.7.10 **Continuing and Additional Obligations During Notice Period**. During the Notice Period, Alexion may continue to place Purchase Orders for Product from Lonza and Lonza shall continue to supply Product to Alexion in accordance with such Purchaser Orders and the other terms of this Agreement. Lonza shall support Alexion in its transition to another supplier(s) on terms reasonably requested by Alexion which support shall include but not be limited to a license of any Intellectual Property required for Alexion to continue to order and receive Product from any such new supplier(s) without interruption.

5.8 **Consequences of Termination**.

5.8.3 In the event that this Agreement is terminated pursuant to Section 5.4.5, 15.4 or 18.2.1, in addition to all other damages and amounts due under this Agreement, the following shall apply

(a) Alexion shall have a non-exclusive right and license (with the right to sublicense to any third party) to utilize the Lonza Patent Rights, Lonza Information (specifically excluding the Lonza Media Formulations) and Lonza Processes for the production of Product (eculizumab). Alexion shall

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pay to Lonza as consideration for such licenses a [*] royalty on Net Sales (without cumulative royalties due to the licensing of multiple items of intellectual property) of Product (eculizumab) produced under such license for the time period that is the longer of (i) [*] from the date of first commercial sale of Product (eculizumab) by Alexion, its Affiliates or sublicensee; or (ii) the life of any valid patent so licensed to Alexion. The preceding payments and terms shall be in lieu of any other payments that may be owed by Alexion or its Affiliates as royalty for Lonza's intellectual property relating to the production of Product (eculizumab), the Parties recognising that Alexion's use of Lonza's [*] is regulated by the License referred to in Exhibit B and not by this Agreement. With regard to Products other than Product (eculizumab), the Parties shall conduct good faith negotiations concerning a right and license to utilize Lonza Patent Rights, Lonza Information (specifically excluding the Lonza Media Formulations) and Lonza Processes and technology transfer with respect to any such new Product(s), based on similar principles to the foregoing and the extent of Lonza Intellectual Property to be transferred.

(b) Lonza shall provide the technology transfer (including technical training) necessary or beneficial for an alternate manufacturer to produce Product using some or all of the Processes, which technology transfer shall be provided on commercially reasonable terms negotiated in good faith between Lonza and Alexion. Notwithstanding the foregoing, Lonza shall not be obligated to provide such technology transfer to more than one alternate manufacturer;

(c) Lonza shall allow Alexion reasonable access to, and rights to cross-reference Lonza's drug master files and other regulatory submissions and approvals to the extent necessary or useful for the production of Product using some or all of the Process;

(d) Lonza shall, upon written request by Alexion, supply a list of the names of all suppliers of Raw Materials;

(e) Lonza shall at Alexion's written request and option and to the extent consistent with Lonza's prior written contractual obligations to such suppliers, assign all or part of the written agreements and purchase orders for Raw Materials or give Alexion reasonable assistance in securing Raw Material supplies from Lonza's existing vendors; and

(f) Lonza shall, upon written request by Alexion, supply a statement setting forth all unused Raw Materials, and (a) offer to Alexion, without further consideration, all Raw Materials previously paid for by

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Alexion hereunder and (b) offer Alexion the right to purchase other unused Raw Materials from Lonza on commercially reasonable terms negotiated in good faith.

5.8.4 **Payment of Amounts Due; Cumulative Remedies**. Expiration or termination of this Agreement for any reason shall not exempt any Party from paying to any other Party any amounts owing to such Party at the time of such expiration or termination. Except as expressly stated otherwise herein, remedies under this Agreement are cumulative, and nothing in this Agreement shall prevent any Party, in the case of a material breach (after expiration of applicable cure period and notice periods), from terminating this Agreement and seeking to enforce its rights under this Agreement.

5.8.5 **Decommissioning Activities**. Upon expiration or termination of a PSA or this Agreement for any reason, unless otherwise provided in this Section 18.3, Lonza will promptly perform the Decommissioning actions set forth below in this Section 18.3.3, taking into account that such actions may be delayed to the extent necessary for Lonza to fulfill any Purchase Orders having a Commencement during the Notice Period. In accordance with the provisions of this Section 18.3.3, the following actions shall be taken with respect to the applicable PSA:

(a) Lonza shall cease and refrain from manufacturing and supplying Product for Alexion in accordance with Section 5.2.4;

(b) Each Party shall deliver to the other Party all of the other Party's Confidential Information;

(a) Lonza shall deliver to Alexion all Alexion intellectual property transferred by Alexion to Lonza hereunder and all copies of all manufacturing records and information relating to the Process and/or Product that Lonza has maintained under this Agreement. Notwithstanding the foregoing, (i) Lonza may retain and continue to use copies of such data, records, information, and documentation to the extent strictly required to comply with all applicable material regional, national, state and local laws, ordinances and governmental rules or regulations, and (ii) Lonza legal department may retain one copy of the foregoing, in each case, subject to its continuing obligation of confidentiality under Article 16;

(b) Lonza shall deliver to Alexion all remaining raw materials or destroy such raw material, as determined in Alexion' sole discretion. Alexion shall purchase any remaining useable raw materials, including without limitation any safety stock, at their Acquisition Cost; and.

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(c) all Alexion equipment will, at Alexion's discretion and Alexion's cost, either be (i) removed and returned to Alexion, (ii) removed and destroyed, or (iii) rendered inoperable.

5.8.6 **Accrued Rights**. Except as otherwise expressly set forth herein, any termination or expiration of this Agreement shall be without prejudice to any right which shall have accrued to the benefit of either Party and shall not relieve either Party of any obligation which has accrued prior to the effective date of such termination or expiration, which obligations shall remain in full force and effect for the period provided therein or, if no period is provided therein, then such obligations shall remain in full force and effect indefinitely.

ARTICLE 6.
GOVERNING LAW AND JURISDICTION

6.9 **Governing Law.** The construction, validity, performance and enforcement of this Agreement shall be governed and enforced pursuant to the laws of Switzerland, without giving effect to the principles of conflicts of law thereof.

6.10 **Dispute Resolution**. Subject to Section 6.8, in the event of the failure on the part of any required representative of the Parties hereto or the Joint Steering Committee to resolve any matter required by this Agreement to be agreed, or in the event of any other dispute or claim arising between the Parties under this Agreement, the Parties shall attempt by good faith negotiations to resolve such dispute or claim between them by reference to the Executive Steering Committee, which shall negotiate in good faith during a period of not less than thirty (30) days to resolve such matter, dispute or claim. If the Executive Steering Committee is not able to resolve such matter, dispute or claim within such thirty (30) day period, the matter, dispute or claim shall be submitted to the Chief Executive Officers of Alexion Inc and Lonza Group AG ("CEOs") for resolution. If the CEOs are unable to resolve such matter, dispute or claim within a further thirty (30) day period, the matter, dispute or claim shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules.

6.11 **Injunctive Relief**. Nothing in this Agreement shall be construed to limit either party's right to seek immediate injunctive relief in the event of a breach hereof for which no monetary damages is calculable, including without limitation any provisions related to confidentiality and intellectual property.

6.12 **No Waiver**. No failure or delay on the part of either Lonza or Alexion to exercise or enforce any rights conferred on it by the Agreement shall be construed or operate as a waiver thereof nor shall any single or partial exercise of any right, power or privilege or

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further exercise thereof operate so as to bar the exercise or enforcement thereof at any time or times thereafter.

6.13 **Severability**. The illegality or invalidity of any provision (or any part thereof) of this Agreement shall not affect the legality, validity or enforceability of the remainder of its provisions or the other parts of such provision, as the case may be.

ARTICLE 7.
FORCE MAJEURE

7.9 **Effect of Force Majeure Event**. No Party shall be in breach of this Agreement if there is any failure of performance under this Agreement (except for payment of any amounts due under this Agreement) occasioned by any reason beyond the control and without the fault or negligence of the Party affected thereby, including an act of God, fire, act of government or state, war, civil commotion, insurrection, embargo, an infectious virus which cannot be detected by testing and which causes a shutdown for a substantial period of a large portion of a Facility due to contamination despite reasonable best efforts by Lonza to prevent such occurrence, prevention from or hindrance in obtaining energy or other utilities, a market shortage of raw materials or necessary components, but specifically excluding labor disputes or work stoppages of whatever nature (a "**Force Majeure Event**"). Nothing in this Section 20.1 shall, however, release such Party from using its Reasonable best efforts to avoid or remove all such causes. Upon cessation of such Force Majeure Event, the affected Party shall promptly resume performance under this Agreement.

7.10 **Notice of Force Majeure; ESC**. Each Party agrees to give the other Party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable fully to perform its obligations under this Agreement. At the request of either Party, the ESC shall meet and discuss in good faith possible ways to correct or remedy the Force Majeure Event. Each Party further agrees to use Reasonable best efforts to correct the Force Majeure Event as quickly as practicable and to give the other Party prompt written notice when it is again fully able to perform such obligations.

7.11 **Termination**. Alexion may terminate this Agreement if Lonza is unable to perform pursuant to this Article 20 for a period of [*] months, and Lonza may terminate this Agreement if Alexion is unable to perform pursuant to this Article 20 for a period of [*] months.

ARTICLE 8.
MISCELLANEOUS

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8.4 **Additional Duties and Obligations of Lonza.**

8.4.1 **Continuous Supply**. Lonza shall [*], and, further, Lonza shall not willfully delay production nor withhold Delivery of the Products.

21.1.2 **Records**. Lonza shall maintain proper technical files and administrative and accounting records with respect to the Services in accordance with all applicable laws. All such original files and records, in whatever form, shall be retained by Lonza for a period not less than [*] years, or any longer periods as per applicable laws, from the date of termination of this Agreement.

21.1.3 **Personnel**. Without relieving or limiting Lonza's obligations hereunder in any way whatsoever, all Services shall be performed by Lonza's personnel or Lonza's contractors who have the necessary technical skills, qualifications, experience and training to complete the Services.

8.5 **Alexion Material**. All Alexion Material (including, but not limited to, manufacturing formula, processing instructions, sampling and testing methods, etc.), whether or not patentable, shall be the sole and exclusive property of Alexion. All Alexion New Material shall be supplied to Alexion or its designee in accordance with the terms of this Agreement. Lonza shall not sell or otherwise dispose of any Alexion Materials, except as expressly authorized by Alexion.

8.6 **Approved Subcontractors**. Lonza shall not subcontract or delegate any portion of its obligations hereunder, except to an Approved Subcontractor, and provided that Lonza shall remain solely and fully liable for the performance of Approved Subcontractors. Lonza shall ensure that any Approved Subcontractor performs its obligations pursuant to the terms of this Agreement, including the Annexes. Lonza shall maintain copies of the documents held by or under the control of the Approved Subcontractors to be provided to Alexion, as required under this Agreement.

8.7 **Facility**. Lonza will Process the Products exclusively at the Facilities specified in the applicable PSA for such Product. Transfer of the Processing of the Products to another facility or Facility requires the prior written approval of Alexion. If Lonza transfers or sells any rights in any Facility it shall ensure that all of Alexion's rights as set forth in this Agreement shall continue to apply in full force and effect after any such transfer or sale.

8.8 **Authorizations and Permits**. Lonza warrants that it holds, and/or will cause its Approved Subcontractors to hold, all necessary authorizations and permits for any and all Processing under this Agreement from the competent authorities of the country or countries where such Processing takes place for the acquisition, manufacture, storage and handling of the Components and the Product. Lonza shall provide, and/or shall cause its Approved Subcontractors to provide copies of any such authorizations and permits to Alexion upon

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Alexion's request. Without prejudice to any of Alexion's other rights under this Agreement, Lonza shall inform Alexion promptly in writing in the event any such authorization or permit is not obtained timely or is withdrawn or otherwise under investigation.

8.9 **Technology Transfer**. At any time during the course of this Agreement, Alexion can request that Lonza transfer the Process for any Product to a Third Party, and the Parties shall enter into a technology transfer agreement according to the terms in Exhibit D.

8.10 **Assignment**. Neither Party shall be entitled to assign this Agreement without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed, except that both Parties shall be entitled without the prior written consent of the other to assign this Agreement (i) to an Affiliate, (ii) to any joint venture company of which that Party is the beneficial owner of more than fifty per cent (50%) of the issued voting share capital thereof or (iii) to any company to which that Party may transfer all or substantially all of its assets or capital stock relating to the activities contemplated under this Agreement, whether through purchase, merger, consolidation or otherwise (each of (i)-(iii) being a "Permitted Assignee"). In the event of transfer or assignment of this Agreement by Lonza to a Permitted Assignee, the obligations of Section 4.2.2 and 4.2.3, including all cross references thereto shall continue to be binding upon the Permitted Assignee and shall still be binding on Lonza for as long as such terms are binding on the assignee or transferee. Any purported assignment contrary to this Section 21.6 shall be null and void.

8.11 **Guarantee of Performance.** Lonza Group hereby guarantees the performance by Lonza of the Services and/or any other obligations on Lonza in this Agreement, and shall be responsible for Lonza's actions and omissions as if they were the actions and omissions of Lonza Group. Alexion Inc hereby guarantees the performance by Alexion of the financial obligations on Alexion in this Agreement, and shall be responsible for Alexion's actions and omissions relating to such financial obligations as if they were the actions and omissions of Alexion Inc.

8.12 **Publicity**. The text of any press release or other communication to be published by or in the media concerning the subject matter of this Agreement (not previously published pursuant to this Section 21.3) shall require the prior written approval of Lonza and Alexion, except to the extent required by law.

8.13 **Independent Contractor**. Each Party to this Agreement acts as an independent contractor and nothing in this Agreement shall be construed to create a relationship of partnership, principal and agent, or joint venture between the Parties.

8.14 **Notices**. Any notice or other communication to be given under this Agreement shall be delivered personally or sent by first class pre-paid registered or certified mail, return receipt requested, nationally recognized courier service or facsimile transmission addressed as follows:

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If to Alexion: Alexion Pharma International Trading
Block 10a, Beckett Way
Park West Business Park
Nangor Road
Dublin, Ireland

Attention: CMO, Business Management
Facsimile:

with a copy to: Alexion Pharmaceuticals, Inc.
352 Knotter Drive
Cheshire, Connecticut 06410 USA
Attn: Alexion General Counsel and Chief Legal Officer

If to Lonza: Lonza Group AG
Muenchensteinerstrasse 38
4002 Basel
Switzerland
Attention: Group General Counsel
Facsimile: 41 61 316 91 11

with a copy to: Lonza Biologics Tuas Pte Ltd
35 Tuas South Avenue 6
SG-Singapore 637377
Attention: Head of Site
Facsimile: +65 6521 4379

with a copy to: Lonza Biologics plc
228 Bath Road
Slough
Sl1 4DX, UK
Attention: UK General Counsel
Facsimile: +44 1753 777001

or to such other address as either Party hereto may hereafter notify the other in accordance with the provisions of this clause. All such notices or other communications shall be deemed to have been delivered as follows: if delivered personally, at the time of such delivery; if sent by registered or certified mail, five (5) business days (Saturdays, Sundays and public holidays excluded) after mailing; if sent by facsimile, upon receipt of the transmission confirmation slip showing completion of the transmission; if sent by courier service, two (2) days after being dispatched.

8.15 **Headings**. The headings in this Agreement are for convenience of reference only and shall not constitute part of this Agreement.

8.16 **Counterparts**. This Agreement may be executed in several counterparts, each of which is an original but all of which shall constitute one instrument.

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8.17 **Binding Effect**. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Other than Indemnitees, no other person or entity shall have any rights or benefits under this Agreement.

[signature page follows]

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.

ALEXION PHARMA INTERNATIONAL TRADING

By:/s/ Julie O'Neill

Name: Julie O'Neill

Title: Director

ALEXION PHARMACEUTICALS, INC.

By:/s/ Stephen Squinto

Name: Stephen Squinto

Title: Executive Vice President, Chief Global Operations Officer

LONZA BIOLOGICS TUAS PTE LTD

By: /s/ Andrew Morgan By:

Name: Andrew Morgan Name:

Title: General Manager, Singapore Title:

LONZA SALES AG

By: /s/ Daniel Blättler By: /s/ Marie Leblanc

Name: Daniel Blättler Name: Marie Leblanc

Title: General Counsel Title: Key Account Management

LONZA GROUP AG

By: /s/ Daniel Blättler By: /s/ Guillaume Daeppen

Name: Daniel Blättler Name: Guillaume Daeppen

Title: General Counsel Title: Head of Group Finance

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EXHIBIT A

FORM OF PSA

PSA for [Product name]

This Product Specific Appendix, effective as of_____, 20__ ("**Effective Date"**) by and between _____ ('**Alexion TBD'**) and _____ ('**Lonza TBD**') is intended to supplement and be read together with that certain agreement titled the Master Manufacturing and Supply Agreement by and between Alexion Pharma International Trading ('**Alexion**'), Lonza Biologics Tuas Pte Ltd ('**Lonza Singapore**'), Lonza Group AG ('**Lonza Group AG**') and Lonza Sales AG ('**Lonza Sales**') of_____, 2014 (the '**Agreement**'). As used herein this PSA, "**Party**" or "**Parties**" means Lonza TBD and/or Alexion TBD, as the context requires.

[Lonza to provide]

This PSA is incorporated herein to the Agreement by this reference.

This PSA submitted in connection with the Agreement, is hereby agreed to by the Parties:

ALEXION TBD LONZA TBD

By: By:__

Name: Name:__

Title: Title:__

By: By:__

Name: Name:__

Title: Title:__

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EXHIBIT B

PAYMENT IN LIEU OF ROYALTY

Alexion acknowledges that a certain license agreement (undated in 1998) between Lonza Biologics plc and Alexion Pharmaceuticals, Inc. in which Lonza licenses certain of its Intellectual Property to Alexion and/or its Affiliates (the "License Agreement") is still in full force and effect. The parties specifically acknowledge and agree that the License Agreement shall continue in force in accordance with its terms, but that it does not apply to the Services provided hereunder, and no royalties are owed in association herewith. Notwithstanding the foregoing, in consideration for Lonza's agreement to transfer the Services to [*], and notwithstanding section 5.1.2 of the License Agreement, Alexion agrees to make a payment in lieu of royalties ("PILR") to Lonza Group (or its Swiss Affiliate Lonza Swiss Licences, AG but not to Lonza, Singapore, the receiving entity being referred to as "Lonza (Switzerland)" for purposes of this Exhibit B) as set forth below:

In respect of Soliris manufactured under this Agreement (whether at the [*] Facility or the [*] Facility or, upon prior written agreement of the Parties, any other Lonza facility that the Parties agree to add to this Agreement), a PILR equal to [*] of Net Sales.

Processes for PILR payments:

1. Alexion shall keep true and accurate records and books of account containing all data necessary for the calculation of the PILR payable to Lonza (Switzerland). Such records and books of account shall be kept for no less than [*] years from the date of sales of the Product (eculizumab) to which they relate and shall, upon reasonable notice having been given by Lonza, be open at all reasonable times during business hours for inspection by Lonza or its duly authorized representative.

2. Alexion shall prepare a statement in respect of each calendar quarter which shall show for the quarter in question details of the sales of Product (eculizumab), the weighted average exchange rates used to convert to US Dollars, and the PILR due and payable to Lonza (Switzerland) thereon. Alexion's best estimate of such statement shall be submitted to Lonza within [*] days of the end of the calendar quarter to which it relates together with a remittance for the estimated

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PILR due to Lonza (Switzerland). Within [*] days of the end of the calendar quarter, Alexion shall submit a final statement of the royalties due in respect of the calendar quarter in question together with a remittance for any royalties not accounted for in the relevant estimated statement (if any). In the event the estimated statement has resulted in an over payment of royalties a credit in the sum equal to such overpayment shall be given by Lonza against Alexion's next following payment obligation, or if there are none, a refund in the sum overpaid.

All payments for PILR due under this Agreement:

a. shall be made in US Dollars to Lonza (Switzerland). Amounts payable to Lonza (Switzerland) based on sales in currencies other than US Dollars shall be converted to US Dollars at the rate of exchange at the close of business on the date Alexion receives the amount from the Alexion customer. The rate of exchange shall be the value of US Dollars compared to the other currency as published by Thomson Reuters. The rate of exchange used reflects the prior day ending rate. Alexion may change the source of such rates not more than [*] every [*] by giving Lonza advance written notice and provided the new source is an internationally recognized provider of managed rates and the rates are consistent with those used for Alexion's audited financial statements.

b. are exclusive of any Value Added Tax or of any other applicable taxes, levies, imposts, duties and fees of whatever nature imposed by or under the authority of any government or public authority which shall be paid by Alexion, provided that an exception shall apply in the case of any withholding taxes, which Alexion is required by applicable law to deduct against PILR payments due under this Agreement. The parties agree to co-operate in all respects necessary to take advantage of the relevant double taxation agreements as may be available to reduce or eliminate any withholding tax at source.

c. shall be made to the following account:

Bank: [*]
Cash Correspondent BIC: [*]
Cash Correspondent Name: [*]
Global Custodian BIC: [*]
Account number: [*]
Account Name: [*]

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ABA Number: [*]
FFC Acct Number: [*]
FFC Acct Name: [*]

Contract conferring rights on a third party. Lonza wishes to benefit and to entitle Lonza Swiss Licences AG, to enforce certain rights out of the Agreement independently and in its own right. Accordingly, the Parties conclude a contract conferring rights on a third party according to article 112 sec. 2 and 3 of the Swiss Code of Obligations:

1. Alexion and, in its capacity as guarantor under Section 21.2 of the Agreement, Alexion Inc, undertake to pay the PILR directly to Lonza Swiss Licences.

2. Lonza Swiss Licences shall be entitled to enforce the payments of the PILR.

3. Lonza Swiss Licences shall be entitled to enforce the audit and the related rights under Exhibit 1 of the Agreement as they relate to the PILR.

4. Lonza Swiss Licences shall become the direct beneficiary of any payments due under Section 19.2.1 of the Agreement.

5. Lonza Swiss Licences has the right to compel performance from Alexion and Alexion Inc according to Art. 112 sec. 2 of the Swiss Code of Obligations.

6. By signing this supplement Lonza Swiss Licences notifies Alexion and Alexion Inc of its intention to exercise the conferred rights according to Art. 112 sec. 3 of the Swiss Code of Obligations.

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7. Payment by Alexion or, as guarantor, Alexion Inc, of any PILR (or of any payment under Section 19.2.1 of the Agreement) to Lonza Swiss Licences shall satisfy all payment obligations of Alexion and Alexion Inc under the Agreement with respect to such PILR (or payment under Section 19.2.1) and shall relieve Alexion and Alexion Inc of any obligation to pay Lonza Group and/or Lonza Biologics Tuas Pte Ltd any amount with respect to such PILR (or such payment under Section 19.2.1). Nothing contained in this Section 2.8 shall relieve Alexion or Alexion Inc of any obligation to Lonza Swiss Licences with respect to the payment of interest that accrues in respect of PILR payments that are not received by the applicable due date and which becomes payable in accordance with Exhibit 1 to the Agreement (under the heading "Late Payments").

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EXHIBIT C

ALEXION PATENT RIGHTS

SOLIRIS ® (eculizumab)				
Title: [*]				
Alexion Ref:	Territory	Application Status	Application Number	Patent Number
13	[*]	CON	[*]	[*]
13	[*]	DIV	[*]	[*]
13	[*]	DIV	[*]	[*]
13	[*]	DIV	[*]	[*]
13	[*]	DIV	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	EPP	[*]	[*]
13	[*]	ORD	[*]	[*]
13	[*]	ORD	[*]	[*]
13	[*]	PCT	[*]	[*]
13	[*]	PCT	[*]	[*]
13	[*]	PCT	[*]	[*]
13	[*]	PCT	[*]	[*]
13	[*]	PCT	[*]	[*]
13	[*]	PCT	[*]	[*]
SOLIRIS ® (eculizumab)	[*]		[*]	[*]
Title: [*]	[*]		[*]	[*]
Alexion Ref:	[*]	Application Status	[*]	[*]
208	[*]	Pending	[*]	[*]
Title: [*]	[*]			

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Alexion Ref:	[*]	Application Status	[*]	[*]
228	[*]	Pending	[*]	[*]
Title: [*]	[*]		[*]	[*]
Alexion Ref:	[*]	Application Status	[*]	[*]
229	[*]	Pending	[*]	[*]
Asfotase alfa	[*]			
[*]	[*]			
Alexion Ref:	[*]	Application Status	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Published	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Published	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
Asfotase alfa	[*]		[*]	[*]
Title: [*]	[*]		[*]	[*]
Alexion Ref:	[*]	Application Status	[*]	[*]
0248-ENO	[*]	Published	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]

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0248-ENO	[*]	Published	[*]	[*]
0248-ENO	[*]	Granted	[*]	[*]
0248-ENO	[*]	Expired	[*]	[*]
0248-ENO	[*]	Expired	[*]	[*]
0248-ENO	[*]	Expired	[*]	[*]
0248-ENO	[*]	Inactive	[*]	[*]
Asfotase alfa	[*]		[*]	[*]
Title: [*]	[*]		[*]	[*]
Alexion Ref:	[*]	Application Status	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Pending	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
Asfotase alfa	[*]		[*]	[*]
Title: [*]	[*]		[*]	[*]
Alexion Ref:	[*]	Application Status	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Pending	[*]	[*]
0249-ENO	[*]	Published	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
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0249-ENO	[*]	Published	[*]	[*]
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0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]

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0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Published	[*]	[*]
0249-ENO	[*]	Published	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
Asfotase alfa	[*]		[*]	[*]
Title: [*]	[*]		[*]	[*]
Alexion Ref:	[*]	Application Status	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Published	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
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0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
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0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]
0249-ENO	[*]	Granted	[*]	[*]

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0249-ENO	[*]	Expired	[*]	[*]
0249-ENO	[*]	Inactive	[*]	[*]

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EXHIBIT D

TECHNOLOGY TRANSFER PROVISIONS

- Product ([*])
  - Lonza shall provide up to [*] hours of support over a period of a maximum of [*], whichever is reached first, but Lonza shall use reasonable commercial endeavours to provide further support to Alexion if the transfer has not been completed by that point.
  - Lonza would initiate support to begin tech transfer within [*] of the official request by Alexion of their intent to tech transfer
  - Alexion shall pay USD [*] for [*] hours of Lonza support, plus all reasonable travel and accommodation expenses of Lonza
  - Not to be carried out at same time as Soliris TT support to another supplier
  - Tech transfer agreement to include a [*] to Alexion to use the Lonza Patent Rights and Lonza Information
  - Tech transfer agreement to include right for Alexion to cross reference Lonza's drug master files and other regulatory submissions
  - No more than [*] in Lonza facility by Alexion (other CMO not to be onsite at any Lonza facility) or [*] to new CMO by Lonza, as reasonably agreed between the Parties
  - Not to be carried out prior to completion of the Asfotase[*]TT and validation batches to [*]

- Product ([*])
  - Up to a maximum of [*] hours of support over a period of a maximum [*], whichever is reached first, but Lonza shall use reasonable commercial endeavours to provide further support to Alexion if the transfer has not been completed by that point.
  - Lonza would initiate support to begin tech transfer within [*] of the official request by Alexion of their intent to tech transfer
  - Alexion shall pay USD [*] for [*] hours of Lonza support, plus all reasonable travel and accommodation expenses of Lonza
  - Not to be carried out prior to completion of the [*] TT and validation batches to Porriño

- Not to be carried out at same time as Asfotase alfa TT support to another supplier
- No more than [*] in Lonza facility by Alexion (other CMO not to be onsite at any Lonza facility) or [*] to new CMO by Lonza, as reasonably agreed between the Parties
- Tech transfer agreement to include a non-exclusive license to Alexion to use the Lonza Patent Rights and Lonza Information
- Tech transfer agreement to include right for Alexion to cross reference Lonza's drug master files and other regulatory submissions

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Exhibit 10.28

FIRST AMENDMENT TO CREDIT AGREEMENT

This **FIRST AMENDMENT TO CREDIT AGREEMENT**, dated as of November 14, 2012 (this "Amendment"), modifies that certain Credit Agreement, dated as of February 7, 2012 (as amended, restated, extended, supplemented or otherwise modified in writing from time to time, the "Credit Agreement"), among **ALEXION PHARMACEUTICALS, INC.**, a Delaware corporation (the "Administrative Borrower"), certain Subsidiaries of the Administrative Borrower party thereto pursuant to Section 2.15 of the Credit Agreement (each a "Designated Borrower" and, together with the Administrative Borrower, the "Borrowers" and, each a "Borrower"), each lender from time to time party thereto (collectively, the "Lenders" and individually, a "Lender"), **BANK OF AMERICA, N.A.**, as administrative agent (in such capacity, the "Administrative Agent"), and **MERRILL LYNCH, PIERCE, FENNER & SMITH INCORPORATED** and **J.P. MORGAN SECURITIES LLC**, as joint lead arrangers and joint book managers. Capitalized terms used herein and not defined shall have the meaning assigned to such terms in the Credit Agreement.

RECITALS

WHEREAS, the Administrative Borrower has requested that the Administrative Agent and the Lenders agree to amend certain of the terms and provisions of the Credit Agreement, as specifically set forth in this Amendment; and

WHEREAS, the undersigned Lenders and the Administrative Agent are prepared to amend the Credit Agreement on the terms, subject to the conditions and in reliance on the representations set forth herein.

NOW THEREFORE, in consideration of the premises and the mutual agreements contained here, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

Section 1. Amendments to Credit Agreement.

(a) Section 1.01 (Definitions and Accounting Terms) of the Credit Agreement is hereby amended by:

(i) inserting the following new definitions in the appropriate alphabetical order:

> ""CT Intercreditor Agreement" shall mean an intercreditor agreement by and among the Administrative Agent, the state of Connecticut or a department, division or agency thereof, the Administrative Borrower and the other parties thereto (if any), in form and substance reasonably satisfactory to the Administrative Agent, as amended, restated, supplemented or otherwise modified and in effect from time to time."; and

""CT Priority Collateral" shall mean assets of the Administrative Borrower and/or its Subsidiaries (and identifiable proceeds thereof) the acquisition of which is financed with Indebtedness permitted under Section 7.02(g)(i)."

(ii) amending the definition of the term "Loan Documents" contained in such Section 1.01 by deleting the text "and (i)" set forth therein and substituting in lieu thereof the text: ", (i) the CT Intercreditor Agreement and (j)";

(iii) amending the definition of the term "Material Foreign Subsidiary" contained in such Section 1.01 by restating such definition in its entirety as follows:

"Material Foreign Subsidiary" means any Foreign Subsidiary which (a) has been designated by the Administrative Borrower as a Material Foreign Subsidiary in a written notice to the Administrative Agent, (b) accounts for 7.5% or more of the Administrative Borrower's consolidated total assets or Consolidated EBITDA (determined without regard to such Foreign Subsidiary's ownership of any other Subsidiary and as at the last day of the most recently ended period of four fiscal quarters for which financial statements have been furnished to the Administrative Agent under Section 6.01(a) or Section 6.01(b)), or (c) solely to the extent that such Foreign Subsidiary together with its Subsidiaries accounts for 7.5% or more of the Administrative Borrower's consolidated total assets or Consolidated EBITDA (determined as at the last day of the most recently ended period of four fiscal quarters for which financial statements have been furnished to the Administrative Agent under Section 6.01(a) or Section 6.01(b)), has been designated by the Administrative Agent as a Material Foreign Subsidiary in a written notice to the Administrative Borrower; provided that if (as of the last day of any period of four fiscal quarters) the combined consolidated total assets or combined Consolidated EBITDA of all Foreign Subsidiaries that neither (x) have been designated under clause (a) or (c) above nor (y) would constitute "Material Foreign Subsidiaries" under clause (b) above, shall have exceeded 10% of the consolidated total assets of the Administrative Borrower or 15% of the Consolidated EBITDA of the Administrative Borrower, then one or more of such excluded Foreign Subsidiaries shall for all purposes of this Agreement be deemed to be Material Foreign Subsidiaries in descending order based on the amounts of their consolidated total assets until such excess shall have been eliminated. As of the Closing Date, the Material Foreign Subsidiaries are Enobia Pharma Inc., Enobia Canada L.P., and Alexion Holding B.V.

(iv) amending the definition of the term "Responsible Officer" contained in such Section 1.01 by adding the phrase "vice president of treasury," immediately prior to the phrase "assistant treasurer" contained therein.

(b) Paragraph (b) of Section 6.01 (Financial Statements) of the Credit Agreement is hereby amended by adding the phrase "vice president of treasury," immediately prior to the word "treasurer" contained therein;

(c) Paragraph (b) of Section 6.02 (Certificates; Other Information) of the Credit Agreement is hereby amended by adding the phrase "vice president of treasury," immediately prior to the word "treasurer" contained therein;

(d) Clause (ii) of Paragraph (i) of Section 7.01 (Liens) of the Credit Agreement is hereby amended by restating such clause in its entirety as follows:

> "(ii) Liens securing Indebtedness permitted under Section 7.02(g)(i); provided that such Liens shall at all times be (x) subject to the CT Intercreditor Agreement and (y) except with respect to the CT Priority Collateral, junior in priority to the Liens on Collateral in favor of the Administrative Agent";

(e) Clause (i) of Paragraph (g) of Section 7.02 (Indebtedness) of the Credit Agreement is hereby amended by deleting the amount "$20,000,000" appearing in the proviso to such clause (i) and inserting in lieu thereof the amount "$26,000,000 plus the aggregate amount of interest thereon which has been capitalized and added to the principal amount thereof";

(f) Paragraph (a) of Section 7.03 (Investments) of the Credit Agreement is hereby amended by replacing the word "and" immediately prior to "(ii)" with the word "or";

(g) Schedule 7.03(a) (Investment Policy) to the Credit Agreement is hereby amended by replacing such Schedule 7.03(a) with Schedule 7.03(a) attached to this Amendment; and

(h) Paragraph (f) of Section 7.05 (Dispositions) of the Credit Agreement is hereby amended by deleting the word "and" in the first line immediately after the word "practice" and inserting a comma in lieu thereof ",";

(i) Clause (c) of Section 7.15 (Prepayments, Etc. of Indebtedness) is hereby amended by restating part (y) contained therein in its entirety as follows:

> "(y) (1) so long as no Default or Event of Default has occurred and is continuing or would result therefrom (other than any Default or Event of Default which has occurred and is continuing under Section 8.01(e) solely as a result of a default under Indebtedness permitted under Section 7.02(g)(i)), Indebtedness permitted under Section 7.02(g)(i) and (2) Indebtedness permitted under Section 7.02(g)(ii) and"

(j) Clause (e) of Section 8.01 (Cross-Default) is hereby amended by:

> (i) deleting the parenthetical "(other than any Swap Contract, as to which clause (ii) below shall apply)" contained in subclause (i)(B) and inserting in lieu thereof the parenthetical "(other than (x) any Swap Contract, as to which clause (ii) below shall apply and (y) indebtedness permitted under Section 7.02(g)(i) (to the extent it

then exceeds the Threshold Amount), as to which clause (iii) below shall apply)"; and

(ii) inserting the following immediately after the end of subclause (ii) "or (iii) fails to observe or perform any agreement or condition relating to any Indebtedness permitted under Section 7.02(g)(i) (to the extent it then exceeds the Threshold Amount), or any other event occurs, the effect of which default or other event is to cause (x) the outstanding amount of such Indebtedness to be demanded or to become due (whether by acceleration or otherwise) or an offer to be required to be made to repurchase, prepay, defease or redeem the outstanding amount of such Indebtedness to be made, prior to its stated maturity or (y) the holder of such Indebtedness to commence any suit to enforce such Indebtedness or commence enforcement of remedies against any collateral securing such Indebtedness;"

(k) Article IX (Administrative Agent) of the Credit Agreement is hereby amended by inserting the following new section in the appropriate numeric order:

"9.12 **Lender Acknowledgement**. The Lenders hereby irrevocably authorize the Administrative Agent to enter into the CT Intercreditor Agreement, and agree to be bound by the provisions of the CT Intercreditor Agreement."

Section 2. Conditions Precedent. This Amendment shall become effective as of the date first written above (the "Effective Date") upon the satisfaction of the following conditions precedent:

(a) Documentation. Administrative Agent shall have received all of the following, in form and substance satisfactory to Administrative Agent:

(i) a fully-executed and effective Amendment executed by the Administrative Borrower, the Designated Borrower, the Guarantors, the Administrative Agent and the Required Lenders;

(ii) an incumbency certificate executed by a Responsible Officer of the Administrative Borrower evidencing the identity, authority and capacity of the vice president of treasury of the Administrative Borrower to act as a Responsible Officer in connection with the Credit Agreement and the other Loan Documents to which the Administrative Borrower is a party or is to be a party ; and

(iii) such additional documents, instruments and information as Administrative Agent may reasonably request to effect the transactions contemplated hereby.

(b) No Default. On the Effective Date and after giving effect to this Amendment, no event shall have occurred and be continuing that would constitute a Default or an Event of Default.

Section 3. Representations and Warranties; Reaffirmation of Grant. Each Loan Party hereby represents and warrants to the Administrative Agent and the Lenders that, as of the

date hereof and after giving effect to this Amendment, (a) all representations and warranties of the Borrowers and each other Loan Party set forth in the Credit Agreement and in any other Loan Document are true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof) on and as of the date hereof to the same extent as though made on and as of such date, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties shall have been true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof) on and as of such earlier date, (b) no Default or Event of Default has occurred and is continuing, (c) the Credit Agreement and all other Loan Documents are and remain legally valid, binding obligations of the Loan Parties party thereto, enforceable against each such Loan Party in accordance with their respective terms, subject to bankruptcy, insolvency, moratorium and other laws applicable to creditors' rights generally and general principles of equity; provided that the Loan Parties make no representation as to the validity or enforceability of Section 11.20 and (d) except as expressly contemplated under any Loan Document, the provisions of the Collateral Documents to which such Loan Party is a party are effective to create in favor of the Administrative Agent for the benefit of the Secured Parties a legal, valid and enforceable first priority Lien (subject only to Permitted Liens) on all right, title and interest of the respective Loan Parties in the Collateral described therein do and shall continue to secure the payment of all Obligations or Foreign Obligor Obligations, as applicable, as set forth in such respective Collateral Documents. Each Loan Party that is a party to the Security Agreement or any of the Collateral Documents hereby reaffirms its grant of a security interest in the Collateral to the Administrative Agent for the ratable benefit of the Secured Parties, as collateral security for the prompt and complete payment and performance when due of the Obligations or Foreign Obligor Obligations, as set forth therein.

Section 4. Survival of Representations and Warranties. All representations and warranties made in this Amendment or any other Loan Document shall survive the execution and delivery of this Amendment, and no investigation by the Administrative Agent or the Lenders shall affect the representations and warranties or the right of the Administrative Agent and the Lenders to rely upon them.

Section 5. Amendment as Loan Document. This Amendment constitutes a "Loan Document" under the Credit Agreement. Accordingly, it shall be an immediate Event of Default under the Credit Agreement if any representation, warranty, certification or statement of fact made by any Loan Party under or in connection with this Amendment shall have been incorrect or misleading in any material respect when made or deemed made.

Section 6. Costs and Expenses. The Administrative Borrower shall pay on demand all reasonable out-of-pocket costs and expenses of the Administrative Agent (including the reasonable fees, charges and disbursements of counsel to the Administrative Agent) incurred in connection with the preparation, negotiation, execution and delivery of this Amendment, in each case, in accordance with Section 11.04 of the Credit Agreement.

Section 7. Governing Law. THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS AMENDMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK (WITHOUT GIVING EFFECT TO ANY CHOICE OR CONFLICT OF LAW PROVISION OR RULE THAT WOULD CAUSE THE APPLICATION OF THE DOMESTIC SUBSTANTIVE LAWS OF ANY OTHER STATE).

Section 8. Execution. This Amendment may be executed in any number of counterparts and by different parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Delivery of an executed counterpart of a signature page to this Amendment by telecopier (or electronic mail (including in PDF format)) shall be effective as delivery of a manually executed counterpart of this Amendment.

Section 9. Limited Effect. This Amendment relates only to the specific matters expressly covered herein, shall not be considered to be an amendment or waiver of any rights or remedies that the Administrative Agent or any Lender may have under the Credit Agreement, under any other Loan Document (except as expressly set forth herein) or under Law, and shall not be considered to create a course of dealing or to otherwise obligate in any respect the Administrative Agent or any Lender to execute similar or other amendments or waivers or grant any amendments or waivers under the same or similar or other circumstances in the future.

Section 10. Ratification by Guarantors. Each of the Guarantors acknowledges that its consent to this Amendment is not required, but each of the undersigned nevertheless does hereby agree and consent to this Amendment and to the documents and agreements referred to herein. Each of the Guarantors agrees and acknowledges that (i) notwithstanding the effectiveness of this Amendment, such Guarantor's Guaranty shall remain in full force and effect without modification thereto and (ii) nothing herein shall in any way limit any of the terms or provisions of such Guarantor's Guaranty or any other Loan Document executed by such Guarantor (as the same may be amended from time to time), all of which are hereby ratified, confirmed and affirmed in all respects. Each of the Guarantors hereby agrees and acknowledges that no other agreement, instrument, consent or document shall be required to give effect to this Section 10. Each of the Guarantors hereby further acknowledges that the Administrative Borrower, the Designated Borrower, the Administrative Agent and any Lender may from time to time enter into any further amendments, modifications, terminations and/or amendments of any provisions of the Loan Documents without notice to or consent from such Guarantor and without affecting the validity or enforceability of such Guarantor's Guaranty or giving rise to any reduction, limitation, impairment, discharge or termination of such Guarantor's Guaranty.

Section 11. Acknowledgement. The Administrative Borrower hereby represents and warrants that, as of the date hereof, attached hereto as Schedule 11 is a true and complete list of all current material assets of Alexion Montreal Corp. located in Quebec, Canada ("Alexion Montreal

Assets"). Pursuant to clause (x) of the last paragraph of Section 6.12 of the Credit Agreement (and notwithstanding the requirements of the Post Closing Agreement), the Administrative Agent hereby acknowledges that, with respect to the Alexion Montreal Assets, the cost of obtaining and perfecting a Lien with respect to such assets outweighs the benefits of the security afforded thereby. Alexion Montreal Corp. hereby acknowledges and agrees that at any time Alexion Montreal Corp. shall acquire any material assets it shall notify the Administrative Agent and, at the Administrative Agent's request, comply with each of the requirements set forth in Section 6.12(c) of the Credit Agreement within the applicable time periods set forth therein. The Administrative Agent hereby acknowledges and agrees that the Continuing Guaranty by Enobia Pharma Corp. in favor of the Agent dated February 7, 2012 and all obligations and liabilities therein, terminated in their entirety upon the liquidation of Enobia Pharma Corp. on March 30, 2012.

Section 12. Amalgamation. Each of the Loan Parties hereby acknowledges and confirms the following amalgamations and transactions have occurred: (a) effective February 9, 2012, Enobia Pharma Inc. changed its name to Alexion Montreal Corp.; (b) effective March 30, 2012, Enobia Pharma Corp. was dissolved; (c) effective May 30, 2012, Alexion Montreal Corp. was continued in the Province of Nova Scotia under the name Alexion Montreal Inc.; and (d) effective June 1, 2012, API Emerald Holdings ULC amalgamated with Alexion Montreal Inc. to continue as Alexion Montreal Corp., an unlimited company ("Amalco") (collectively, such corporate changes and the amalgamation are referred to herein as the "Amalgamation"). Each of the Loan Parties (including, for greater certainty, Amalco) hereby acknowledges and confirms that, to the extent necessary, it consented to the Amalgamation, and hereby confirms that each of the Loan Documents to which it is a party continue to remain in full force and effect, unamended (except in accordance with the terms hereof) and without abrogation, impairment or limitation following the Amalgamation. Amalco acknowledges, confirms and agrees that:

(i) Amalco is a Loan Party;

(ii) Amalco is bound by and liable to perform all of the covenants, agreements and other obligations contained in the continuing guaranty given by Enobia Pharma Inc., Enobia Canada Limited Partnership and Alexion Holdings B.V. dated February 7, 2012, as if Amalco had executed such continuing guaranty in the first instance; and

(iii) all of the debts, liabilities and obligations of each of API Emerald Holdings ULC, Alexion Montreal Inc., Enobia Pharma Inc. or Alexion Montreal Corp. (collectively, the "Predecessor Entities" and each a "Predecessor Entity") arising under, by virtue of or otherwise in connection with the Loan Documents are the debts, liabilities and obligations of Amalco.

[*Remainder of Page Intentionally Left Blank***]**

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed and delivered as of the date first above written.

BORROWERS:

ALEXION PHARMACEUTICALS, INC., as Administrative Borrower

By: /s/ Vikas Sinha
Name: Vikas Sinha
Title: Executive Vice President and Chief Financial Officer

ALEXION PHARMA INTERNATIONAL SÀRL, as Designated Borrower

By: /s/ Nick Moore
Name: Nick Moore
Title: Vice President Finance and General Manager

GUARANTORS:

ALEXION DELAWARE HOLDING LLC

By: **ALEXION PHARMACEUTICALS, INC.,** its sole member

By: /s/ Vikas Sinha
Name: Vikas Sinha
Title: Executive Vice President and Chief Financial Officer

ALEXION CAMBRIDGE CORPORATION

By: /s/ Michael V. Greco

Name: Michael V. Greco
Title: President, Secretary and Treasurer

GUARANTORS (cont'd):

ALEXION HOLDING B.V.

By: /s/ Michael V. Greco
Name: Michael V. Greco
Title: Director A

By: /s/ Justin Verbond
Name: Justin Verbond
Title: Director B

ALEXION MONTREAL CORP. (as successor by amalgamation to ENOBIA PHARMA INC.)

By: /s/ Michael V. Greco
Name: Michael V. Greco
Title: President

ENOBIA CANADA LIMITED PARTNERSHIP

By: **ALEXION MONTREAL CORP.,** its general partner

By: /s/ Michael V. Greco
Name: Michael V. Greco
Title: President

ADMINISTRATIVE AGENT:

BANK OF AMERICA, N.A.

By: /s/ Maurice Washington
Name: Maurice Washington
Title: Vice President

LENDERS:

BANK OF AMERICA, N.A., as a Lender, an L/C Issuer and Swing Line Lender

By: /s/ Lori Jou Egan
Name: Lori Jou Egan
Title: Vice President

LENDERS (cont'd):

JPMORGAN CHASE BANK, N.A.

By: /s/ Peter M. Killea
Name: Peter M. Killea
Title: Senior Vice President

LENDERS (cont'd):

RBS CITIZENS, NATIONAL ASSOCIATION

By: /s/ Cheryl Carangelo
Name: Cheryl Carangelo
Title: Senior Vice President

LENDERS (cont'd):

SUNTRUST BANK

By: /s/ Dana Dhaliwal_____
Name: Dana Dhaliwal
Title: Director

LENDERS (cont'd):

SOVEREIGN BANK, N.A.

By: /s/ William R. Rogers
Name: William R. Rogers
Title: Senior Vice President

LENDERS (cont'd):

PEOPLE'S UNITED BANK

By: /s/ William R. Rogers
Name: Robert Hazard
Title: Senior Vice President

LENDERS (cont'd):

THE HUNTINGTON NATIONAL BANK

By: /s/ Jared Shaner
Name: Jared Shaner
Title: Authorized Signer

INVESTMENT POLICY

SCHEDULE 11

ALEXION MONTREAL ASSETS

99.99% direct ownership of Enobia Canada L.P. As of the Closing Date, Enobia Canada L.P. held the Company's intellectual property. Subsequent to the Closing Date and pursuant to the Restructuring, the intellectual property held by Enobia Canada L.P. was transferred to Alexion Pharma International Sàrl (a Designated Borrower and the direct parent of Alexion Montreal Corp.). The Administrative Borrower expects to liquidate Enobia Canada L.P. in the fourth quarter of 2012 or early 2013.

CONSENT AND SECOND AMENDMENT TO CREDIT AGREEMENT AND FIRST AMENDMENT TO ADMINISTRATIVE BORROWER GUARANTY, DOMESTIC SUBSIDIARY GUARANTY AND FOREIGN SUBSIDIARY GUARANTY

This **CONSENT AND SECOND AMENDMENT TO CREDIT AGREEMENT AND FIRST AMENDMENT TO ADMINISTRATIVE** BORROWER GUARANTY, DOMESTIC SUBSIDIARY GUARANTY AND FOREIGN SUBSIDIARY GUARANTY, dated as of December 17, 2013 (this "Amendment"), modifies (i) that certain Credit Agreement, dated as of February 7, 2012, as amended by that certain First Amendment to Credit Agreement, dated as of November 14, 2012 (the "Credit Agreement"), among **ALEXION PHARMACEUTICALS, INC.**, a Delaware corporation (the "Administrative Borrower"), certain Subsidiaries of the Administrative Borrower party thereto pursuant to Section 2.15 of the Credit Agreement (each a "Designated Borrower" and, together with the Administrative Borrower, the "Borrowers" and, each a "Borrower"), each lender from time to time party thereto (collectively, the "Lenders" and individually, a "Lender"), **BANK OF AMERICA, N.A.**, as administrative agent (in such capacity, the "Administrative Agent"), and **MERRILL LYNCH, PIERCE, FENNER & SMITH INCORPORATED** and **J.P. MORGAN SECURITIES LLC**, as joint lead arrangers and joint book managers, (ii) that certain Continuing Guaranty (Administrative Borrower), dated as of February 7, 2012 (as amended and in effect immediately prior to giving effect to this Amendment, the "Administrative Borrower Guaranty"), made by the Administrative Borrower in favor of the Secured Parties, (iii) that certain Continuing Guaranty (Existing Domestic Subsidiary Guarantors), dated as of February 7, 2012 (as amended and in effect immediately prior to giving effect to this Amendment, the "Domestic Subsidiary Guaranty"), made by Alexion Delaware Holding, LLC and Alexion Cambridge Corporation in favor of the Secured Parties, and (iv) that certain Continuing Guaranty (Foreign Subsidiary Guarantors), dated as of February 7, 2012, as supplemented by that certain Joinder to Guaranty, dated June 28, 2013, as further supplemented by that certain Joinder to Guaranty, dated November 7, 2013 (as modified and in effect immediately prior to giving effect to this Amendment, the "Foreign Subsidiary Guaranty"), made by Alexion Holding, B.V., Alexion Montreal Corp. (as successor by amalgamation to Enobia Pharma Inc.), Enobia Canada Limited Partnership, Alexion Pharma Holding and Alexion Pharma International Trading in favor of the Secured Parties. Capitalized terms used herein and not defined shall have the meaning assigned to such terms in the Credit Agreement, as amended by this Amendment.

RECITALS

WHEREAS, the Administrative Borrower has requested that the Administrative Agent and the Lenders (a) consent to the transfer of IP Rights owned by the U.S. Loan Parties to one or more Loan Parties organized in Ireland (hereinafter, the "Specified IP Transfer") and (b) agree to amend certain of the terms and provisions of the Credit Agreement, the Administrative Borrower Guaranty, the Domestic Subsidiary Guaranty and the Foreign Subsidiary Guaranty, in each case, as specifically set forth in this Amendment; and

WHEREAS, the undersigned Lenders and the Administrative Agent are prepared to (a) consent to the Specified IP Transfer and (b) amend the Credit Agreement, the Administrative Borrower Guaranty, the Domestic Subsidiary Guaranty and the Foreign Subsidiary Guaranty, in each case. on the terms, subject to the conditions and in reliance on the representations set forth herein.

NOW THEREFORE, in consideration of the premises and the mutual agreements contained here, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

Section 1. Consent to Specified IP Transfer. Notwithstanding the restrictions contained in Section 7.05(d) of the Credit Agreement, the Administrative Agent and the undersigned Lenders hereby consent to Specified IP Transfer.

Section 2. Amendments to Credit Agreement.

(a) Section 1.01 (Definitions and Accounting Terms) of the Credit Agreement is hereby amended by:

(i) inserting the following new definitions in the appropriate alphabetical order:

""Commodity Exchange Act" means the Commodity Exchange Act (7 U.S.C. § 1 et seq.), as amended from time to time, and any successor statute."

""Excluded Swap Obligation" means, with respect to any Guarantor, any Swap Obligation if, and to the extent that, all or a portion of the Guaranty of such Guarantor of, or the grant by such Guarantor of a security interest to secure, such Swap Obligation (or any Guaranty thereof) is or becomes illegal under the Commodity Exchange Act or any rule, regulation or order of the Commodity Futures Trading Commission (or the application or official interpretation of any thereof) by virtue of such Guarantor's failure for any reason to constitute an "eligible contract participant" as defined in the Commodity Exchange Act and the regulations thereunder (including, for the avoidance of any doubt, after giving effect to each applicable sections of each Guaranty (including Article X hereof) entitled "Keepwell" and any other "keepwell, support or other agreement" for the benefit of such Guarantor and any and all guarantees of such Guarantor's Swap Obligations by other Loan Parties) at the time the Guaranty of such Guarantor, or a grant by such Guarantor of a security interest, becomes effective with respect to such Swap Obligation. If a Swap Obligation arises under a master agreement governing more than one swap, such exclusion shall apply only to the portion of such Swap Obligation that is attributable to swaps for which such Guaranty or security interest is or becomes excluded in accordance with the first sentence of this definition."

""Impacted Loans" has the meaning specified in Section 3.03."

““Investment Policy” means the investment policy of the Administrative Borrower and its Subsidiaries approved and duly adopted by the board of directors (or other governing body) of the Administrative Borrower, as the same may be amended or otherwise duly modified from time to time.”

““Irish Borrower” means a Borrower incorporated in Ireland.”

““Irish Qualifying Lender” means a Lender which is beneficially entitled to the interest payable to that Lender in respect of an advance under this Agreement and:

(a) which is a bank licensed pursuant to Section 9 of the Central Bank Act, 1971 to carry on banking business in Ireland and which is carrying on a bona fide banking business in Ireland (for the purposes of Section 246(3) of the TCA) and whose Lending Office is located in Ireland; or

(b) which is a building society (as defined for the purposes of Section 256(1) of the TCA) and which is carrying on a bona fide banking business in Ireland (for the purposes of Section 246(3) of the TCA) and whose Lending Office is located in Ireland; or

(c) which is an authorized credit institution under the terms of Directive 2006/48/EC and has duly established a branch in Ireland having made all necessary notifications to its home state competent authorities required thereunder in relation to its intention to carry on banking business in Ireland and such credit institution is carrying on a bona fide banking business in Ireland (for the purposes of Section 246(3) of the TCA) and whose Lending Office is located in Ireland; or

(d) which is a company (within the meaning of Section 4 of the TCA);

(i) which, by virtue of the law of a Relevant Territory is resident in the Relevant Territory for the purposes of tax and that jurisdiction imposes a tax that generally applies to interest receivable in that jurisdiction by companies from sources outside that jurisdiction; or

(ii) in receipt of interest which: (I) is exempted from the charge to Irish income tax pursuant to the terms of a double taxation treaty entered into between Ireland and another jurisdiction that is in force on the date the relevant interest is paid; or (II) would be exempted from the charge to Irish income tax pursuant to the terms of a double taxation treaty signed between Ireland and another jurisdiction on or before the date on which the relevant interest is paid but not in force on that date, assuming that treaty had the force of law on that date;

provided that, in the case of both (i) and (ii) above, such company does not provide its commitment in connection with a trade or business which is carried on in Ireland through a branch or agency in Ireland; or

(e) which is a U.S. corporation that is incorporated in the United States and is subject to tax in the United States on its worldwide income provided that such U.S. corporation does not provide its commitment in connection with a trade or business which is carried on in Ireland through a branch or agency in Ireland; or

(f) which is a U.S. limited liability company, where the ultimate recipients of the interest payable to that limited liability company satisfy the requirements set out in clause (d) above and the business conducted through the limited liability company is so structured for market reasons and not for tax avoidance purposes; or

(g) which is a company (within the meaning of Section 4 of the TCA);

(i) which advances money in the ordinary course of a trade which includes the lending of money; (ii) in whose hands any interest payable in respect of money so advanced is taken into account in computing the trading income of that company; (iii) which has complied with the notification requirements set out in Section 246(5)(a) of the TCA; and (iv) whose Lending Office is located in Ireland; or

(h) which is a qualifying company (within the meaning of section 110 of the TCA) and whose Lending Office is located in Ireland; or

(i) which is an investment undertaking (within the meaning of Section 739B of the TCA) and whose Lending Office is located in Ireland; or

(j) which is a Treaty Lender."

""Irish Withholding Tax" means any withholding tax imposed by Ireland."

""LIBOR Quoted Currency" means each of the following currencies: Dollars, Euro, Sterling, Swiss Francs and Yen; in each case as long as there is a published LIBOR rate with respect thereto."

""Non-LIBOR Quoted Currency" means any currency other than a LIBOR Quoted Currency."

"""Qualified ECP Guarantor" shall mean, at any time in respect of any Swap Obligations, each Loan Party with total assets exceeding $10,000,000 at the time the relevant Guarantee or grant of relevant security interest becomes effective with respect to such Swap Obligation or such other Person that qualifies at such time as an "eligible contract participant" under the Commodity Exchange Act and can cause another person to qualify as an "eligible contract participant" at such time under Section 1a(18)(A)(v)(II) of the Commodity Exchange Act."

""Rate Determination Date" means two (2) Business Days prior to the commencement of such Interest Period (or such other day as is generally treated as the rate fixing day by market practice in such interbank market, as reasonably

determined by the Administrative Agent; provided that to the extent such market practice is not administratively feasible for the Administrative Agent, such other day as otherwise reasonably determined by the Administrative Agent)."

""Relevant Territory" means (i) a member state of the European Union (other than Ireland), or (ii) to the extent not a member state of the European Union, a jurisdiction with which Ireland has entered into a double taxation treaty that either has the force of law by virtue of section 826(1) of the TCA or which will have the force of law on completion of the procedures set out in section 826(1) of the TCA."

""Second Amendment Effective Date" means December 17, 2013."

""Specified Loan Party" means any Loan Party that is not an "eligible contract participant" under the Commodity Exchange Act and the regulations thereunder (without giving effect to the applicable section in each Guaranty (including Article X hereof) entitled "Keepwell")."

""Swap Obligations" means, with respect to any Guarantor, any obligation to pay or perform under any agreement, contract or transaction that constitutes a "swap" within the meaning of Section 1a(47) of the Commodity Exchange Act."

""TCA" means the Tax Consolidation Act, 1997."

""Treaty Lender" means a Lender other than a Lender falling within paragraph (d), (e) or (f) of the definition of Irish Qualifying Lender set out above which is on the date any relevant payment is made entitled under a double taxation agreement (a "Treaty") in force on that date to that payment without any deduction of Tax."

(ii) amending the definition of the term "Eurodollar Rate" contained in such Section 1.01 by restating such definition in its entirety as follows:

""Eurodollar Rate" means:

(a) With respect to any Credit Extension:

(i) denominated in a LIBOR Quoted Currency, the rate per annum equal to the London Interbank Offered Rate ("LIBOR"), or a comparable or successor rate which rate is approved by the Administrative Agent in its reasonable discretion, as published on the applicable Reuters screen page (or such other commercially available source providing such quotations as may be designated by the Administrative Agent in its reasonable discretion from time to time) at approximately 11:00 a.m., London time, two Business Days prior to the commencement of such Interest Period, for deposits in the relevant currency (for delivery on the first day of such Interest Period) with a term equivalent to such Interest Period;

(ii) denominated in Australian dollars, the rate per annum equal to the Bank Bill Swap Reference Bid Rate ("BBSY") or a comparable or successor rate, which rate is approved by the Administrative Agent in its reasonable discretion, as published on the applicable Reuters screen page (or such other commercially available source providing such quotations as may be designated by the Administrative Agent in its reasonable discretion from time to time) at or about 10:30 a.m. (Melbourne, Australia time) on the Rate Determination Date with a term equivalent to such Interest Period;

(iii) denominated in any other Non-LIBOR Quoted Currency, the rate per annum as designated with respect to such Alternative Currency at the time such Alternative Currency is approved by the Administrative Agent, the Revolving Credit Lenders and the L/C Issuer pursuant to Section 1.06(a); and

(b) for any rate calculation with respect to a Base Rate Loan on any date, the rate per annum equal to LIBOR, at or about 11:00 a.m., London time determined two Business Days prior to such date for U.S. Dollar deposits with a term of one month commencing that day;

provided that to the extent a comparable or successor rate is approved by the Administrative Agent in its reasonable discretion in connection with any rate set forth in this definition, the approved rate shall be applied in a manner consistent with market practice; provided, further that to the extent such market practice is not administratively feasible for the Administrative Agent, such approved rate shall be applied in a manner as otherwise reasonably determined by the Administrative Agent."

(iii) amending the definition of the term "Foreign Obligor Obligations" contained in such Section 1.01 by deleting the "." at the end of such definition and substituting in lieu thereof the following text: ", provided that, notwithstanding anything to the contrary in any Loan Document, the "Foreign Obligor Obligations" shall exclude any Excluded Swap Obligations."

(iv) amending the definition of the term "Foreign Subsidiary F/X Obligations" contained in such Section 1.01 by deleting the "." at the end of such definition and substituting in lieu thereof the following text: ", provided that, notwithstanding anything to the contrary in any Loan Document, the "Foreign Subsidiary F/X Obligations" shall exclude any Excluded Swap Obligations.".

(v) amending the definition of the term "Guarantor" contained in such Section 1.01 by restating such definition in its entirety as follows:

""Guarantors" means, collectively, (a) the Domestic Subsidiary Guarantors, (b) the Foreign Subsidiary Guarantors, and (c) with respect to the payment and performance by each Specified Loan Party of its obligations under its Guaranty with respect to

Swap Obligations, the Administrative Borrower. For the avoidance of doubt, to the extent (x) not otherwise mutually agreed to by the Administrative Borrower and the Administrative Agent, (y) permitted by applicable Law and (z) no material adverse tax consequence would result therefrom, each Designated Borrower (other than APIS) shall guarantee the obligations of each other Designated Borrower under the Credit Agreement and the other Loan Documents."

(vi) amending the definition of the term "Guarantor Primary Obligations" contained in such Section 1.01 by deleting the "." at the end of such definition and substituting in lieu thereof the following text: ", provided that, notwithstanding anything to the contrary in any Loan Document, the "Guarantor Primary Obligations" shall exclude any Excluded Swap Obligations."

(vii) amending the definition of the term "Interest Rate" contained in such Section 1.01 by restating the portion of such sentence before the first proviso therein in its entirety as follows:

"Interest Period" means, as to each Eurodollar Rate Loan, the period commencing on the date such Eurodollar Rate Loan is disbursed or converted to or continued as a Eurodollar Rate Loan and ending on the date one, two, three or six months thereafter (in each case, subject to availability), as selected by the Borrowers in their Committed Loan Notice, or such other period that is twelve months or less requested by the Borrowers and consented to by all of the Appropriate Lenders;

(viii) amending the definition of the term "Mortgage" contained in such Section 1.01 by deleting the address "30 Hanton Road" appearing in such definition and substituting in lieu thereof the address "30 Hanton City Road".

(ix) amending the definition of the term "Obligations" contained in such Section 1.01 by deleting the "." at the end of such definition and substituting in lieu thereof the following text: ", provided that, notwithstanding anything to the contrary in any Loan Document, the "Obligations" shall exclude any Excluded Swap Obligations."

(x) amending the definition of the term "Threshold Amount" contained in such Section 1.01 by restating such definition in its entirety as follows:

""Threshold Amount" means $25,000,000.";

(b) Section 1.05 (Exchange Rates; Currency Equivalents) of the Credit Agreement is hereby amended by adding the following sentence to the end of such Section: "The Administrative Agent does not warrant, nor accept responsibility, nor shall the Administrative Agent have any liability with respect to the administration, submission or any other matter related to the rates in the definition of "Eurodollar Rate" or with respect to any comparable or successor rate thereto, in the absence of its own gross negligence or willful misconduct as determined by a court of competent jurisdiction by final and non-appealable judgment.";

(c) Clause (iii)(C) of paragraph (a) of Section 3.01 (Taxes) of the Credit Agreement is hereby amended by restating such clause in its entirety as follows:

> "(C) to the extent that the withholding or deduction is made on account of Indemnified Taxes or Other Taxes, the sum payable by the applicable Loan Party shall be increased as necessary so that after any required withholding or the making of all required deductions (including deductions applicable to additional sums payable under this Section 3.01) the applicable Recipient receives an amount equal to the sum it would have received had no such withholding or deduction been made, except that no Loan Party is required to make an increased payment to a specific Lender (i.e. without prejudice to the rights of all other Lenders hereunder) under paragraph (C) or to make an increased interest payment in accordance with Section 2.10 in connection with the deduction of (i) Swiss Withholding Tax, if (x) a Swiss Borrower has breached the Ten Non-Bank Rule as a direct consequence of that Lender not complying with its obligations under Section 11.06(b)(iii)(B) or Section 11.06(d) or having acquired any rights pursuant to Section 11.06 against the Swiss Borrower as a result of such breach, or (y) the payment could have been made to the relevant Lender without a tax deduction if it was a Qualifying Bank, but on that date that Lender has ceased to be a Qualifying Bank other than as a result of any Change of Law, or (ii) in the case of any Lender (other than a Lender that is a party to this Agreement as of the Second Amendment Effective Date), Irish Withholding Tax solely to extent the payment could have been made to such relevant Lender without a Tax deduction if it was an Irish Qualifying Lender, but on that date the Lender is not or has ceased to be an Irish Qualifying Lender (other than as a result of any Change in Law after the date on which such Lender became party to this Agreement).";

(d) The first sentence of clause (i) of paragraph (c) of Section 3.01 (Taxes) of the Credit Agreement is hereby amended by restating the portion of such sentence before the first proviso therein in its entirety as follows:

> "(i) The Administrative Borrower shall, and does hereby, indemnify each Recipient, and shall make payment in respect thereof within 10 Business Days after written demand therefor, for the full amount of any Indemnified Taxes or Other Taxes (including Indemnified Taxes or Other Taxes imposed or asserted on or attributable to amounts payable under this Section 3.01) payable or paid by such Recipient or required to be withheld or deducted from a payment to such Recipient, and any penalties, interest and reasonable expenses arising therefrom or with respect thereto (except that no Loan Party is required to indemnify a specific Lender (i.e. without prejudice to the rights of all other Lenders hereunder) under paragraph (c) in connection with the deduction of (i) Swiss Withholding Tax, if (x) a Swiss Borrower has breached the Ten Non-Bank Rule as a direct consequence of that Lender not complying with its obligations under Section 11.06(b)(iii)(B) or Section 11.06(d) or having acquired any rights pursuant to Section 11.06 against the Swiss Borrower as a result of such breach, or (y) the payment could have been made to the relevant Lender without a tax deduction if it was a Qualifying Bank, but on that date that

Lender has ceased to be a Qualifying Bank other than as a result of any Change of Law, or (ii) in the case of any Lender (other than a Lender that is a party to this Agreement as of the Second Amendment Effective Date), Irish Withholding Tax, if the payment could have been made to such relevant Lender without a Tax deduction if it was an Irish Qualifying Lender, but on that date the Lender is not or has ceased to be an Irish Qualifying Lender other than as a result of any Change in Law after the date on which such Lender became party to this Agreement);";

(e) The first sentence of paragraph (e) of Section 3.01 (Taxes) of the Credit Agreement is hereby amended by deleting the first word of such sentence and substituting in lieu thereof the following text:

"Any Lender to which interest may be paid free of withholding tax due to such Lender falling within paragraph (d) of the definition of an Irish Qualifying Lender shall, following a request from a Borrower, (x) provide details of its name, address and country of tax residence to the Borrower to enable it to comply with its reporting obligations under Section 891A of the TCA and (y) provide the Irish Borrower with any correct, complete and accurate information that may be required for the Irish Borrower to comply with its obligations under Section 891E of the TCA and any";

(f) Paragraph (e) of Section 3.01 (Taxes) of the Credit Agreement is hereby amended by inserting the following new subparagraph (iv) immediately following existing subparagraph (iii):

(iv) Each Recipient to which interest is payable by an Irish Borrower:

(A) shall within ten (10) Business Days after the request of the Administrative Borrower or the Administrative Agent, confirm in writing to the Administrative Borrower or the Administrative Agent, as applicable, such Person is:

(I) not an Irish Qualifying Lender;

(II) an Irish Qualifying Lender (other than a Treaty Lender); or

(III) a Treaty Lender.

As provided in clause (iii) above, each Recipient agrees that if any certification previously delivered pursuant to this Section 3.01(e)(iv) expires or becomes obsolete or inaccurate in any respect, it shall update such certification.

(g) Section 3.03 (Inability to Determine Rates) of the Credit Agreement is hereby amended by restating such Section in its entirety as follows:

"If in connection with any request for a Eurodollar Rate Loan or a conversion to or continuation thereof, (a) (i) the Administrative Agent determines that deposits (whether in Dollars or an Alternative Currency) are not being offered to banks in the applicable offshore interbank market for such currency for the applicable amount and Interest Period of such Eurodollar Rate Loan, or (ii) adequate and reasonable means do not exist for determining the Eurodollar Rate for any requested Interest Period with respect to a proposed Eurodollar Rate Loan (whether denominated in Dollars or an Alternative Currency) or in connection with an existing or proposed Base Rate Loan, (in each case with respect to clause (a) above, "Impacted Loans"), or (b) the Administrative Agent or the Required Lenders determine that for any reason the Eurodollar Rate for any requested Interest Period with respect to a proposed Eurodollar Rate Loan does not adequately and fairly reflect the cost to such Lenders of funding such Eurodollar Rate Loan, the Administrative Agent will promptly so notify the Administrative Borrower and each Lender. Thereafter, (x) the obligation of the Lenders to make or maintain Eurodollar Rate Loans in the affected currency or currencies shall be suspended, (to the extent of the affected Eurodollar Rate Loans or Interest Periods), and (y) in the event of a determination described in the preceding sentence with respect to the Eurodollar Rate component of the Base Rate, the utilization of the Eurodollar Rate component in determining the Base Rate shall be suspended, in each case until the Administrative Agent (upon the instruction of the Required Lenders) revokes such notice. Upon receipt of such notice, the Administrative Borrower may revoke any pending request for a Borrowing of, conversion to or continuation of Eurodollar Rate Loans in the affected currency or currencies (to the extent of the affected Eurodollar Rate Loans or Interest Periods) or, failing that, will be deemed to have converted such request into a request for a Borrowing of Base Rate Loans in the amount specified therein.

Notwithstanding the foregoing, if the Administrative Agent has made the determination described in this Section 3.03, the Administrative Agent, in consultation with the Administrative Borrower and the affected Lenders, may establish an alternative interest rate for the Impacted Loans, in which case, such alternative rate of interest shall apply with respect to the Impacted Loans until (1) the Administrative Agent revokes the notice delivered with respect to the Impacted Loans under clause (a) of the first sentence of this Section 3.03, (2) the Administrative Agent or the Required Lenders notify the Administrative Agent and the Administrative Borrower that such alternative interest rate does not adequately and fairly reflect the cost to such Lenders of funding the Impacted Loans, or (3) any Lender determines that any applicable Law has made it unlawful, or that any applicable Governmental Authority has asserted that it is unlawful, for such Lender or its applicable Lending Office to make, maintain or fund Loans whose interest is determined by reference to such alternative rate of interest or to determine or charge interest rates based upon such rate or any Governmental Authority has imposed material restrictions on the authority of such Lender to do any of the foregoing and provides the Administrative Agent and the Administrative Borrower written notice thereof.";

(h) Section 5.11 (Taxes) of the Credit Agreement is hereby amended by adding the following sentence to the end of such Section 5.11:

> "No Irish Borrower is required to make any deduction for or on account of Irish Withholding Tax from any payment it may make under a Loan Document to a Person that is an Irish Qualifying Lender.";

(i) Paragraph (b) of Section 6.02 (Certificates; Other Information) of the Credit Agreement is hereby amended by deleting the text "concurrently with" set forth therein and inserting in lieu thereof the text "within 5 days of";

(j) Paragraph (e) of Section 6.03 (Notices) of the Credit Agreement is hereby amended by restating such paragraph in its entirety as follows:

> "(e) of any intent by any Borrower or any of their Subsidiaries to initiate a voluntary product recall affecting products manufactured or distributed by any Borrower or any Subsidiary with a fair market value in excess of the Threshold Amount;";

(k) Paragraph (g) of Section 6.03 (Notices) of the Credit Agreement is hereby amended by deleting such paragraph in its entirety and inserting in lieu thereof the text "[Reserved]";

(l) Paragraph (b) of Section 6.12 (Covenant to Guarantee and Give Security) of the Credit Agreement is hereby amended by (i) deleting the text "30 days" appearing in clause (i) therein and inserting in lieu thereof the text "90 days", (ii) deleting the text "30 days" appearing in clause (ii) therein and inserting in lieu thereof the text "90 days", (iii) deleting the text "45 days" appearing in clause (iii) therein and inserting in lieu thereof the text "90 days", (iv) deleting the text "60 days" appearing in clause (iv) therein and inserting in lieu thereof the text "90 days", and (v) deleting the text "60 days" appearing in clause (v) therein and inserting in lieu thereof the text "90 days".

(m) Section 6.21 (Milestone and Earnout Payments) of the Credit Agreement is hereby amended by deleting such Section in its entirety and inserting in lieu thereof the text "[Reserved]";

(n) Clause (i) of Paragraph (b) of Section 7.02 (Indebtedness) of the Credit Agreement is hereby amended by deleting the amount "$10,000,000" appearing therein and inserting in lieu thereof the amount "$75,000,000";

(o) Paragraph (d) of Section 7.02 (Indebtedness) of the Credit Agreement is hereby amended by (i) deleting the phase "U.S. Loan Parties" appearing therein and inserting in lieu thereof the phrase "Loan Parties" and (ii) deleting the phrase "with respect to the incurrence by the Administrative Borrower of any unsecured Indebtedness in an aggregate principal amount of $50,000,000 or more," appearing in clause (iii) therein and inserting in lieu thereof the phrase "with respect to the incurrence by any Loan Party of any unsecured Indebtedness in an aggregate principal amount of $50,000,000 or more,";

(p) Paragraph (q) of Section 7.02 (Indebtedness) of the Credit Agreement is hereby amended by deleting such paragraph in its entirety and inserting in lieu thereof the text "[Reserved]";

(q) Paragraph (a) of Section 7.03 (Investments) of the Credit Agreement is hereby amended by restating such paragraph in its entirety as follows:

> "(a) Investments held by the Borrowers and their Subsidiaries (i) in the form of Cash Equivalents or (ii) as permitted by the Investment Policy;";

(r) Schedule 7.03(a) (Investment Policy) to the Credit Agreement is hereby amended by deleting such Schedule 7.03(a) in its entirety;

(s) The first sentence of paragraph (m) of Section 8.01 (Specific Covenants) of the Credit Agreement is hereby amended by deleting the text ", if the aggregate sales price of the products so recalled shall, individually or together with all other similar recalls of such products during any twelve consecutive month period, equal or exceed $50,000,000" appearing therein and inserting in lieu thereof the text "that has, or could reasonably be expected to have, individually or in the aggregate with all other similar recalls, a Material Adverse Change";

(t) Section 8.03 (Application of Funds) of the Credit Agreement is hereby amended by inserting the following new sentence to the end of the penultimate paragraph thereof:

> "Excluded Swap Obligations with respect to any Guarantor shall not be paid with amounts received from such Guarantor or its assets, but appropriate adjustments shall be made with respect to payments from other Loan Parties to preserve the allocation to Obligations otherwise set forth above in this Section 8.03.";

(u) The first sentence of Section 10.01 (Guaranty of Subsidiary Obligations) is hereby amended by inserting the following text immediately following the phrase "Debtor Relief Laws" therein: "provided that the term "Guaranteed Subsidiary Obligations" (as hereinafter defined) shall exclude any Excluded Swap Obligations"; and

(v) The Credit Agreement is hereby amended by inserting the following new text as a new Section 10.08 (Keepwell) immediately after Section 10.07 thereof:

> "**10.08 Keepwell.** The Administrative Borrower at the time any Guaranty or the grant of the security interest under the Loan Documents, in each case, by any Specified Loan Party, becomes effective with respect to any Swap Obligation, hereby jointly and severally, absolutely, unconditionally and irrevocably undertakes to provide such funds or other support to each Specified Loan Party with respect to such Swap Obligation as may be needed by such Specified Loan Party from time to time to honor all of its obligations under its Guaranty and the other Loan Documents in respect of such Swap Obligation (but, in each case, only up to the maximum amount of such liability that can be hereby incurred without rendering such

Administrative Borrower's obligations and undertakings under this Section 10.08 voidable under applicable law relating to fraudulent conveyance or fraudulent transfer, and not for any greater amount). The obligations and undertakings of the Administrative Borrower under this Section 10.08 shall remain in full force and effect until the Obligations have been indefeasibly paid in full. The Administrative Borrower intends this Section 10.08 to constitute, and this Section 10.08 shall be deemed to constitute, a guarantee of the obligations of, and a "keepwell, support, or other agreement" for the benefit of, each Specified Loan Party for all purposes of the Commodity Exchange Act.";

Section 3. Amendments to Administrative Borrower Guaranty. The Administrative Borrower Guaranty is hereby amended as follows:

(a) The first sentence of Section 2 (Guaranty) thereof is hereby amended by inserting the following text immediately prior to the text "(collectively, the "Guaranteed Obligations") therein: "provided that, notwithstanding anything to the contrary in any Loan Document, the term "Guaranteed Obligations" (as hereinafter defined) shall exclude any Excluded Swap Obligations"; and

(b) The following new text shall be inserted therein as a new Section 23 (Keepwell) immediately after Section 22 thereof:

"23. **Keepwell**. The Administrative Borrower at the time any Guaranty or the grant of the security interest under the Loan Documents, in each case, by any Specified Loan Party, becomes effective with respect to any Swap Obligation, hereby jointly and severally, absolutely, unconditionally and irrevocably undertakes to provide such funds or other support to each Specified Loan Party with respect to such Swap Obligation as may be needed by such Specified Loan Party from time to time to honor all of its obligations under its Guaranty and the other Loan Documents in respect of such Swap Obligation (but, in each case, only up to the maximum amount of such liability that can be hereby incurred without rendering such Administrative Borrower's obligations and undertakings under this Section 23 voidable under applicable law relating to fraudulent conveyance or fraudulent transfer, and not for any greater amount). The obligations and undertakings of the Administrative Borrower under this Section 23 shall remain in full force and effect until the Obligations have been indefeasibly paid and performed in full. The Administrative Borrower intends this Section 23 to constitute, and this Section 23 shall be deemed to constitute, a guarantee of the obligations of, and a "keepwell, support, or other agreement" for the benefit of, each Specified Loan Party for all purposes of the Commodity Exchange Act."

Section 4. Amendments to Domestic Subsidiary Guaranty. The Domestic Subsidiary Guaranty is hereby amended as follows:

(a) The first sentence of Section 2 (Guaranty) thereof is hereby amended by inserting the following text immediately prior to the text "(collectively, the "Guaranteed Obligations") therein: "provided that the term "Guaranteed Obligations" (as hereinafter defined) shall exclude any Excluded Swap Obligations"; and

(b) The following new text shall be inserted therein as a new Section 24 (Keepwell) immediately after Section 23 thereof:

> "24. **Keepwell**. Each U.S. Guarantor that is a Qualified ECP Guarantor at the time any Guaranty or the grant of the security interest under the Loan Documents, in each case, by any Specified Loan Party, becomes effective with respect to any Swap Obligation, hereby jointly and severally, absolutely, unconditionally and irrevocably undertakes to provide such funds or other support to each Specified Loan Party with respect to such Swap Obligation as may be needed by such Specified Loan Party from time to time to honor all of its obligations under its Guaranty and the other Loan Documents in respect of such Swap Obligation (but, in each case, only up to the maximum amount of such liability that can be hereby incurred without rendering such U.S. Guarantor's obligations and undertakings under this Section 24 voidable under applicable law relating to fraudulent conveyance or fraudulent transfer, and not for any greater amount). The obligations and undertakings of the U.S. Guarantors under this Section 24 shall remain in full force and effect until the Obligations have been indefeasibly paid and performed in full. The U.S. Guarantor intends this Section 24 to constitute, and this Section 24 shall be deemed to constitute, a guarantee of the obligations of, and a "keepwell, support, or other agreement" for the benefit of, each Specified Loan Party for all purposes of the Commodity Exchange Act."

Section 4. Amendments to Foreign Subsidiary Guaranty. The Foreign Subsidiary Guaranty is hereby amended as follows:

(c) The first sentence of Section 2 (Guaranty) thereof is hereby amended by inserting the following text immediately prior to the text "(collectively, the "Guaranteed Obligations") therein: "provided that the term "Guaranteed Obligations" (as hereinafter defined) shall exclude any Excluded Swap Obligations"; and

(d) The following new text shall be inserted therein as a new Section 25 (Keepwell) immediately after Section 24 thereof:

> "25. **Keepwell**. Each Foreign Guarantor that is a Qualified ECP Guarantor at the time any Guaranty of the Foreign Obligor Obligations or the grant of a security interest with respect to Foreign Obligor Obligations under the Loan Documents, in each case, by a Specified Loan Party that is a Foreign Obligor, becomes effective with respect to any Swap Obligation, hereby jointly and severally, absolutely, unconditionally and irrevocably undertakes to provide such funds or other support to each Specified Loan Party that is a Foreign Obligor with respect to such Swap

Obligation as may be needed by such Specified Loan Party that is a Foreign Obligor from time to time to honor all of its obligations under its Guaranty and the other Loan Documents to which it is a party in respect of such Swap Obligation (but, in each case, only up to the maximum amount of such liability that can be hereby incurred without rendering such Foreign Guarantor's obligations and undertakings under this Section 25 voidable under applicable law relating to fraudulent conveyance or fraudulent transfer, and not for any greater amount). The obligations and undertakings of the Foreign Guarantors under this Section 25 shall remain in full force and effect until the Foreign Obligor Obligations have been indefeasibly paid and performed in full. Each Foreign Guarantor intends this Section 25 to constitute, and this Section 25 shall be deemed to constitute, a guarantee of the obligations of, and a "keepwell, support, or other agreement" for the benefit of, each Specified Loan Party that is a Foreign Obligor for all purposes of the Commodity Exchange Act."

Section 6. Conditions Precedent. This Amendment shall become effective as of the date first written above (the "Effective Date") upon the satisfaction of the following conditions precedent:

(a) Documentation. Administrative Agent shall have received all of the following, in form and substance satisfactory to Administrative Agent:

(i) a fully-executed and effective Amendment executed by the Administrative Borrower, the Designated Borrower, the Guarantors, the Administrative Agent and the Lenders; and

(ii) such additional documents, instruments and information as Administrative Agent may reasonably request to effect the transactions contemplated hereby.

(b) No Default. On the Effective Date and after giving effect to this Amendment, no event shall have occurred and be continuing that would constitute a Default or an Event of Default.

Section 7. Representations and Warranties; Reaffirmation of Grant. Each Loan Party hereby represents and warrants to the Administrative Agent and the Lenders that, as of the date hereof and after giving effect to this Amendment, (a) all representations and warranties of the Borrowers and each other Loan Party set forth in the Credit Agreement and in any other Loan Document are true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof) on and as of the date hereof to the same extent as though made on and as of such date, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties shall have been true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof) on and as of such earlier date, (b) no Default or Event of Default has occurred and is continuing, (c) the Credit Agreement and all other Loan Documents are and remain legally valid, binding obligations of the Loan Parties party thereto, enforceable against each such Loan Party in

accordance with their respective terms, subject to bankruptcy, insolvency, moratorium and other laws applicable to creditors' rights generally and general principles of equity; provided that the Loan Parties make no representation as to the validity or enforceability of Section 11.20 of the Credit Agreement and (d) except as expressly contemplated under any Loan Document, the provisions of the Collateral Documents to which such Loan Party is a party are effective to create in favor of the Administrative Agent for the benefit of the Secured Parties a legal, valid and enforceable first priority Lien (subject only to Permitted Liens) on all right, title and interest of the respective Loan Parties in the Collateral described therein do and shall continue to secure the payment of all Obligations or Foreign Obligor Obligations, as applicable, as set forth in such respective Collateral Documents. Each Loan Party that is a party to the Security Agreement or any of the Collateral Documents hereby reaffirms its grant of a security interest in the Collateral to the Administrative Agent for the ratable benefit of the Secured Parties, as collateral security for the prompt and complete payment and performance when due of the Obligations or Foreign Obligor Obligations, as set forth therein.

Section 8. Survival of Representations and Warranties. All representations and warranties made in this Amendment or any other Loan Document shall survive the execution and delivery of this Amendment, and no investigation by the Administrative Agent or the Lenders shall affect the representations and warranties or the right of the Administrative Agent and the Lenders to rely upon them.

Section 9. Amendment as Loan Document. This Amendment constitutes a "Loan Document" under the Credit Agreement. Accordingly, it shall be an immediate Event of Default under the Credit Agreement if any representation, warranty, certification or statement of fact made by any Loan Party under or in connection with this Amendment shall have been incorrect or misleading in any material respect when made or deemed made.

Section 10. Costs and Expenses. The Administrative Borrower shall pay on demand all reasonable out-of-pocket costs and expenses of the Administrative Agent (including the reasonable fees, charges and disbursements of counsel to the Administrative Agent) incurred in connection with the preparation, negotiation, execution and delivery of this Amendment, in each case, in accordance with Section 11.04 of the Credit Agreement.

Section 11. Governing Law. THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS AMENDMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK (WITHOUT GIVING EFFECT TO ANY CHOICE OR CONFLICT OF LAW PROVISION OR RULE THAT WOULD CAUSE THE APPLICATION OF THE DOMESTIC SUBSTANTIVE LAWS OF ANY OTHER STATE).

Section 12. Execution. This Amendment may be executed in any number of counterparts and by different parties hereto in separate counterparts, each of which when so executed shall be

deemed to be an original and all of which taken together shall constitute one and the same agreement. Delivery of an executed counterpart of a signature page to this Amendment by telecopier (or electronic mail (including in PDF format)) shall be effective as delivery of a manually executed counterpart of this Amendment.

Section 13. Limited Effect. This Amendment relates only to the specific matters expressly covered herein, shall not be considered to be an amendment or waiver of any rights or remedies that the Administrative Agent or any Lender may have under the Credit Agreement, under any other Loan Document (except as expressly set forth herein) or under Law, and shall not be considered to create a course of dealing or to otherwise obligate in any respect the Administrative Agent or any Lender to execute similar or other amendments or waivers or grant any amendments or waivers under the same or similar or other circumstances in the future.

Section 14. Ratification by Guarantors. Each of the undersigned Guarantors does hereby agree and consent to this Amendment, the amendments to the Administrative Borrower Guaranty, the Domestic Subsidiary Guaranty and the Foreign Subsidiary Guaranty and to the other documents and agreements referred to herein. Each of the Guarantors agrees and acknowledges that (i) notwithstanding the effectiveness of this Amendment (and the amendments to the Administrative Borrower Guaranty, the Domestic Subsidiary Guaranty and the Foreign Subsidiary Guaranty set forth herein), such Guarantor's Guaranty, as applicable, shall remain in full force and effect on a continuous basis and (ii) nothing herein shall in any way limit any of the terms or provisions of , the Administrative Borrower Guaranty, the Domestic Subsidiary Guaranty and the Foreign Subsidiary Guaranty or any other Loan Document (except with respect to any Excluded Swap Obligations) executed by such Guarantor (as the same may be amended from time to time), all of which are hereby ratified, confirmed and affirmed in all respects. Each of the Guarantors hereby agrees and acknowledges that no other agreement, instrument, consent or document shall be required to give effect to this Section 14. Each of the Guarantors hereby further acknowledges that the Administrative Borrower, the Designated Borrower, the Administrative Agent and any Lender may from time to time enter into any further amendments, modifications, terminations and/or amendments of any provisions of the Loan Documents without notice to or consent from such Guarantor and without affecting the validity or enforceability of such Guarantor's Guaranty or giving rise to any reduction, limitation, impairment, discharge or termination of such Guarantor's Guaranty.

[*Remainder of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed and delivered as of the date first above written.

BORROWERS:

ALEXION PHARMACEUTICALS, INC., as Administrative Borrower

By:/s/ Prasanna Thombre
Name: Prasanna Thombre
Title: Vice President, Treasury

ALEXION PHARMA INTERNATIONAL SÀRL, as Designated Borrower

By:/s/ Nick Moore
Name: Nick Moore
Title: Vice President Finance and General Manager

ALEXION PHARMA HOLDING

By: /s/ Kirk Caza
Name: Kirk Caza
Title: Director

ALEXION PHARMA INTERNATIONAL TRADING

By: /s/ Diane Flood
Name: Diane Flood
Title: Director

GUARANTORS:

ALEXION DELAWARE HOLDING LLC

By: **ALEXION PHARMACEUTICALS, INC.,** its sole member

By: Prasanna Thombre
Name: Prasanna Thombre
Title: Vice President, Treasury

ALEXION CAMBRIDGE CORPORATION

By: /s/ Michael Greco
Name: Michael V. Greco
Title: President

GUARANTORS (cont'd):

ALEXION HOLDING B.V.

By: /s/ Michael Greco
Name: Michael V. Greco
Title: Director A

By: /s/ Justin Verbond
Name: Justin Verbond
Title: Director B

ALEXION MONTREAL CORP. (as successor by amalgamation to ENOBIA PHARMA INC. and ENOBIA CANADA LIMITED PARTNERSHIP)

By: /s/ Michael Greco
Name: Michael V. Greco
Title: President

ADMINISTRATIVE AGENT:

BANK OF AMERICA, N.A.

By: /s/ Alan Tapley
Name: Alan Tapley
Title: Assistant Vice President

LENDERS:

BANK OF AMERICA, N.A., as a Lender, an L/C Issuer and Swing Line Lender

By: /s/ Linda Alto
Name: Linda Alto
Title: Senior Vice President

LENDERS (cont'd):

JPMORGAN CHASE BANK, N.A.

By: /s/ D. Scott Farquhar
Name: D. Scott Farquhar
Title: Senior Vice President

LENDERS (cont'd):

RBS CITIZENS, NATIONAL ASSOCIATION

By: /s/ Andrea B. Goldman
Name: Andrea B. Goldman
Title: Senior Vice President

LENDERS (cont'd):

SUNTRUST BANK

By: /s/ Katherine Bass
Name: Katherine Bass
Title: Director

LENDERS (cont'd):

WELLS FARGO BANK, NATIONAL ASSOCIATION

By: /s/ Melinda A. White
Name: Melinda A. White
Title: Senior Vice President

LENDERS (cont'd):

SANTANDER BANK, N.A.

By: /s/ A. Neil Sweeny
Name: A. Neil Sweeny
Title: Senior Vice President

LENDERS (cont'd):

PEOPLE'S UNITED BANK

By: /s/ Robert Hazard
Name: Robert Hazard
Title: Senior Vice President

LENDERS (cont'd):

UNION BANK, N.A.

By: /s/ Michael Tschida
Name: Michael Tschida
Title: Vice President

LENDERS (cont'd):

U.S. BANK NATIONAL ASSOCIATION

By: /s/ Jennifer Hwang
Name: Jennifer Hwang
Title: Vice President

LENDERS (cont'd):

WEBSTER BANK, N.A.

By: /s/ George G. Sims
Name: George G. Sims
Title: Vice President

LENDERS (cont'd):

THE HUNTINGTON NATIONAL BANK

By: /s/ Jared Shaner
Name: Jared Shaner
Title: Assistant Vice President

Exhibit 21.1

SUBSIDIARIES OF ALEXION PHARMACEUTICALS, INC.

Alexion Delaware Holding LLC is organized in the State of Delaware

Alexion Services Latin America, Inc. is organized in the state of Delaware

Alexion Pharma Argentina SRL is organized in Argentina

Alexion Pharmaceuticals Australasia PTY LTD is organized in Australia

Alexion Pharma Belgium Sprl is organized in Belgium

Alexion Services Europe Sprl is organized in Belgium

Alexion Bermuda L.P. is organized in Bermuda

Alexion Bermuda II L.P. is organized in Bermuda

Alexion Bermuda Holding ULC is organized in Bermuda

Alexion Farmacêutica Brasil Importação e Distribuição de Produtos e Serviços de Administração de Vendas Ltda. (doing business as Alexion Brasil) is organized in Brazil

Alexion Farmacêutica América Latina Serviços de Administração de Vendas Ltda. (doing business as Alexion Latina America) is organized in Brazil

Alexion Pharma Canada Corp. is organized in Canada

Alexion (Shanghai) Company Limited is organized in Shanghai

Alexion Pharma Colombia SAS is organized in Colombia

Alexion Pharma Czech s.r.o is organized in the Czech Republic

Alexion Pharma Middle East FZ-LL is organized in Dubai

Alexion Europe SAS is organized in France

Alexion Pharma France is organized in France

Alexion R&D France SAS is organized in France

Alexion Pharma Germany GmbH is organized in Germany

Alexion Business Services Private Limited is organized in India

Alexion Pharma International Trading is organized in Ireland

Alexion Pharma Holding is organized in Ireland

Alexion Pharma Israel Ltd. is organized in Israel

Alexion Pharma Italy Sarl is organized in Italy

Alexion Pharma GK is organized in Japan

Alexion Pharma Mexico, S. de R.L. de C.V. is organized in Mexico

Alexion Holding B.V. is organized in the Netherlands

Alexion Pharma Netherlands B.V. is organized in the Netherlands

Alexion Pharma OOO is organized in Russia

Alexion Pharma Spain S.L. is organized in Spain

Alexion Pharma Nordics AB is organized in Sweden

Alexion Pharma International Sàrl is organized in Switzerland

Alexion Ilaç Ticaret Limited Þirketi is organized in Turkey

Alexion Pharma UK is organized in the United Kingdom

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-181595, 333-128085, 333-127471, 333-123828, 333-91265, 333-29617, 333-41397, 333-47645, 333-89343, 333-36738, 333-52886, 333-114449, 333-110828, 333-47954, and 333-59702) and Form S-8 (No. 333-146319, 333-139600, 333-123212, 333-119749, 333-24863, 333-52856, 333-69478, 333-71879, 333-71985, 333-106854 and 333-153612) of Alexion Pharmaceuticals, Inc. of our report dated February 6, 2015 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP
Hartford, Connecticut
February 6, 2015

Exhibit 31.1

I, Leonard Bell, M.D., certify that:

1 I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2014 of Alexion Pharmaceuticals, Inc.;

2 Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3 Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4 The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5 The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 6, 2015

/s/ Leonard Bell, M.D.

Chairman and Chief Executive Officer

Exhibit 31.2

I, Vikas Sinha, certify that:

1 I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2014 of Alexion Pharmaceuticals, Inc.;

2 Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3 Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4 The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5 The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 6, 2015

/s/ VIKAS SINHA

Executive Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Alexion Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2014 as filed with the Securities and Exchange Commission (the "Report"), I, Leonard Bell, M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 6, 2015

/s/ LEONARD BELL, M.D.

Chairman and Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Alexion Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2014 as filed with the Securities and Exchange Commission (the "Report"), I, Vikas Sinha, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 6, 2015

/s/ VIKAS SINHA

Executive Vice President and Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.