ALEXION PHARMACEUTICALS INC
Form 10-K
February 10, 2014

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, 2013
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, 2013, was $17,833,350,643.(1)

The number of shares of Common Stock outstanding as of February 3, 2014 was 197,830,376.

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, 2014, are incorporated by reference into Part III of this report.

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(1) Excludes 1,898,588 shares of common stock held by directors and executive officers at June 30, 2013. 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.

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 in the March 2013 Warning Letter, 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, prospects for regulatory approval, 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 ultra-rare 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 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 an inflammatory response. This inflammatory response is one of the immune system's weapons against foreign pathogens or otherwise diseased tissue. However, under certain circumstances, the complement cascade may cause excessive or inappropriate activation, and/or an individual may be deficient in naturally occurring complement inhibitors, all of which may result in acute and chronic inflammatory conditions and damage to healthy tissues.

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 production of inflammation-causing proteins of the complement cascade. We believe that selective suppression of this immune response may provide a significant therapeutic advantage relative to existing therapies. In addition to PNH and aHUS, for which the use of eculizumab has been approved in the United States, Europe and Japan, 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	Indication	Development Stage
Soliris (eculizumab)	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Commercial
		PNH Registry	Phase IV
	Hematology/Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)	Commercial
		aHUS Adult and Long-term Follow-up	Phase IV
		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 (thrombotic microangiopathy, or TMA) leading to kidney failure, stroke, heart attack and death. Soliris is the first and only therapy approved for the treatment of 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.

Clinical Development Program

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

Product	Development Area	Indication	Development Stage
Soliris (eculizumab)	Nephrology	Acute Antibody Mediated Rejection (AMR) Presensitized Renal Transplant - Living Donor	Phase II
		Acute Antibody Mediated Rejection (AMR) Presensitized Renal Transplant - Deceased Donor	Phase II
		Delayed Kidney Transplant Graft Function*	Phase II
		STEC-HUS (Shiga-toxin producing E. Coli Hemolytic Uremic Syndrome)	Phase II
	Neurology	Neuromyelitis Optica (NMO)*	Phase II
		Myasthenia Gravis (MG)	Phase II
	Hematology	Cold Agglutinin Disease (CAD)*	Phase II
Asfotase alfa	Metabolic Disorders	Hypophosphatasia (HPP)	Phase II
cPMP (ALXN 1101)	Metabolic Disorders	MoCD Type A	Phase I
ALXN 1102/1103	Hematology	PNH	Phase I
ALXN 1007	Inflammatory Disorders		Phase I

* Investigator Initiated Trial

Soliris (eculizumab)

Nephrology

Acute Antibody Mediated Rejection (AMR) in Presensitized Kidney Transplant Patients

Enrollment is complete 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. AMR is the term used to describe a type of transplant rejection that occurs when the recipient has antibodies to the donor organ. Enrollment is ongoing 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.

In September, researchers presented positive preliminary data from the eculizumab deceased-donor AMR kidney transplant study at the European Society of Organ Transplant (ESOT) in Vienna, Austria.

Delayed Kidney Transplant Graft Function

Enrollment has been completed in an investigator-initiated Phase II study of eculizumab in patients at elevated risk for delayed graft function (DGF) following kidney transplant. 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. We have been granted orphan drug designation from the FDA and received a positive opinion on orphan drug designation for eculizumab in DGF from the Commission on Orphan Medical Products (COMP).

Shiga-toxin producing E. coli Hemolytic Uremic Syndrome (STEC-HUS)

STEC-HUS is an ultra-rare disorder, comprising only a small sub-set of the already rare population of patients with enterohemorrhagic Escherichia coli (EHEC). Following an authorization by the Paul-Ehrlich-Institut, Germany's health care regulatory body for biologics, and an access program for patients initiated in May 2011, we initiated an open-label clinical trial to investigate eculizumab as a treatment for patients with STEC-HUS. Enrollment in this trial has been completed. We are

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obtaining and analyzing additional control clinical outcome data from an epidemiologic study in approximately 400 STEC-HUS patients who received only best supportive care. The FDA and the EC have each granted orphan designation for eculizumab as a treatment for patients with STEC-HUS.

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. A single pivotal trial in patients with relapsing NMO is expected to start in early 2014. The FDA and the EC 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 and the subsequent failure of neuromuscular transmission. Data from a Phase II trial evaluating the safety and efficacy of eculizumab in patients with refractory generalized MG demonstrated an encouraging disease improvement signal. We have completed collaborations with investigators on the design of a Phase III trial to evaluate eculizumab as a treatment for patients with refractory generalized MG, and this trial is expected to start in early 2014.

Hematology

Cold Agglutinin Disease (CAD)

We are aware that dosing is ongoing in an investigator-initiated Phase II study of eculizumab in patients for the treatment of CAD. CAD is a severe, ultra-rare complement-mediated autoimmune disease characterized by the presence of high concentrations of circulating complement-activating antibodies directed against red blood cells. As observed with PNH patients, CAD patients also suffer from the clinical consequences of severe hemolysis.

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, crippling and life-threatening complications in patients with HPP. Initial studies with asfotase alfa in HPP patients indicate that the treatment significantly decreases the levels of targeted metabolic substrates.

We have completed enrollment in a natural history study in infantile-onset patients with HPP and have completed our initial analysis for the study. We believe that the analysis is supportive of our anticipated filing. We continue to enroll and dose patients in a separate multinational Phase II open-label study of infants and children with HPP. Interim results of this trial were presented at the European Society of Pediatric Endocrinology meeting held in September 2013 in Milan, Italy. 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. These results provide data in a broader patient population of infants and children. Earlier in the year, asfotase alfa received Breakthrough Therapy Designation from the FDA.

cPMP (ALXN 1101)

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

MoCD Type A is a 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 cPMP replacement

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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 healthy volunteers is ongoing.

ALXN 1102/1103

ALXN 1102/1103 is a novel alternative pathway complement inhibitor with a mechanism of action unique from Soliris. ALXN 1102 is currently being investigated in a Phase I single dose, dose escalating safety and pharmacology study. ALXN 1103 is being dosed in the same Phase I trial as a subcutaneous or intravenous formulation.

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. Results are currently being analyzed. We also completed successful meetings with the FDA to discuss initiation of proof of concept studies. As a result, proof of concept studies in two severe life-threatening and ultra-rare conditions are expected to start in early 2014.

Manufacturing

We currently rely on three manufacturing facilities, Alexion's Rhode Island manufacturing facility (ARIMF) and two facilities 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 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, vialing and labeling.

We have various agreements with Lonza, with remaining total commitments of approximately $147,000 through 2019. 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.

In March 2013, we received a 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. We continue to manufacture products, including Soliris, in this facility. 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 European Medicines Agency (EMA) inspected ARIMF in January 2013, and a GMP certificate was issued in May 2013.

In August 2013, we initiated a voluntary recall and replacement of the remaining vials of a single lot of Soliris due to the presence of visible particles in a limited number of vials in the lot. The recall did not interrupt the supply of Soliris to patients and had no material impact on operations or financial results. Subsequently, in November 2013, we initiated a voluntary recall and replacement of a limited number of vials of Soliris due to the presence of similar visible particles. Following investigation, we believe that we have identified the filling process step that resulted in the presence of the visible particles and we are implementing 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 expected disposal of inventory in 2014.

Sales and Marketing

We have established a commercial organization to support current and future sales of Soliris in the United States, in the major markets in European Union, Japan, Asia Pacific countries, and other territories. Our sales force for Soliris is small compared to that of other drugs with similar gross 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, we may expand our own commercial organizations in such territories and market and sell Soliris through our own sales force in these territories. However, we will evaluate each jurisdiction on a country-by-country basis, and it is possible that we will promote Soliris in collaboration with marketing partners or rely on relationships with one or more companies with established distribution systems and direct sales forces in certain countries.

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 2013, sales to our largest customer accounted for 20% of our Soliris net product sales. During 2012, sales to our two largest customers accounted for 21% and 12%, respectively, 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

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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, 2013, we owned or in-licensed 95 U.S. patents, 126 foreign patents, 69 U.S. patent applications and 450 foreign patent applications. These patents and patent applications relate to C5 inhibitors, high throughput screening, vectors, cancer, recombinant antibodies, bone delivery conjugates, 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 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. For example, 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). In October 2013, we and Novartis agreed to resolve all claims asserted by Novartis in the action. 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 we believe 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. A pathway for biosimilars also exists in certain other countries markets, including Europe.

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 Agreements

In March 1996, we entered into a license agreement with the Medical Research Council (MRC) whereby MRC granted to us worldwide non-exclusive rights to certain patents related to the humanization and production of monoclonal antibodies. The license agreement requires us to pay MRC royalties on a quarterly basis with respect to sales of Soliris. 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.

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 in accordance with the terms of 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 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 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 addition to the option agreement, we purchased $25,000 of preferred equity of

Moderna LLC, Moderna's parent company.

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

Clinical trials involve the administration of the investigational product to healthy volunteers or to patients, under the supervision of qualified principal investigators. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the criteria for determining subject eligibility, the dosing plan, patient monitoring requirements 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.

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

Phase III trials are undertaken to further evaluate clinical efficacy of a specific endpoint and to test further for safety within an expanded patient population at geographically dispersed clinical study sites. Phase I, Phase II or Phase III testing

might not be completed successfully within any specific time period, if at all, with respect to any of our product candidates. Results from one trial are not necessarily predictive of results from later trials. Furthermore, the FDA, 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.

Under the Food and Drug Administration Amendments Act of 2007 (FDAAA), we must register each controlled clinical trial, other than Phase I trials, on a website administered by National Institutes of Health (NIH). 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.

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 found 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. The FDA's established goal is to review 90% of Priority BLA applications and original efficacy supplements within six months and 90% of Standard applications and original efficacy supplements in ten months, whereupon a review decision is to be made. The FDA, however, may not approve a drug within these established goals and its review goals are subject to change from time to time 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 us.

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. 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. Also 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 approved 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 approval of the reference biological 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. In February 2012, the FDA published draft guidance documents on biosimilar product development. The guidance defines 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, 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 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 for “off-label” uses - that is, uses not approved by the FDA and therefore not described in the drug'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 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 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 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 for the indication for which it has such designation, the product is entitled to an orphan exclusivity period, in which the FDA may not approve any other applications to market the same drug for the

same indication for seven years, except in limited circumstances, such as where the sponsor of different version of the drug 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 drug that treats the same disease or condition or the same drug 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 used to treat life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the European Union and medicinal products which, for economic reasons, would be unlikely to be developed without incentives 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 nor the EMA are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same orphan 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.

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, and for the prevention of delayed graft function in renal transplant patients in the United States. 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.

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, 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 postmarketing 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 or decentralized marketing authorization procedure. The centralized procedure provides for the grant of a single marketing authorization for a medicinal product by the EC 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 approval authority of all European Union member states in which the product is to be marketed. One national approval

authority, selected by the applicant, assesses the application for marketing authorization. The authorities of the other European Union member states subsequently decide whether to grant or refuse marketing authorization for their territory on the basis of this assessment. The mutual recognition procedure provides for mutual recognition of marketing authorizations delivered by the national approval 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 approval authority of a European Union member state requesting that this authority recognize the marketing authorization delivered by the approval 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 control of compliance by these entities with European Union cGMP rules.

Failure to comply with European Union laws and the related national laws of individual European Union member states governing the conduct of clinical trials, 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 refusal to authorize the conduct of clinical trials, refusal to grant marketing authorization, product withdrawals and recalls, product seizures, suspension or withdrawal of the marketing authorization, fines and criminal penalties.

We submitted our Marketing Authorization Application for Soliris for the treatment of PNH and aHUS to the EMA using the centralized marketing authorization procedure.

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

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 taking efforts to control those costs, including cost containment measures to control, restrict access to, or influence the purchase of drugs, biologics, 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.

Medicare is a U.S. federal government insurance program that covers individuals aged 65 years or older as well as individuals with certain disabilities. 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 biologics 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) on a quarterly basis. Generally, drugs and biologics are reimbursed under Part B at a certain percentage of the applicable product’s ASP. For 2013, the reimbursement rate for drugs and biologics in both the hospital outpatient department setting and the physician office setting is ASP + 6%. 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 classes of drugs or biologics and to have at least two drugs in each unique therapeutic category or class, with certain exceptions.

Medicaid is a government insurance program for certain low-income and disabled individuals, including children. 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 biologics thus varies by state. Drugs and biologics 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 biologics. Medicaid also includes the Drug Rebate Program, which requires manufacturers provide states rebates for products covered and reimbursed by state Medicaid programs. As a result of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the PPACA), many states are expanding their Medicaid programs. The manner in which this expansion occurs may affect beneficiary access to prescription drugs and the types of utilization management controls that apply.

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 are subject to various U.S. federal and state laws, as well as foreign 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 or civil sanctions, including fines and civil monetary penalties and exclusion from federal healthcare programs (including Medicare and

Medicaid). Violations of international fraud and abuse laws could result in similar penalties, including exclusion from participation in health programs outside the U.S. Applicable U.S. statutes, include, but are not limited to, the following:

- The federal Anti-Kickback Statute, which prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration in exchange for or to generate business, including the purchase or prescription of a drug, that is reimbursable by a federal healthcare program such as Medicare and Medicaid.

- The federal False Claims Act ("FCA"), which generally prohibits knowingly and willingly presenting, or causing to be presented, for payment to the federal government any claims for reimbursed drugs or services that are (1) false or fraudulent; (2) for items or services not provided as claimed; or (3) for medically unnecessary items or services. 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 claims submitted involving inadequate care, kickbacks, improper promotion of off-label uses, and misreporting of drug prices to federal agencies.
- The federal False Statements Statute, which prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services.
- The federal Prohibition Against Beneficiary Inducements statute, which imposes civil monetary penalties for any offers or transfers of remuneration to any individual eligible for Medicare or Medicaid benefits that are likely to influence the individual to order or receive Medicare- or Medicaid-covered services from a particular provider, practitioner, or supplier.
- The federal Civil Monetary Penalties law, which authorizes the imposition of substantial civil money penalties against an entity, such as a pharmaceutical manufacturer, that engages in activities including (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) offering or giving remuneration to any beneficiary of a government-payer program likely to influence the receipt of reimbursable items or services; (3) arranging for reimbursable services with an entity that is excluded from participation from a government-payer healthcare program; or (4) knowingly or willfully soliciting or receiving remuneration for a referral of a federal healthcare program beneficiary.
- 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, and state laws that require pharmaceutical companies to certify compliance with the pharmaceutical industry's voluntary compliance guidelines.

Federal and state authorities are paying increased attention 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.

Other U.S. Healthcare Laws

PPACA contains several provisions that have or could potentially impact our business, including (1) an increase in the minimum Medicaid rebate to states participating in the Medicaid program on branded prescription drugs (from 15.6% to 23.1%) (effective January 1, 2010); (2) the extension of the Medicaid rebate to managed care organizations that dispense drugs to Medicaid beneficiaries; (3) the expansion of the 340B Public Health Service Act drug pricing program, which provides outpatient drugs at reduced rates, to include certain children's hospitals, free standing cancer hospitals, critical access hospitals, and rural referral centers; (4) the state-based option of the expansion of Medicaid in 2014 to families with incomes up to 133% of U.S. federal poverty levels; and (5) the creation of the individual mandate pursuant to which each U.S. citizen will be required to purchase insurance effective March 31, 2014, and may do so via federally subsidized programs like the healthcare marketplaces, or the exchanges.

Additionally, the federal "sunshine" provisions, enacted in 2010 as part of PPACA, require pharmaceutical manufacturers, among others, to disclose annually to the federal government (for re-disclosure to the public) certain payments made to physicians and certain other healthcare practitioners or to 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. 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, our operations may be affected by 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, which established uniform standards for certain “covered entities” (healthcare providers, health plans and

healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. Although we believe that we are neither a "covered entity" nor a regulated "business associate" under HIPAA or HITECH, we cannot assure you that regulatory authorities would agree with our assessment; in addition, HIPAA and HITECH may affect our interactions with customers who are covered entities or their business associates. State laws may also govern the privacy and security of health information in some circumstances and may contain different or broader privacy protections than the federal provisions.

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 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 that we interact with may deemed to be a foreign government official for purposes of the FCPA. The U.K. Bribery Act prohibits giving and receiving bribes in the public and private sectors, bribing a foreign public official, and failing to have adequate procedures to prevent employees and other agents from giving bribes. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances.

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 applying biotechnology to their operations. A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us; in some instances, these products have already entered clinical trials or are already being marketed. Other companies are engaged in research and development based on complement proteins.

Several companies have either publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system or have had programs to develop complement inhibitor therapies. We believe that 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, 2013, we had 1,774 full-time, world-wide employees, of which 759 were engaged in research, product development, manufacturing, and clinical development, 667 in sales and marketing, and 348 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, 2014 are as follows:

Name	Age	Position with Alexion
Leonard Bell, M.D.	55	Chief Executive Officer, Treasurer and Director
Stephen P. Squinto, Ph.D.	57	Executive Vice President and Chief Global Operations Officer
Vikas Sinha, M.B.A., C.A., C.P.A.	50	Executive Vice President and Chief Financial Officer
David L. Hallal	47	Executive Vice President and Chief Commercial Officer
Martin Mackay	57	Executive Vice President and Global Head of Research and Development
Clare Carmichael	54	Senior Vice President and Chief Human Resources Officer
Frank J. Wright	66	Senior Vice President and President of Alexion Pharma International Sàrl
John B. Moriarty, J.D.	46	Senior Vice President and General Counsel
Saqib Islam	44	Senior Vice President and Chief Strategy and Portfolio Officer

Leonard Bell, M.D. is the principal founder of Alexion and has been a director of Alexion since February 1992 and the Company’s Chief Executive Officer since January 1992. 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.

Stephen P. Squinto, Ph.D. is a founder of Alexion and has served as an executive of the Company since 1992. Since May 2013, he has served as Executive Vice President and Chief Global Operations Officer. From June 2007 to May 2013, Dr. Squinto was Alexion's Executive Vice President and Head of Research and Development, and from August 2000 to June 2007 served as Executive Vice President and Head of Research. Prior to joining Alexion, Dr. Squinto held various positions at Regeneron Pharmaceuticals, Inc. and was also an Assistant Professor of Biochemistry and Molecular Biology at Louisiana State University Medical Center and an Adjunct Professor of Neuroscience at the Tulane University Medical School. Dr. Squinto’s work has led to over 70 scientific papers in the fields of gene regulation, growth factor biology and gene transfer. Dr. Squinto’s work is primarily in the fields of molecular and cellular biology. Dr. Squinto received his B.A. in Chemistry and Ph.D. in Biochemistry and Biophysics from Loyola University of Chicago.

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.
David L. Hallal has been with Alexion since June 2006 and has served as Executive Vice President and Chief Commercial Officer since October 2012. 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, and then Senior Vice President, Global Commercial Operations from May 2010 until October 2012. 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.

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.

Clare Carmichael has been Senior Vice President and Chief Human Resources Officer since joining Alexion in August 2011. 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.

Frank J. Wright has been Senior Vice President and President of Alexion Pharma International Sàrl since joining Alexion in January 2013. From August 2011 to February 2012, Mr. Wright served as Interim President of the Clinical Trials Distribution Unit at Marken Limited, a global clinical supply chain solutions provider. Mr. Wright co-founded Aptuit LLC in 2004, a provider of integrated drug discovery and development services, and from 2004 to 2010 served as its Vice Chairman and Chief Operating Officer. From 2000 to 2004, he was an independent consultant advising pharmaceutical and biotechnology companies and private equity firms with respect to acquisitions, asset valuation and emerging markets. From 1994 to 2000, Mr. Wright held various positions of increasing responsibility at ChiRex, Inc., a NASDAQ-listed services company providing process research and development and contract manufacturing services, acquired by Rhodia Pharma in 2000, including as Co-Chief Executive Officer and Chief Operating Officer. Prior to joining ChiRex, Mr. Wright served at Glaxo for 15 years in various operational management, outsourcing and procurement positions. Mr. Wright studied Mechanical Engineering at the University of Strathclyde, Glasgow.

John B. Moriarty, J.D. has been Senior Vice President and General Counsel since joining Alexion in December 2012. 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.

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.

Available Information

Our internet website address is http://www.alxn.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 Lead Product Soliris

We depend heavily on the success of our lead product, Soliris. If we are unable to increase sales of Soliris, or obtain approval or commercialize Soliris in new territories for the treatment of PNH, 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 in the United States, Europe, Japan and in a number of key markets in the rest of the world 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. 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 in new territories and the maintenance of marketing approvals for the treatment of PNH in the United States, the European Union, Japan and other territories;
- receipt and maintenance of marketing approvals for Soliris for the treatment of aHUS in other territories and the maintenance of the marketing approval in the United States, Japan and the European Union;
- 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 successful launch in countries where we have not yet obtained, or only recently obtained, marketing approval or commenced sales;
- successfully launching commercial sales of Soliris for the treatment of aHUS in the United States, Japan and Europe, and in countries where we have not yet obtained marketing approval;
- 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, including aHUS.

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

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

PNH and aHUS are each ultra-rare diseases with small patient populations that have not been definitively determined. There can be no guarantee that any of our programs will be effective at identifying patients and the number of patients in the United States, Japan and Europe and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with Soliris, or new patients may become increasingly difficult to identify, all of which would adversely affect our results of operations and our business.

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

We may not be able to sell Soliris on a profitable basis or our profitability may be reduced if we are required to sell our product at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. Soliris is significantly more expensive than traditional drug treatments and almost all patients require some form of third party coverage to afford its cost. Our future revenues and profitability will be adversely affected if we cannot depend on governmental payers, such as Medicare and Medicaid in the United States or country specific governmental organizations, 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. For example, in January 2013, we were informed by the Advisory Group for National Specialised Services that although Soliris would help save lives and improve the quality of life for children and adults with aHUS, the U.K. Health Ministers decided not to recommend national commissioning of Soliris for the treatment of aHUS and at that time determined to refer the evaluation of Soliris for treatment of patients with aHUS to National Institute for Health and Clinical Excellence (NICE) for further review as part of its new Highly Specialised Technologies program. In July 2013, the Government's Clinical Priorities Advisory Group (CPAG) decided to recommend a formal clinical access policy that includes aHUS patients who have functioning kidneys as well as patients on dialysis who are transplantable. In September 2013, England's National Health Service adopted the positive CPAG recommendation and commissioned Soliris for the treatment of children and adults with aHUS. Funding for patients in England is expected to be available through completion of NICE review. The NICE decision is anticipated in 2014. 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. Government and other third-party payers in the United States and the European Union member states are challenging the prices charged for health care products and increasingly limiting and attempting to limit both coverage and 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 “Government initiatives that affect coverage and reimbursement of drug products could adversely affect our business” and “The credit and financial market conditions may aggravate certain risks affecting our business.” In addition, certain countries establish pricing and reimbursement amounts by reference to the price of the same or similar products in other countries. If coverage or the level of reimbursement is limited in one or more countries, we may be unable to obtain or maintain anticipated pricing or reimbursement in current or new territories. Many third-party 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.

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 for related charitable purposes. We are not able to predict the financial impact of the support we may provide for these and other charitable purposes; however, substantial support could have a material adverse effect on our 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 under the heading "Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candidates." As eculizumab is approved by regulatory agencies for indications other than PNH, the potential increase in the number of patients receiving Soliris may cause third-party payers to refuse coverage or reimbursement for Soliris for the treatment of PNH or 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 gain or maintain market acceptance among the medical community or patients, which would prevent us from maintaining profitability or growth in the future.

We cannot be certain that Soliris will gain or 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. Medical doctors' willingness to prescribe, and patients' willingness to accept, Soliris depends on many factors, including prevalence and severity of adverse side effects in both clinical trials and commercial use, effectiveness of our marketing strategy and the pricing of Soliris, publicity concerning Soliris, our

other product candidates or competing products, our ability to obtain and maintain third-party coverage or reimbursement, and availability of alternative treatments, including bone marrow transplant as an alternative treatment for PNH. The likelihood of medical doctors 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. If Soliris fails to achieve or maintain market acceptance among the medical community or patients in a particular country, we may not be able to market and sell it successfully in such country, which would limit our ability to generate revenue and could harm our overall business.

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

We cannot guarantee that we will be able to maintain our regulatory approvals for Soliris. If we do not maintain our regulatory approvals for Soliris, the value of our company and our results of operations will be materially harmed. We and our current and future partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by the FDA, other federal and state agencies, and governmental authorities in other territories. For example, in March 2013, we received a Warning Letter (Warning Letter) from the FDA relating to compliance with cGMP at ARIMF. While we believe that we will successfully resolve outstanding concerns expressed by the FDA in the Warning Letter, we cannot guarantee that we will do so to the satisfaction of the FDA, EMA or other regulatory agencies and approval of the facility by any such agencies could be withdrawn as a result.

Regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, finishing, vialing, 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. 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 ones we voluntarily initiated in August and November 2013. 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.

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 or withdrawal of a previously granted approval for Soliris;
- interruption of production;
- operating restrictions, such as a shutdown of production facilities or production lines;
- suspension of ongoing clinical trials;
- delays in approving or refusal to approve Soliris or a facility that manufactures Soliris;
- seizing or detaining product;
- 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.

Although we obtained regulatory approval to market and sell Soliris for PNH and aHUS in the United States, the European Union and Japan, and Soliris for PNH in other territories, we cannot guarantee that we will obtain the regulatory approval or reimbursement approval for Soliris for the treatment of PNH, aHUS or other diseases in each territory where we seek approvals.

Governments in countries where we seek to commercialize Soliris regulate the distribution of drugs and the facilities where such drugs are manufactured, and obtaining their approvals can be lengthy, expensive and highly uncertain. The approval process varies from country to country, and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. In certain jurisdictions, we are required to finalize operational, reimbursement, price approval and funding processes prior to marketing our products, even in countries where marketing approval has been obtained. We have received regulatory approval for Soliris for treatment of patients with PNH in the United States, the European Union, Japan and other territories. In September and November 2011 we received regulatory approval for Soliris for the treatment of patients with aHUS in the United States and the European Union, respectively. In September 2013, the MHLW approved Soliris for the treatment of patients with aHUS in Japan. We may not receive regulatory or reimbursement approval for Soliris for the treatment of PNH, aHUS or any other disease in any other territories on a timely basis, if ever.

Regulatory agencies may require additional information or data with respect to our submissions for Soliris, including the marketing authorization applications submitted to the EMA for the treatment of patients with aHUS. We may have to conduct additional lengthy clinical testing and other costly and time-consuming procedures to satisfy foreign regulatory agencies. Even with approval of Soliris in certain countries, the regulatory agencies in other countries may not agree with our interpretations of our clinical trial data for Soliris and may decide that our results are not adequate to support approval for marketing of Soliris. In those circumstances, we would not be able to obtain regulatory approval in such country on a timely basis, if ever. Even if approval is granted in such country, the approval may require limitations on the indicated uses for which the drug may be

marketed. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. We must obtain approval of a product by the comparable regulatory authorities and ethics committees of foreign countries before we can commence clinical trials or marketing of the product in those countries. We were required to conduct clinical studies with Soliris in patients with PNH in Japan prior to obtaining marketing approval in that country and Japanese authorities could require additional studies in Japan for Soliris for the treatment of patients with aHUS. We are also conducting prospective clinical trials in adult and pediatric patients to confirm the benefit of Soliris for the treatment of aHUS. Commercialization of Soliris for the treatment of PNH, aHUS or any other indication could be delayed, limited or may not occur in territories where we seek marketing approval if the applicable regulatory agency requires additional information or data.

Our commercialization of Soliris may be stopped, delayed or made less profitable if we or any other third party provider fails to provide sufficient quantities of Soliris. Commercial quantities of Soliris can only be manufactured at three facilities, including our own facility in Rhode Island. Vial filling can only be performed at three third party facilities.

Commercial quantities of Soliris are manufactured by Alexion at ARIMF and by Lonza. Manufacturing processes must comply with applicable regulations and manufacturing practices, as well as our own quality standards. In particular, the manufacture of Soliris is heavily regulated by governmental authorities around the world, including the FDA, EMA, the competent authorities of the European Union member states, and MHLW. If we do not resolve outstanding concerns expressed by the FDA in the Warning Letter to the satisfaction of the FDA, EMA or any other regulatory agency, or we or our third-party providers, including our product vialers, packagers and labelers, fail to comply fully with applicable regulations then we may be required to initiate a recall or withdrawal of our products. 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. Regulatory agencies could take action that leads to product shortages. Such action may include:

- issuing warning or untitled letters, such as the Warning Letter;
- requiring corrective action or restrictions on operations, including costly and time-consuming new manufacturing requirements;
- ordering shutdown of production facilities or production lines;
- seizing or detaining product;
- suspending or withdrawing the approval of Soliris;
- imposing significant civil penalties and criminal fines;
- suspending ongoing clinical studies for Soliris;
- require 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; and/or
- refusing to approve pending BLAs or BLA supplements for Soliris.

The manufacture of Soliris is difficult. Manufacture of a biologic requires a multi-step controlled process and even minor problems or deviations could result in defects or failures. We cannot be certain that we, 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, 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. If we are forced to find an alternative supplier or other third party providers for Soliris, in addition to loss of sales, we may also incur significant costs and experience significant delay in establishing a new arrangement.

We are authorized to sell product 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.

In September and November 2011 we received marketing approval for Soliris for the treatment of patients with aHUS in the United States and European Union, respectively. In September 2013, the MHLW approved Soliris for the treatment of patients with aHUS in Japan. If Soliris is approved in other territories for the treatment of patients with aHUS, or for additional indications, 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 finishing, packaging, vialing and labeling. We have changed or added third party vialers in the past in order to support uninterrupted supply, and may do so in the future. We currently rely on two third party vialers to support our commercial requirements in the United States, three to support requirements in the European Union, and two to support requirements in Japan. No guarantee can be made that any third party vialer 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 $14,277 with respect to the recall initiated in November 2013. 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 recall, initiated by us and our affiliate in November 2013 and August 2013, respectively, due to the presence of visible particles in a limited number of vials in specific lots.

In January 2014 we agreed to acquire a vialing 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 vialers and have never operated our own vialing 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 vialing 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.

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

For the year ended December 31, 2013, our largest customer accounted for 20% of our global Soliris net product sales, and our three largest customers accounted for approximately 39% of our global net product sales. As of December 31, 2013, our single largest customer accounted for 20% of the global accounts receivable balance. We expect such customer concentration to continue for the foreseeable future. We typically sell Soliris to third party distributors, such as specialty pharmacies, who in turn sell to patient health care providers. We do not promote Soliris to these distributors, and they do not set or determine demand for Soliris. Our ability to successfully commercialize Soliris will depend, in part, on the extent to which we are able to provide adequate distribution of Soliris to patients. Although a number of specialty distributors and specialty pharmacies, which supply physician office clinics, hospital outpatient clinics, infusion clinics, home health care providers, and governmental organizations, distribute Soliris, they generally carry a very limited inventory and may be reluctant to distribute Soliris in the future if demand for the product does not increase. Further, it is possible that our distributors could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to distribute smaller volume products such as Soliris, or cause higher product distribution costs, lower margins or the need to find alternative methods of distributing our product. Although we believe we can find alternative distributors on a relatively short notice, our revenue during that period of time may suffer and we may incur additional costs to replace a distributor. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us or any failure to pay for the products we have shipped to them could materially and adversely affect our results of operations and financial condition.

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

We are marketing and selling Soliris 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. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, patients, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing, or recommending may be subject to scrutiny 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 Federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the Federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been investigated and have reached substantial financial settlements with the Federal government under this Act 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.

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, state or foreign enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is later determined we are not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our position and have to divert significant management resources from other matters.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion

of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors and because government scrutiny in this area is high, it is possible that some of our business activities could come under that scrutiny.

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. Similar legislation is being considered in other states. Additionally, as part of the Patient Protection and Affordable Care Act, the Federal government has enacted the Physician Payment Sunshine provisions, which when fully implemented requires manufacturers to publicly report gifts and payments made to physicians and teaching hospitals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Similar strict restrictions are imposed on the promotion and marketing of drug products in the European Union and other countries. 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 drug product which does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of drug products is 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 drug products. Violations of the rules governing the promotion of drug products in the European Union 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 drug 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. Violations of these rules could lead to the imposition of fines or imprisonment.

Laws, including those governing promotion, marketing and anti-kickback provisions, industry regulations and professional codes of conduct are often strictly enforced. Increasing regulatory scrutiny of the promotional activities of pharmaceutical companies has been observed in a number of European Union member states. 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 pertaining to our financial relationships with government officials. Worldwide regulators are increasing their regulatory and enforcement efforts in this area. For example, the Bribery Act in the United Kingdom entered into force in 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.

Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candidates

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, 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. Similarly, Soliris has not been approved for any indication other than for the treatment of patients with PNH in the United States, the European Union, Japan and other territories, and for patients with aHUS in the United States, the European Union and Japan. 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 do not know when or if our other product candidates will be approved. Our product candidates are subject to strict regulation by regulatory authorities in the United States, in the European Union and in other territories. We cannot market any product candidate until we have completed all necessary preclinical studies and clinical trials and have obtained the necessary regulatory approvals. We do not know whether regulatory agencies will grant approval for any of our product candidates. Even if we complete preclinical studies and clinical trials successfully, we may not be able to obtain regulatory approvals or we may not receive approvals to make claims about our products that we believe to be necessary to effectively market our products. Data obtained from preclinical studies and clinical trials are subject to varying interpretations that could delay, limit or prevent regulatory approval, failure to comply with regulatory

requirements, resolve pending concerns described in the Warning Letter, and inadequate manufacturing processes are examples of other problems that could prevent approval. In addition, we may encounter delays or rejections due to additional government regulation from future legislation, administrative action or changes in the FDA policy. Even if the FDA approves a product, the approval will be limited to those indications covered in the approval.

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

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

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.

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 before marketing or selling any of them. It is not possible to predict how long the approval processes of the FDA or any other applicable federal or foreign regulatory authority or agency for any of our product candidates will take or whether any such approvals ultimately will be granted. The FDA and foreign regulatory agencies have substantial discretion in the drug approval process, and positive results in preclinical testing or early phases of clinical studies offer no assurance of success in later phases of the approval process. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. Generally, preclinical and clinical testing of product candidates can take many years and require the expenditure of substantial resources, and the data obtained from these tests and trials can be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. If we encounter significant delays in the regulatory process, 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;
- 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.

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

Physicians may elect not to recommend our drugs even if they receive marketing approval for a variety of reasons, including the timing of the market introduction of competitive drugs; lower demonstrated clinical safety and efficacy compared to other drugs; perceived lack of cost-effectiveness; lack of availability of reimbursement from third-party payers; convenience and ease of administration; prevalence and severity of adverse side effects; other potential advantages of alternative treatment methods; and ineffective marketing and distribution support. Sales of pharmaceutical products depend in significant part on the coverage and reimbursement policies of government programs, including Medicare and Medicaid in the United States and similar programs in other countries, and other third-party payers. These 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 candidates 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 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.

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

Clinical quantities of eculizumab are manufactured by us at ARIMF and by Lonza. Clinical quantities of our other product candidates are manufactured by us at ARIMF or by a third party. We also depend on a very limited number of third party providers for other services with respect to our clinical and commercial requirements, including product finishing, packaging, vialing and labeling. We have changed or added third party vialers in the past in order to support uninterrupted supply, and may do so in the future. No guarantee can be made that regulators will approve additional third party vialers in a timely manner or at all, or that any third party vialer will be able to perform such services for sufficient product volumes for any country or territory. Manufacture of our drug products is highly technical, and only a small number of companies have the ability and capacity to manufacture our drug products for our development and commercialization needs. Due to the highly technical requirements of manufacturing our drug products and the strict quality and control specifications, we and our third party providers may be unable to manufacture or supply our drug products despite our and their efforts. In addition, we cannot be certain that any third party will be able or willing to honor the terms of its agreement, including any obligations to manufacture the drug products in accordance with regulatory requirements and to our quality specifications and volume requirements. Further, we have limited experience manufacturing the drug candidates that we acquired from third parties, such as asfotase alfa, ALXN1102 and cPMP. We cannot guarantee that we or any third party provider will be able to manufacture or supply such drug candidates, or that we or a third party provider will be able to manufacture or supply sufficient quantities to satisfy our requirements.

Manufacture of drug products, including the need to develop and utilize manufacturing processes that consistently produce our drug products to their required quality specifications, is highly regulated by the FDA, EMA and other domestic and foreign authorities. Regulatory authorities must approve the facilities in which our products are manufactured vialed, packaged and labeled prior to granting marketing approval for any product candidate. Such facilities are also subject to ongoing inspections, and minor changes in manufacturing or other related processes may require additional regulatory approvals. For example, if future inspections by regulatory authorities of our facilities or the facilities of our third party providers identify issues, including issues similar to those raised in the Warning Letter, then manufacture of some of our product candidates and our business may be adversely affected. Further, we cannot assure you that we or our third party providers will successfully comply with all requirements and regulations. In the past we have had to write-off and incur other charges and expenses for production that failed to meet requirements and in August and November 2013 we instituted a voluntary recall due to the presence of visible particles in a limited number of vials in specific lots. Failure to comply with all requirements and regulations by third parties in the future could have a material adverse effect on our business.

We currently have limited experience in manufacturing drug products in volumes that would be necessary to support commercial sales, and we can provide no assurance that we will be able to do so successfully. We acquired ARIMF in July 2006. The EC, the FDA and MHLW have approved the use of ARIMF for the production of Soliris, and we are authorized to sell Soliris manufactured in ARIMF in the United States, the European Union, Japan and certain other territories. We are entirely dependent on only one third party provider for commercial vialing in certain territories, including Japan. We have limited experience in developing commercial-scale manufacturing. We can provide no assurance that we will be able to manufacture our drug products at ARIMF under conditions required by the FDA or foreign regulatory agencies on a timely basis, if at all. ARIMF is subject to approval by other national and regional regulatory agencies before we can begin sales of Soliris or other drug products manufactured in this facility in the applicable countries or regions, and we will continue to be subject to ongoing regulatory inspections thereafter.

We, and our third party providers, may experience higher failure rates than in the past if and when we attempt to increase production volume. If we experience interruptions in the manufacture or supply of our products, our drug development and commercialization efforts will be delayed. If any of our outside third party providers stops manufacturing or supplying our products or reduces the amount manufactured or supplied, or is otherwise unable to provide our required amounts at our required quality, we may need to find other alternatives, which is likely to be expensive and time consuming, and also may result in reduced revenue during this period. Even if we are able to find alternatives they may ultimately be insufficient for our needs. As a result, our ability to conduct testing and drug trials

and our plans for commercialization could be materially adversely affected. Submission of products and new development programs for regulatory approval, as well as our plans for commercialization, would be delayed or suspended. Our competitive position and our prospects for achieving or maintaining profitability could be materially and adversely affected.

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

Risks Related to Intellectual Property

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

In order to protect our drugs and technology more effectively, we need to obtain and maintain patents covering the drugs and technologies we develop. We have and may in the future obtain patents or the right to practice patents through ownership or license. Our patent applications may not result in the issue of patents in the United States or other countries. Our patents may not afford adequate protection for our products. Third parties 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 launched Soliris for sale for the treatment of patients with PNH in the United States and Europe during 2007. We obtained marketing approval from the FDA and the EC for Soliris for the treatment of patients with aHUS in September and November 2011, respectively. In September 2013, the MHLW approved Soliris for the treatment of patients with aHUS in Japan. We have not obtained marketing approval for aHUS in any other country or territory. 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 incurred significant debt to finance the acquisition of Enobia and 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 Soliris in additional countries and regions and for aHUS and other indications, our ability to successfully market Soliris in additional countries and regions, our ability to successfully manufacture and commercialize our drug candidates and our ability to successfully bring our other product candidates, including product candidates we acquired from Enobia, Taligen and Orphatec, 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 satisfy our debt service obligations or obtain the capital necessary to fund our operations, we will be unable to continue the commercialization of Soliris or continue or complete our product development.

We have used our cash on hand and incurred debt under the terms of a senior secured credit facility to finance acquisitions and collaborations. In addition, we are party to definitive agreements relating to these transactions that include significant contingent payments that will become payable if and when certain development and commercial milestones are achieved. We have also entered into strategic license agreements that require us to make significant payments if and when research, development or commercial milestones are achieved. We expect to enter into similar agreements in the future. In May 2012, Alexion issued 5,000 shares of its common stock in a public offering resulting in net proceeds of approximately $462,000. We believe that revenues and collections from sales of Soliris along with our existing cash and cash equivalents will provide sufficient capital to satisfy our debt service obligations and the contingent consideration required by the acquisitions, and to fund our operations and product development for at least 12 months. We may need to raise additional capital before or after that time to complete or continue the development or commercialization of our products and product candidates or for other purposes. We are currently selling or preparing for the commercialization of Soliris in the United States, the European Union, Japan, and several other territories, evaluating and preparing regulatory submissions for Soliris in several countries, and conducting, preparing or evaluating several clinical trials. Funding needs may shift between projects and potentially accelerate and increase as we continue launch and commercialization activities throughout the world and as we initiate or continue clinical trials for our product candidates.

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

- the cost necessary to sell, market and distribute Soliris;
- the rate of new patient sales and drug utilization by treated patients;
- the time and cost necessary to obtain and maintain regulatory approvals for Soliris in multiple countries;
- the ability to obtain and maintain reimbursement approvals and funding for Soliris and the time necessary to obtain such approvals and funding;
- the time and cost necessary to develop sales, marketing and distribution capabilities outside the United States;
- the time and cost necessary to purchase or to further develop manufacturing processes, arrange for contract manufacturing or build manufacturing facilities and obtain and maintain the necessary regulatory approvals for those facilities;
- changes in applicable governmental regulatory policies or requests by regulatory agencies for additional information or data;
- the progress, timing and scope of our research and development programs;
- the progress, timing and scope of our preclinical studies and clinical trials;
- any new collaborative, licensing or other commercial relationships that we may establish; and
- the cost of any acquisition.

We may not receive additional funding when we need it or funding may only be available on unfavorable terms. Financial markets in the United States, Europe and the rest of the world have been experiencing significant volatility in security prices, substantially diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. There can be no assurance that we will be able to access additional credit or the equity markets in order to

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

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

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

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

The terms of our Credit Agreement may restrict our current and future operations, including our ability to respond to changes or to take certain actions.

We and certain of our wholly-owned subsidiaries are party to a Credit Agreement with a syndicate of banks. The Credit Agreement provides for a $240,000 senior secured term loan facility 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. 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 the foreign borrowers 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.

The credit facilities, and the contingent consideration payable in connection with our acquisitions and collaborations remain outstanding or available, and the degree to which we are leveraged could, among other things:

- make it difficult for us to make payments on the credit facilities;
- make it difficult for us to obtain financing for additional acquisitions or in-licensing opportunities or other purposes on favorable terms, if at all;
- make us more vulnerable to industry downturns and competitive pressures; and
- limit our flexibility in planning for, or reacting to changes in, our business.

Our ability to meet our debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control. A breach of the covenants under the Credit Agreement could result in an event of default. 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 Credit Agreement. Furthermore, if we were unable to repay the amounts due and payable under our Credit Agreement, those lenders could proceed against the collateral granted to them to secure that indebtedness, which could force us into bankruptcy or liquidation. In the event our administrative agent or lenders accelerate the repayment of our borrowings, we and our subsidiaries may not have sufficient assets to repay that indebtedness.

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

Our business strategy includes expanding our products and capabilities. 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.

We have limited experience in the acquisition and integration of other companies. We cannot assure you that any acquisition or in-licensing of new products will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or an acquired or in-licensed product. In addition, the future success of such transactions would depend in part on our ability to manage the rapid growth associated with any such acquisitions or in-licensing. We cannot assure you that we will be able to make the combination of our business with that of any acquired businesses or companies work or be successful.

We compete with pharmaceutical companies that have significantly greater resources than we for many of the same acquisition and in-licensing opportunities. Such pharmaceutical companies may be less leveraged and have better access to capital resources that may preclude us from completing any acquisition or in-licensing. In addition, several pharmaceutical 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 find acceptable, or at all. Furthermore, the development or expansion of our business, any acquired business or any acquired or in-licensed products may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our capital stock, which could dilute current stockholders' ownership interest in our company, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest in our company upon conversion.

Our 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.

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

As a company with international operations, we are subject to income taxes, as well as non-income based taxes, in both the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities. Although we believe our estimates are reasonable, the ultimate outcome with respect to the taxes we owe may differ from the amounts recorded in our financial statements. If the Internal Revenue Service, or other taxing authority, disagrees with the positions 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. In addition, the United States government and other governments are considering and may adopt tax reform measures that significantly increase our worldwide tax liabilities. There are several proposals under consideration in the United States to reform tax law, including proposals that may reduce or eliminate the deferral of U.S. income tax on our unrepatriated foreign earnings. A significant change to U.S. tax policy, such as a change to the taxation of income earned outside the United States, could have a material and adverse effect on our business, financial condition and results of operations.

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

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

We enter into foreign exchange forward

contracts, with durations of up to 36 months, to hedge exposures resulting from portions of our forecasted 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. See also Footnote 7, Derivative Instruments and Hedging Activities, in the Consolidated Financial Statements included in this Annual Report on Form 10-K.

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

Sales of Soliris are dependent, in large part, on reimbursement from government health administration organizations and private and governmental third-party 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 Soliris in the future, which could have a material adverse effect on our business and results of operations. For example, in July 2011, we received non-interest bearing bonds issued by the Greek government that mature in 2012 and 2013 for payment on receivables from 2008 and 2009 as part of the Greek government's plan repayment of its debt to international pharmaceutical companies. We sold the associated bonds in July 2011 and recorded expense of approximately $4,100 through December 31, 2011 related to the reduction of value of the Greek bonds and other delays impacting the book value of our accounts receivable in other countries. 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. The credit and economic conditions in Greece, Italy and Spain, among other members of the European Union deteriorated in 2011 and 2012. These conditions have in the past resulted in an increase in the average length of time it takes to collect our outstanding accounts receivable in these countries. We have recorded an allowance related to all or a portion of receivables in each of Greece, Italy and Spain that have been outstanding for greater than one year as of December 31, 2013.

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.

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

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, in March 2010, the PPACA, which 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, and fraud and abuse

enforcement. While the constitutionality of key provisions of PPACA have been upheld by the Supreme Court, legislative changes remain possible. In addition, our industry may be affected by broader legislation addressing federal spending, including, for example, a sequester that took effect in March 2013 and cuts to most Medicare spending by 2%. As another example, the governments of Germany and Spain each approved increases to mandatory rebates on the sales of pharmaceutical products. Further in January 2013, Alexion was informed by the Advisory Group for National Specialised Services that although Soliris would help save lives and improve the quality of life for children and adults with aHUS, the U.K. Health Ministers decided not to recommend national commissioning of Soliris for the treatment of aHUS and at that time determined to refer the evaluation of Soliris for treatment of patients with aHUS to NICE for further review as part of its new Highly Specialised Technologies program. In July 2013, CPAG recommended a formal clinical access policy that includes aHUS patients who have functioning kidneys as well as patients on dialysis who are transplantable. In September 2013, England's National Health Service adopted the positive CPAG recommendation and commissioned Soliris for the treatment of children and adults with aHUS. Funding for patients in England is expected to be available through completion of NICE review. The NICE decision is anticipated in 2014.

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.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, customers and business partners, and personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

Natural disasters, acts of war or terrorism, shipping embargoes, labor unrest or political instability, could adversely affect our operations, including our ability to supply and commercialize Soliris.

Natural disasters such as earthquakes, hurricanes, tsunamis or other adverse weather and climate conditions, whether occurring in the U.S. or abroad, and the effects of these natural disasters, as well as acts of war or terrorism, shipping embargoes, labor unrest or political instability could disrupt our operations, or the operations of our vendors and other suppliers. Such events could adversely impact our facilities, or interfere with the manufacture or distribution of Soliris and our product candidates.

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, which were amended in October 2013, 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.

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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 January 2014, we agreed to purchase a vialing facility in Athlone, Ireland. The closing of the acquisition is expected to occur during the first quarter of 2014 upon satisfaction of agreed upon closing conditions. Following closing and refurbishment of the facility, and after successful completion of the appropriate validation processes and regulatory approvals, such facility will become our first company-owned vialing facility for Soliris and other clinical and commercial products.

Item 3. LEGAL PROCEEDINGS.

(amounts in thousands)

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.

Item 4. MINE SAFETY DISCLOSURES.

None.

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, 2012.

Fiscal 2012	High	Low
First Quarter (January 1, 2012 to March 31, 2012)	$95.01	$69.82
Second Quarter (April 1, 2012 to June 30, 2012)	$99.70	$81.28
Third Quarter (July 1, 2012 to September 30, 2012)	$116.43	$94.80
Fourth Quarter (October 1, 2012 to December 31, 2012)	$119.54	$86.20
Fiscal 2013		
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

As of January 24, 2014, we had approximately 353 stockholders of record of our common stock and an estimated 131,030 beneficial owners. The closing sale price of our common stock on January 24, 2014 was $133.64 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)

On November 8, 2012, we announced that our Board of Directors authorized the repurchase of up to $400,000 of our common stock. This repurchase program does not have an expiration date. There was no common stock repurchase activity during the fourth quarter of 2013. As of December 31, 2013, the maximum dollar value of shares remaining for purchase under the program was $322,311.

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)	8,619	$50.69	6.66	14,406
Equity compensation plans not approved by stockholders	—	$—	—	—

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(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 14,406 shares of common stock remaining available for future issuance are available under the Amended and Restated 2004 Incentive Plan.

(2) Does not include 1,789 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, 2008 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

	12/08	12/09	12/10	12/11	12/12	12/13
Alexion Pharmaceuticals, Inc.	100.00	134.90	222.58	395.14	518.04	734.37
NASDAQ Composite	100.00	144.88	170.58	171.30	199.99	283.39
NASDAQ Biotechnology	100.00	104.67	112.89	127.04	169.50	288.38

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,				
	2013	2012	2011	2010	2009
Net product sales	$1,551,346	$1,134,114	$783,431	$540,957	$386,800
Cost of sales:					
Cost of sales	168,375	126,214	93,140	64,437	45,059
Change in contingent liability from intellectual property settlements	9,181	(53,377)	—	—	—
Total cost of sales	177,556	72,837	93,140	64,437	45,059
Operating expenses:					
Research and development	317,093	222,732	137,421	98,394	81,915
Selling, general and administrative	489,720	384,678	308,176	226,766	172,767
Acquisition-related costs	5,029	22,812	13,486	722	—
Impairment of intangible assets	33,521	26,300	—	—	—
Amortization of purchased intangible assets	417	417	382	—	—
Total operating expenses	845,780	656,939	459,465	325,882	254,682
Operating income	528,010	404,338	230,826	150,638	87,059
Other expense	(1,741)	(6,772)	(1,158)	(1,627)	(3,745)
Income before income taxes	526,269	397,566	229,668	149,011	83,314
Income tax provision (benefit)	273,374	142,744	54,353	51,981	(211,852)
Net income	$252,895	$254,822	$175,315	$97,030	$295,166
Earnings per common share					
Basic	$1.29	$1.34	$0.96	$0.54	$1.73
Diluted	$1.27	$1.28	$0.91	$0.52	$1.63
Shares used in computing earnings per common share					
Basic	195,532	190,461	183,220	178,542	170,652
Diluted	199,712	198,501	191,806	186,074	181,164

Consolidated Balance Sheet Data:

	As of December 31,				
	2013	2012	2011	2010	2009
Cash, cash equivalents and marketable securities	$1,514,851	$989,501	$540,865	$361,605	$176,220
Total assets	3,317,696	2,613,560	1,394,751	1,012,037	786,401
Long-term debt and convertible notes (current and noncurrent)	113,000	149,000	—	3,718	9,918
Contingent consideration (current and noncurrent)	142,676	141,670	18,120	—	—
Facility lease obligation	32,230	—	—	—	—
Total stockholders' equity	2,382,079	1,970,850	1,134,492	859,736	688,356

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 ultra-rare 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;
- 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.

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. Revenue is recorded upon receipt of the product by the end customer, which is typically a hospital, physician's office, private or government pharmacy or other health care facility. Amounts collected from customers and remitted to governmental authorities, such as value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in 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 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 have provided balances and activity in the rebates payable account for the years ended December 31, 2013, 2012 and 2011 as follows:

	Rebates Payable
Balance at December 31, 2010	$4,660
Current provisions relating to sales in current year	36,045
Adjustments relating to prior years	(1,462)
Payments/credits relating to sales in current year	(15,226)
Payments/credits relating to sales in prior years	(2,271)
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

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 sovereign debt issues in Europe, 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 "Liquidity and Capital Resources" section below.

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

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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 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 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 judgments 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. 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.

Research and Development Expenses

We accrue costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations (CRO’s), clinical study sites, laboratories, consultants, or other clinical trial vendors that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a

combination of these elements. Activity levels are monitored through close communication with the CRO's and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and

significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter for each individual trial. The estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in research and development expenses for the related period. For clinical study sites, which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. The estimates may differ from the actual amount subsequently invoiced, which may result in adjustment to research and development expense several months after the related services were performed. Adjustments for prior period estimates have not had a material impact on our results of operations.

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 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 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 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 estimate the anticipated achievement of performance targets, including forecasting 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 also estimate expected term until exercise, forfeiture or cancellation, as well as the reduction in the expense from expected forfeitures. We currently use historical exercise and cancellation patterns as our best estimate of future estimated life. Actual volatility and lives of options may be significantly different from our estimates. If factors change or we employ different assumptions, 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 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 recognized an impairment charge of $3,785 associated with a purchased technology asset acquired in connection with the Taligen acquisition.

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 2013 and 2012, we recognized impairment charges of $29,736 and $26,300, respectively, associated with early stage indefinite-lived intangible assets acquired in connection with the purchase of Taligen. As of December 31, 2013, the remaining carrying value of our IPR&D was not impaired.

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, 2013 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 any 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 January 2013, the Financial Accounting Standards Board issued an update to clarify the scope of disclosures for offsetting assets and liabilities. The standard is effective for interim and annual periods beginning on or after January 1, 2013 and requires disclosure for all comparative periods. We adopted the provisions of this guidance, including the additional disclosure noted above, in 2013.

In February 2013, the Financial Accounting Standards Board issued a new standard to improve the reporting of reclassifications out of accumulated other comprehensive income. The new standard requires the disclosure of significant amounts reclassified from each component of accumulated other comprehensive income and the income statement line items affected by the reclassification. The standard is effective prospectively for interim and annual periods beginning after December 15, 2012. We adopted the provisions of this guidance, including the additional disclosure noted above, in 2013.

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,		
	2013	2012	2011
Net product sales	$1,551,346	$1,134,114	$783,431
Cost of sales:			
Cost of sales	168,375	126,214	93,140
Change in contingent liability from intellectual property settlements	9,181	(53,377)	—
Total cost of sales	177,556	72,837	93,140
Operating expenses:			
Research and development	317,093	222,732	137,421
Selling, general and administrative	489,720	384,678	308,176
Acquisition-related costs	5,029	22,812	13,486
Impairment of intangible assets	33,521	26,300	—
Amortization of purchased intangible assets	417	417	382
Total operating expenses	845,780	656,939	459,465
Operating income	528,010	404,338	230,826
Interest and other expense	(1,741)	(6,772)	(1,158)
Income before income taxes	526,269	397,566	229,668
Income tax provision	273,374	142,744	54,353
Net income	$252,895	$254,822	$175,315
Earnings per common share:			
Basic	$1.29	$1.34	$0.96
Diluted	$1.27	$1.28	$0.91

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,			
	2013	2012	% Variance	
Net product sales:				
United States	$561,405	$400,483	40	%
Europe	514,987	418,321	23	%
Asia Pacific (primarily Japan)	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

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. 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. 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, 2013	Year Ended December 31, 2012	$ Variance	% Variance
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 for 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 upfront payments 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 the continued 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	Accumulated Expenditures (Non-Approved Products)
External direct expenses			
Eculizumab	$44,577	$35,732	(a)
Asfotase alfa	13,677	4,800	$ 18,477
cPMP	6,408	2,144	8,552
Other programs	5,546	3,396	13,090
Unallocated	2,073	639	12,595
	$72,281	$46,711	$ 52,714

(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.

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 2014 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 legal expenses.

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

	Year Ended December 31, 2013	Year Ended December 31, 2012	$ Variance
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.

We expect our selling, general and administrative expenses to increase, at a lower rate than our revenue, in 2014, reflecting our continued growth as a commercial organization throughout the world.

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	$ Variance
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 and marketable securities. 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 and the tax expense 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.

Comparison of the Year Ended December 31, 2012 to the Year Ended December 31, 2011

Net Product Sales

Net product sales by significant geographic region are as follows:

	Year Ended December 31,			
Net product sales:	2012	2011	% Variance	
United States	$400,483	$263,387	52	%
Europe	418,321	340,812	23	%
Asia Pacific (primarily Japan)	161,480	115,377	40	%
Other	153,830	63,855	141	%
	$1,134,114	$783,431	45	%

The increase in revenue for fiscal year 2012 versus 2011 was primarily due to an increased volume of unit shipments, partially offset by a negative impact of price and foreign exchange. We also recognized $3,300 related to an agreement reached with a payer in the second quarter of 2012 related to product shipped during 2011.

The increase in revenue of 45% for the year ended December 31, 2012 was due to an increase in unit volumes of 49%, offset by a negative price impact of 3%, and a negative impact on foreign exchange of 2%. The increase in volume was largely due to physicians globally requesting Soliris therapy for additional patients, as well as reimbursement and price approvals in additional territories and reimbursement for aHUS in the United States. The negative price impact of 3% for the year ended December 31, 2012 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 $14,629, or 2%, for the year ended December 31, 2012 was due to changes in foreign currency exchange rates (inclusive of hedging activity) versus the U.S. dollar for the year ended December 31, 2011. The negative impact was primarily due to the Euro, offset by a positive impact of the Japanese Yen. We recorded a gain (loss) in revenue of $12,869 and $(6,558) 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, 2012 and 2011, respectively.

Cost of Sales

Exclusive of the change in estimate of contingent liability noted above of $53,377, cost of sales was $126,214 and $93,140, or 11% and 12% of product revenue, respectively, for the years ended December 31, 2012 and 2011. Cost of sales includes manufacturing costs as well as actual and estimated royalty expenses associated with sales of Soliris.

Research and Development Expenses

The following table provides information regarding research and development expenses:

	Year Ended December 31, 2012	Year Ended December 31, 2011	$ Variance	% Variance	
Clinical development	$46,711	$33,417	$13,294	40	%
Product development	57,028	23,133	33,895	147	%
Discovery research	8,271	5,850	2,421	41	%
Total external direct expenses	112,010	62,400	49,610	80	%
Payroll and benefits	95,609	64,068	31,541	49	%
Operating and occupancy	7,958	5,046	2,912	58	%
Depreciation and amortization	7,155	5,907	1,248	21	%
Total other R&D expenses	110,722	75,021	35,701	48	%
Research and development expense	$222,732	$137,421	$85,311	62	%

During the year ended December 31, 2012, we incurred research and development expenses of $222,732, an increase of $85,311, or 62%, versus the $137,421 incurred during the year ended December 31, 2011. The increase was primarily related to the following:

- Increase of $13,294 in external clinical development expenses related primarily to an expansion of studies of eculizumab and our asfotase alfa program acquired in February 2012, as well as an increase in costs related to other clinical programs. See table below.
- Increase of $33,895 in external product development expenses related primarily to the production of clinical amounts of asfotase alfa.
- Increase of $31,541 in research and development 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, 2012	Year Ended December 31, 2011
External direct expenses		
Eculizumab	$35,732	$31,630
Asfotase alfa	4,800	—
cPMP	2,144	—
Other programs	3,396	1,044
Unallocated	639	743
	$46,711	$33,417

Selling, General and Administrative Expense

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

	Year Ended December 31, 2012	Year Ended December 31, 2011	$ Variance
Salary, benefits and other labor expense	$223,053	$185,018	$38,035
External selling, general and administrative expense	161,625	123,158	38,467
Total selling, general and administrative expense	$384,678	$308,176	$76,502

During the year ended December 31, 2012, we incurred selling, general and administrative expenses of $384,678, an increase of $76,502, or 25%, versus the $308,176 incurred during the year ended December 31, 2011. The increase was primarily related to the following:

- Increase in salaries, benefits and other labor expenses of $38,035. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of $25,400 related to our global commercial staff to support global expansion. This increase was also due to increases in payroll and benefits of $12,600 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 $38,467. This increase was primarily due to costs associated with marketing and professional services of $18,400, increased distribution costs of $3,000, increased charitable contributions of $4,800, increased occupancy costs of $4,300 due to expansion of current facilities in the United States and Switzerland and new facilities associated with the acquisition of Enobia, and an increase of $7,000 in other administrative costs incurred in connection with our infrastructure growth..

Acquisition-related Costs

For the years ended December 31, 2012 and 2011, acquisition-related costs associated with our business combinations included the following:

	Year Ended December 31, 2012	Year Ended December 31, 2011
Separately-identifiable employee costs	$3,669	$6,597
Professional fees	12,593	5,489
Changes in fair value of contingent consideration	6,550	1,400
	$22,812	$13,486

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

	Year Ended December 31, 2012	Year Ended December 31, 2011
Enobia Pharma Corp.	$23,673	$2,039
Taligen Therapeutics, Inc.	(2,948)	10,375
Orphatec Pharmaceuticals GmbH	2,087	1,072
	$22,812	$13,486

Included in the acquisition-related costs for Taligen for the year ended December 31, 2012 is a gain of $4,331 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 the negative scientific findings, decrease in value and related deprioritization of the age-related macular degeneration program.

Other Income and Expense

The following table provides information regarding other income and expense:

	Year Ended December 31, 2012	Year Ended December 31, 2011	$ Variance
Investment income	$1,838	$1,911	$(73)
Interest expense	(7,402)	(788)	(6,614)
Foreign currency loss	(1,208)	(2,281)	1,073
Total other income (expense)	$(6,772)	$(1,158)	$(5,614)

We recognize investment income primarily from our portfolio of cash equivalents. During the year ended December 31, 2012, investment income decreased $73, or 4%, to $1,838.

During the year ended December 31, 2012, interest expense increased $6,614 to $7,402 due to interest on borrowings under our credit facility used in the acquisition of Enobia in February 2012.

During the year ended December 31, 2012, we recognized $1,208 of foreign currency loss, a decrease of $1,073, versus a loss of $2,281 incurred during the year ended December 31, 2011. The losses 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, 2012, we recorded an income tax provision of $142,744 and an effective tax rate of 35.9%, compared to an income tax provision of $54,353 and an effective tax rate of 23.7% for the year ended December 31, 2011.

The income tax provision for 2012 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations, as well as the tax expense of $21,812 associated with the structuring of the Enobia business. The tax provision for 2011 is principally attributable to the U.S. federal, state, and foreign income taxes in our profitable operations. In September

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2011, we completed our assessment of the impact the election to claim federal foreign tax credits and the federal orphan drug credits would have on our historical tax returns. Based on this assessment, we elected to claim both the foreign tax credit for the tax year ended December 31, 2010 and orphan drug credit for the tax years ended December 31, 2010 and 2009. The net federal income tax benefit recorded during 2011 as a result of the election to claim the federal foreign tax credit for 2010 and the federal orphan drug credit for 2010 and 2009 was approximately $15,400.

Liquidity and Capital Resources (amounts in thousands)

The following table summarizes the components of our financial condition as of December 31, 2013 and 2012:

	December 31, 2013	December 31, 2012	$ Variance
Cash and cash equivalents	$529,857	$989,501	$(459,644)
Marketable securities	984,994	—	984,994
Long-term debt (includes current portion)	113,000	149,000	(36,000)
Current assets	$2,186,857	$1,495,600	$691,257
Current liabilities	582,429	360,089	222,340
Working capital	$1,604,428	$1,135,511	$468,917

The decrease in cash and cash equivalents was primarily attributable to the purchase of marketable securities and the repurchase of common stock, offset by 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. During the second quarter of 2013, we began investing excess cash in high-quality marketable securities which are intended for use in meeting our ongoing liquidity needs.

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

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, for the foreseeable future, 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, 2013, two individual customers accounted for 20% and 10% of the accounts receivable balance. At December 31, 2012, two individual customers accounted for 18% and 12% of the accounts receivable balance. For the year ended December 31, 2013, one customer accounted for 20% of our product sales. For the year ended December 31, 2012, two customers accounted for 21% and 12% of our product sales.

We continue to monitor economic conditions, including volatility associated with international economies and the sovereign debt issues in Europe, and the associated impacts on the financial markets and our business. The credit and economic conditions in Greece, Italy and Spain, among other members of the European Union, have deteriorated over the last several years. These conditions have in the past resulted in an increase in the average length of time it takes to collect our outstanding accounts receivable in these countries. 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. Our exposure to the sovereign debt issue in Greece is limited, as we do not have a material

amount of accounts receivable in Greece.

As of December 31, 2013 and 2012, our gross accounts receivable in Italy and Spain totaled approximately $78,072 and $82,200, respectively. As of December 31, 2013 and 2012, approximately $17,318 and $21,100, respectively, of these amounts has been outstanding for greater than one year, and we have recorded an allowance of approximately $1,493 and $2,000, respectively, related to these gross receivables. As of December 31, 2013 and 2012, we recorded $8,052 and $21,334 of accounts receivable in Spain within other non-current assets, which approximates the amount of the receivables that we estimate with collection periods beyond one year.

During the years ended December 31, 2013 and 2012, we recorded income (expense) of approximately $944 and $(1,100), respectively, related to recoveries of past due amounts from these countries or the expectation of delayed payment. Our net accounts receivable from these countries as of December 31, 2013 and 2012 are summarized as follows:

	Total Accounts Receivable, Net		Accounts Receivable, Net > one year	
	2013	2012	2013	2012
Italy	$28,510	$35,758	$2,660	$7,197
Spain	$48,069	$44,465	$13,165	$12,873

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, 2013, we have foreign exchange forward contracts with notional amounts totaling $1,222,464. These outstanding foreign exchange forward contracts had a net fair value of $(3,438), of which an unrealized gain of $31,654 is included in other assets, offset by an unrealized loss of $35,092 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, 2013, 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 money market funds, marketable securities 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. During the next 12 months, we expect to make milestone payments totaling approximately $40,000. We do not expect these amounts to have an impact on our liquidity in the near-term. As 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.

Leases

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, 2013, our construction-in-process asset associated with the new facility and the offsetting lease obligation totaled $32,230.

License Agreements

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 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 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 addition to the option agreement, we purchased $25,000 of preferred equity of Moderna LLC, Moderna's parent company.

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, 2013, we had $113,000 outstanding on the term loan. As of December 31, 2013, we had open letters of credit of $17,134, and our borrowing availability under the revolving facility was $182,866 at December 31, 2013. We expect that cash generated from operations will be sufficient to meet debt service obligations.

Lonza Agreement

We have supply agreements with Lonza 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 commitments of approximately $147,000 through 2019. 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.

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. 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. 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 resulted in repatriation of a significant portion of our unremitted 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. At December 31, 2013, approximately $190,000 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. In connection with the acquisition of Enobia, certain of our foreign subsidiaries have bank debt which remains outstanding at December 31, 2013. Due to the liability position of our foreign

subsidiaries, these subsidiaries will repay the bank debt, as well as 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.

At December 31, 2013, we have pre-tax federal and state net operating loss carryforwards of $8,809, and $33,969, respectively. These NOL's expire between 2021 and 2032. We also have federal and state income tax credit carryforwards of $184,919 and $6,194, respectively. These income tax credits expire between 2014 and 2033. As we have exhausted much of our U.S. federal net operating loss and credit carryforwards, we anticipate that we will have a U.S. federal income tax liability within the next twelve months. We continue to pay cash taxes in various U.S. states and in foreign jurisdictions where we have operations and have utilized all of our net operating losses.

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.

Common Stock Repurchase Program

In November 2012, we announced that our Board of Directors authorized the repurchase of up to $400,000 of our common stock. This repurchase program does not have an expiration date. 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 758 and 130 shares of our common stock at a cost of $66,136 and $11,553 during the years ended December 31, 2013 and 2012, respectively. At December 31, 2013, there is a total of $322,311 remaining for repurchases under the program.

Cash Flows

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

	Year Ended December 31,		
	2013	2012	$ Variance
Net cash provided by operating activities	$497,349	$410,613	$86,736
Net cash used in investing activities	(1,027,141)	(627,585)	(399,556)
Net cash provided by financing activities	71,639	666,376	(594,737)
Effect of exchange rate changes on cash	(1,491)	(768)	(723)
Net change in cash and cash equivalents	$(459,644)	$448,636	$(908,280)

The decrease in cash and cash equivalents was primarily attributable to the purchase of marketable securities and the repurchase of common stock, offset by 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.

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 $252,895 and $254,822 for the years ended December 31, 2013 and 2012, respectively.
- 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, deferred taxes, unrealized foreign currency gains and losses, and unrealized gains and losses on forward contracts, and were $240,529 and $177,072 for the years ended December 31, 2013 and 2012, respectively.

Net cash outflow due to changes in operating assets and liabilities was $3,925 and $21,281 for the years ended December 31, 2013 and 2012, respectively. The $3,925 change in operating assets and liabilities primarily relates to:

- Increase in accounts receivable of $116,439 due to the increased number of patients treated with Soliris globally.
- Increase of $39,879 in prepaid expenses and other assets primarily related to prepaid taxes, prepaid manufacturing costs and interest receivable on investments.
- Increase of $136,641 in accounts payable, accrued expenses and other liabilities primarily related to increases in accruals for income taxes, rebates, royalties and compensation.
- Increase in deferred revenue of $23,476 due to increased shipments in advance of recognizing revenue.

In 2014, 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 $1,048,429 for the year ended December 31, 2013, offset by proceeds from the maturity or sale of available-for-sale marketable securities of $60,917 during the same period.
- Additions to property, plant and equipment of $29,329 and $21,846 for the years ended December 31, 2013 and 2012, respectively.
- Payment of $605,735 for the year ended December 31, 2012 related to the acquisition of Enobia in the first quarter of 2012.

Financing Activities

Net cash flows from financing activities reflected proceeds from the exercise of stock options of $71,281 and $66,438 for the years ended December 31, 2013 and 2012, respectively. Net cash flows from financing activities for the years ended December 31, 2013 and 2012 also include $105,714 and $7,228, 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. In addition, during 2012, we recognized proceeds of $462,212 in connection with the sale of 5,000 shares of our common stock.

In connection with the acquisition of Enobia in February 2012, we borrowed $240,000 under the term loan facility and $80,000 under the revolving facility, and we used our available cash for the remaining purchase price. During the year ended December 31, 2012, we repaid the revolving facility in full and made payments of $91,000 against the term loan facility. During the year ended December 31, 2013, we made payments of $36,000 against the term loan facility and the facility had $113,000 remaining outstanding as of December 31, 2013.

During the years ended December 31, 2013 and 2012, we repurchased $66,136 and $11,553 worth of shares of our common stock under a repurchase program that was approved by our Board of Directors in November 2012. As of December 31, 2013, $322,311 remains available for repurchases under the program.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2013 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	$113,000	$5,000	$96,000	$12,000	$—
Interest expense (1)	3,507	1,598	1,867	42	—
Pension obligations	18,187	2,140	3,870	3,871	8,306
Operating leases (2)	62,636	17,641	24,335	14,498	6,162
Total contractual obligations	$197,330	$26,379	$126,072	$30,411	$14,468
Commercial commitments:					
Clinical and manufacturing development	$146,931	$71,555	$35,616	$32,368	$7,392
Licenses (3)	10,786	1,963	2,925	3,825	2,073
Total commercial commitments	$157,717	$73,518	$38,541	$36,193	$9,465

(1) Interest on variable rate debt calculated based on interest rates at December 31, 2013.

(2) Operating lease commitments do not include potential lease termination fees associated with an early exit from our Cheshire facilities or contractual payments associated with our New Haven facility lease as the precise timing of these payments is not certain and is contingent on construction of the facility over the next several years. Lease payments related to the New Haven lease will commence six months following the landlord's substantial completion of the building and will continue for a minimum of 12 years. Monthly lease payments will range from $971 to $1,108 and total contractual commitments during the minimum lease term are approximately $149,529. Termination fees associated with our current facilities total approximately $3,800.

(3) License commitments do not include the $100,000 upfront payment associated with the license agreement we entered into with Moderna in January 2014.

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 10 "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 $46,389 at December 31, 2013. The timing of the settlement of these amounts was not reasonably estimable at December 31, 2013. 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, 2013. 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 $40,000.

Credit Facilities

On February 7, 2012, we entered into a 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 Alexion Pharma International Sàrl 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.

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 November 2012, we entered into a new operating lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. The construction of the facility began in June 2013 and is expected to be completed in 2015. 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. The lease provides for monthly payments, ranging from $971 to $1,108, over the term of the lease. Upon completion of the New Haven facility, we will relocate our headquarters and Cheshire operations to New Haven.

In November 2012, in connection with the planned construction of facilities in New Haven, Connecticut, 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. 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. It is unlikely that we will be able to realize the full value of the available tax credits, and we are currently exploring alternatives for the disposition of these credits. As of December 31, 2013, we have not received any grant funds or tax credits associated with our agreement with the State of Connecticut.

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.

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Additional Commercial Commitments

Additional payments related to our commercial commitments, such as licenses, aggregating to approximately $4,000, would be required if specified development and commercial milestones are achieved. These amounts are not included in the above table.

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

(amounts in thousands, except percentages)

Interest Rate Risk

As of December 31, 2013, 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 invest in, 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 $(11,376) and $6,459, 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, 2013, we had approximately $113,000 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 $1,130.

Foreign Exchange Market Risk

As a result of our foreign operations, we have exposure to movements in foreign currency exchange rates, primarily the Euro, Japanese Yen, Swiss Franc and British Pound against the U.S. dollar. The current exposures arise primarily from cash, accounts receivable, intercompany receivables and payables, and product sales denominated in foreign currencies. Both positive and negative impacts to our international product sales from movements in foreign currency exchange rates are partially mitigated by the natural, opposite impact that foreign currency exchange rates have on our international operating expenses. We have 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, including intercompany sales, using contracts with durations of up to 36 months. The objectives of this program are 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. This program utilizes foreign exchange forward contracts intended to reduce, not eliminate, the impact of fluctuations in foreign currency rates.

As of December 31, 2013 and 2012, we held foreign exchange forward contracts with notional amounts totaling $1,222,464 and $964,189, respectively. As of December 31, 2013 and 2012, our outstanding foreign exchange forward contracts had a net fair value of $(3,438) and $17,180, respectively. The increase in outstanding foreign exchange forward contracts resulted primarily from increases in forecasted intercompany revenues.

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, 2013, 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 $109,000 at December 31, 2013. 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 an increase in the value of the underlying monetary assets and liabilities.

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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. We continue to monitor economic conditions, including volatility associated with international economies and the sovereign debt issues in Europe, and the associated impacts on the financial markets and our business. The credit and economic conditions in Greece, Italy and Spain, among other members of the European Union, have deteriorated over the last several years. These conditions have in the past resulted in an increase in the average length of time it takes to collect our outstanding accounts receivable in these countries. 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. Our exposure to the sovereign debt issue in Greece is limited, as we do not have a material amount of accounts receivable in Greece. We have provided detail on amounts outstanding in Italy and Spain in the "Liquidity and Capital Resources" section in Item 7 above.

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, 2013. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2013, 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 (1992)” 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, 2013. Based on the assessment, management has concluded that, as of December 31, 2013, our internal control over financial reporting is effective.

The effectiveness of our internal control over financial reporting as of December 31, 2013 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, 2013 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	Large-Scale Product Supply Agreement, dated December 18, 2002, between Alexion Pharma International Sarl and Lonza Sales AG, as amended.(21)+
10.17	Amendment No. 13 to the Large-Scale Product Supply Agreement dated December 18, 2002, between Alexion Pharma International Sarl and Lonza Sales AG, dated June 8, 2007.(22)+
10.18	Form of Stock Option Agreement for Directors.(23)**
10.19	Form of Stock Option Agreement for Executive Officers (Form A).(24)**
10.20	Form of Stock Option Agreement for Executive Officers (Form B).(24)**
10.21	Form of Restricted Stock Award Agreement for Executive Officers (Form A).(25)**
10.22	Form of Stock Option Agreement (Incentive Stock Options).(22)
10.23	Form of Stock Option Agreement (Nonqualified Stock Options).(22)
10.24	Form of Restricted Stock Award Agreement.(22)
10.25	Form of Restricted Stock Unit Award Agreement.(26)
10.26	Form of Stock Option Agreement for Participants in France.(22)**
10.27	Form of Restricted Stock Unit Agreement for Participants in France.(22)**
10.28	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)
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, 2013 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.

(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 Quarterly Report on Form 10-Q for the quarter ended January 31, 2003.
(22) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.
(23) Incorporated by reference to our report on Form 8-K, filed on December 16, 2004.
(24) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2005.
(25) Incorporated by reference to our report on Form 8-K, filed on March 14, 2005.
(26) 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.
** 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.
Chief Executive Officer and Treasurer
Dated: February 10, 2014

By: /s/ Vikas Sinha
Vikas Sinha, M.B.A., C.A.
Executive Vice President and Chief Financial Officer
Dated: February 10, 2014

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.	Chief Executive Officer, Treasurer and Director (principal executive officer)	February 10, 2014
/s/ Vikas Sinha Vikas Sinha, M.B.A., C.A.	Executive Vice President and Chief Financial Officer (principal financial officer)	February 10, 2014
/s/ Scott Phillips Scott Phillips, C.P.A.	Vice President, Corporate Controller and Chief Accounting Officer (principal accounting officer)	February 10, 2014
/s/ Max Link Max Link, Ph.D.	Chairman of the Board of Directors	February 10, 2014
/s/ William R. Keller William R. Keller	Director	February 10, 2014
/s/ Larry L. Mathis Larry L. Mathis	Director	February 10, 2014
/s/ Joseph A. Madri Joseph A. Madri, Ph.D., M.D.	Director	February 10, 2014
/s/ R. Douglas Norby R. Douglas Norby	Director	February 10, 2014
/s/ Alvin S. Parven Alvin S. Parven	Director	February 10, 2014

/s/ Andreas Rummelt Andreas Rummelt, Ph.D.	Director	February 10, 2014
/s/ Ann Veneman Ann Veneman	Director	February 10, 2014

Alexion Pharmaceuticals, Inc.
Contents
For the Years Ended December 31, 2013, 2012 and 2011

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, 2013 and December 31, 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 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, 2013, based on criteria established in Internal Control - Integrated Framework (1992) 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 10, 2014

Alexion Pharmaceuticals, Inc.
Consolidated Balance Sheets
(amounts in thousands, except per share amounts)

	December 31, 2013	2012
Assets		
Current Assets:		
Cash and cash equivalents	$529,857	$989,501
Marketable securities	984,994	—
Trade accounts receivable, net	421,752	295,598
Inventories	102,602	94,521
Prepaid manufacturing costs	18,927	14,619
Deferred tax assets	41,432	26,086
Prepaid expenses and other current assets	87,293	75,275
Total current assets	2,186,857	1,495,600
Property, plant and equipment, net	201,109	165,629
Intangible assets, net	609,719	646,678
Goodwill	254,073	253,645
Deferred tax assets	3,394	13,954
Other assets	62,544	38,054
Total assets	$3,317,696	$2,613,560
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$21,596	$21,488
Accrued expenses	402,344	249,787
Deferred revenue	53,801	31,266
Current portion of long-term debt	48,000	48,000
Other current liabilities	56,688	9,548
Total current liabilities	582,429	360,089
Long-term debt, less current portion	65,000	101,000
Contingent consideration	106,744	139,002
Facility lease obligation	32,230	—
Deferred tax liabilities	101,241	19,827
Other liabilities	47,973	22,792
Total liabilities	935,617	642,710
Commitments and contingencies (Note 10)		
Stockholders' Equity:		
Preferred stock, $.0001 par value; 5,000 shares authorized, no shares issued or outstanding	—	—
Common stock, $.0001 par value; 290,000 shares authorized; 197,941 and 194,918 shares issued at December 31, 2013 and 2012, respectively	20	20
Additional paid-in capital	2,106,183	1,852,221
Treasury stock, at cost, 985 and 227 shares at December 31, 2013 and 2012, respectively	(80,365)	(14,229)
Accumulated other comprehensive income (loss)	(22,857)	6,635
Retained earnings	379,098	126,203
Total stockholders' equity	2,382,079	1,970,850
Total liabilities and stockholders' equity	$3,317,696	$2,613,560

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,		
	2013	2012	2011
Net product sales	$1,551,346	$1,134,114	$783,431
Cost of sales:			
Cost of sales	168,375	126,214	93,140
Change in contingent liability from intellectual property settlements	9,181	(53,377)	—
Total cost of sales	177,556	72,837	93,140
Operating expenses:			
Research and development	317,093	222,732	137,421
Selling, general and administrative	489,720	384,678	308,176
Acquisition-related costs	5,029	22,812	13,486
Impairment of intangible assets	33,521	26,300	—
Amortization of purchased intangible assets	417	417	382
Total operating expenses	845,780	656,939	459,465
Operating income	528,010	404,338	230,826
Other income and expense:			
Investment income	3,346	1,838	1,911
Interest expense	(4,112)	(7,402)	(788)
Foreign currency loss	(975)	(1,208)	(2,281)
Income before income taxes	526,269	397,566	229,668
Income tax provision	273,374	142,744	54,353
Net income	$252,895	$254,822	$175,315
Earnings per common share			
Basic	$1.29	$1.34	$0.96
Diluted	$1.27	$1.28	$0.91
Shares used in computing earnings per common share			
Basic	195,532	190,461	183,220
Diluted	199,712	198,501	191,806

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,		
	2013	2012	2011
Net income	$252,895	$254,822	$175,315
Other comprehensive income (loss), net of tax:			
Foreign currency translation	(4,573)	150	(1,328)
Unrealized losses on marketable securities, net of tax of $(75), $0 and $0, respectively	(146)	—	(10)
Unrealized losses on pension obligation, net of tax of $(547), $(143) and $(72), respectively	(5,790)	(1,529)	(1,165)
Unrealized (losses) gains on hedging activities, net of tax of $(871), $232 and $872, respectively	(18,983)	3,835	13,822
Other comprehensive income (loss), net of tax	(29,492)	2,456	11,319
Comprehensive income	$223,403	$257,278	$186,634

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, 2010	182,374	$18	$1,173,468	97	$(2,676)	$ (7,140)	$(303,934)	$859,736
Costs associated with 2 for 1 stock split	—	—	(55)	—	—	—	—	(55)
Conversion of convertible notes to common stock	381	—	2,996	—	—	—	—	2,996
Issuance of common stock from exercise of options	2,744	1	35,820	—	—	—	—	35,821
Issuance of restricted common stock	117	—	—	—	—	—	—	—
Excess tax benefit from stock options	—	—	4,016	—	—	—	—	4,016
Share-based compensation expense	—	—	45,344	—	—	—	—	45,344
Net income	—	—	—	—	—	—	175,315	175,315
Other comprehensive income	—	—	—	—	—	11,319	—	11,319
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

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,		
	2013	2012	2011
Cash flows from operating activities:			
Net income	$252,895	$254,822	$175,315
Adjustments to reconcile net income to net cash flows from operating activities:			
Depreciation and amortization	28,693	23,887	17,616
Impairment of intangible assets	33,521	26,300	—
Change in fair value of contingent consideration	4,006	6,550	1,400
Share-based compensation expense	76,203	54,013	44,763
Premium amortization of available-for-sale securities	3,235	—	(24)
Deferred taxes	92,831	71,155	42,066
Unrealized foreign currency loss (gain)	1,144	(3,019)	5,516
Unrealized loss (gain) on forward contracts	764	(2,694)	479
Other	132	880	136
Changes in operating assets and liabilities, excluding the effect of acquisitions:			
Accounts receivable	(116,439)	(72,870)	(78,778)
Inventories	126	(6,265)	(12,179)
Prepaid expenses and other assets	(39,879)	(17,041)	(21,040)
Accounts payable, accrued expenses and other liabilities	136,641	61,723	79,781
Deferred revenue	23,476	13,172	15,033
Net cash provided by operating activities	497,349	410,613	270,084
Cash flows from investing activities:			
Purchases of available-for-sale securities	(1,048,429)	—	—
Proceeds from maturity or sale of available-for-sale securities	60,917	—	94,458
Purchases of trading securities	(985)	—	—
Purchases of property, plant and equipment	(29,329)	(21,846)	(21,982)
Payments for acquisitions of businesses, net of cash acquired	—	(605,735)	(105,886)
Other	(9,315)	(4)	(307)
Net cash used in investing activities	(1,027,141)	(627,585)	(33,717)
Cash flows from financing activities:			
Debt issuance costs	—	(6,184)	—
Proceeds from revolving credit facility	—	115,000	60,000
Payments on revolving credit facility	—	(115,000)	(60,000)
Proceeds from term loan	—	240,000	—
Payments on term loan	(36,000)	(91,000)	—
Excess tax benefit from stock options	105,714	7,228	4,016
Repurchase of common stock	(66,136)	(11,553)	—
Net proceeds from issuance of common stock	—	462,212	—
Net proceeds from the exercise of stock options	71,281	66,438	35,765
Payment of contingent consideration	(3,000)	—	—
Other	(220)	(765)	(731)
Net cash provided by financing activities	71,639	666,376	39,050
Effect of exchange rate changes on cash	(1,491)	(768)	(1,697)
Net change in cash and cash equivalents	(459,644)	448,636	273,720

Cash and cash equivalents at beginning of period	989,501	540,865	267,145
Cash and cash equivalents at end of period	$529,857	$989,501	$540,865
Supplemental cash flow disclosures:			
Cash paid for interest (net of amounts capitalized)	$2,831	$4,475	$538
Cash paid for income taxes	$76,165	$18,272	$10,221
Supplemental cash flow disclosures from investing and financing activities:			
Contingent consideration issued in acquisitions	$—	$117,000	$16,720
Construction in process related to facility lease obligation	$32,230	$—	$—

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

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2013, 2012 and 2011
(amounts in thousands except per share amounts)

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 ultra-rare 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 offer a nonqualified deferred compensation plan which allows participants 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 70 to 80 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.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
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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.

For the year ended December 31, 2013, two individual customers accounted for 20% and 10% of the accounts receivable balance and one customer accounted for 20% of net product sales. For the year ended December 31, 2012, two individual customers accounted for 18% and 12% of the accounts receivable balance and 21% and 12% of net product sales. No other customers accounted for more than 10% of net product sales or accounts receivable.

We continue to monitor economic conditions, including volatility associated with international economies and the sovereign debt issues in Europe, and the associated impacts on the financial markets and our business. The credit and economic conditions in Greece, Italy and Spain, among other members of the European Union, have deteriorated over the last several years. These conditions have in the past resulted in an increase in the average length of time it takes to collect our outstanding accounts receivable in these countries. 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. Our exposure to the sovereign debt issue in Greece is limited, as we do not have a material amount of accounts receivable in Greece.

As of December 31, 2013 and 2012, our gross accounts receivable in Italy and Spain totaled approximately $78,072 and $82,200, respectively. As of December 31, 2013 and 2012, approximately $17,318 and $21,100, respectively, of these amounts has been outstanding for greater than one year, and we have recorded an allowance of approximately $1,493 and $2,000, respectively, related to these gross receivables. As of December 31, 2013 and 2012, we recorded $8,052 and $21,334 of accounts receivable in Spain within other non-current assets, which approximates the amount of the receivables that we estimate with collection periods beyond one year.

During the years ended December 31, 2013 and 2012, we recorded income (expense) of approximately $944 and $(1,100), respectively, related to recoveries of past due amounts from these countries or the expectation of delayed payment. Our net accounts receivable from these countries as of December 31, 2013 and 2012 are summarized as follows:

	Total Accounts Receivable, Net		Accounts Receivable, Net > one year	
	2013	2012	2013	2012
Italy	$28,510	$35,758	$2,660	$7,197
Spain	$48,069	$44,465	$13,165	$12,873

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,	
	2013	2012

Raw materials	$12,170	$6,485
Work-in-process	62,192	43,899
Finished goods	28,240	44,137
	$102,602	$94,521

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, 2013, we did not have any inventory capitalized associated with products awaiting regulatory approval.

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 would require adjustments to our inventory values. We also apply judgments 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. 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.

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.

Alexion Pharmaceuticals, Inc.
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Prepaid Manufacturing Costs

Cash advances paid by us prior to receipt of the inventory are recorded as prepaid manufacturing costs. The cash advances are subject to forfeiture if we terminate the scheduled production. We expect the carrying value of the prepaid manufacturing costs to be fully realized.

Property, Plant and Equipment

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

- Building and improvements—five to thirty years
- Machinery and laboratory equipment—three to thirty years
- Computer hardware and software—two to five years
- Furniture and office equipment—three to seven 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 for impairment if certain events occur as described in "Impairment of Long-Lived Assets" below.

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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 would be deemed finite-lived and would then be 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, 2013 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 assets acquired in connection with the purchase of Taligen of $33,521 in 2013 associated with an early state indefinite-lived intangible asset and a purchased technology asset and $26,300 in 2012, associated with early stage indefinite-lived intangible asset. We did not recognize any other impairment loss for long-lived assets during the years ended December 31, 2013, 2012 and 2011.

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 any 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.

Contingent Liabilities

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

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

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.

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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. Revenue is recorded upon receipt of the product by the end customer, which is typically a hospital, physician's office, private or government pharmacy or other health care facility. Amounts collected from customers and remitted to governmental authorities, such as value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in 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 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 an adjustment is made.

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,

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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 non-market performance conditions.

Compensation expense 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 recognized a straight-line basis over the requisite service period of the individual grants, which typically equals the vesting period. Generally, stock options, restricted stock and restricted stock units granted to employees fully vest four years from the grant date. Performance-based restricted stock units have a three year vesting period. Stock options have a contractual term of 10 years.

Compensation expense for awards with performance conditions is recognized using the graded-vesting method. We estimate the anticipated achievement of performance targets, including forecasting 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.

Earnings Per Common Share

Basic earnings per common share (EPS) are computed by dividing net income by the weighted-average number of shares of common stock outstanding. For purposes of calculating diluted EPS, net income is adjusted for the after-tax amount of interest and deferred financing costs associated with our convertible debt, if any, and 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, as well as the potential dilution if the remaining convertible notes were converted to common stock.

The following table summarizes the calculation of basic and diluted EPS for years ended December 31, 2013, 2012 and 2011:

	Year Ended December 31,		
	2013	2012	2011
Net income used for basic calculation	$252,895	$254,822	$175,315
Weighted-average effect of dilutive securities:			
Interest expense and debt financing cost amortization, net of tax, related to our 1.375% convertible senior notes	—	—	26
Net income used for diluted calculation	$252,895	$254,822	$175,341
Shares used in computing earnings per common share—basic	195,532	190,461	183,220
Weighted-average effect of dilutive securities:			
Shares issuable upon the assumed conversion of our 1.375% convertible senior notes	—	8	198
Stock awards	4,180	8,032	8,388
Dilutive potential common shares	4,180	8,040	8,586
Shares used in computing earnings per common share—diluted	199,712	198,501	191,806
Earnings per common share:			
Basic	$1.29	$1.34	$0.96
Diluted	$1.27	$1.28	$0.91

The following table represents the potentially dilutive shares excluded from the calculation of EPS for the years ended December 31, 2013, 2012 and 2011 because their effect is anti-dilutive:

	Year Ended December 31,

	2013	2012	2011
Potentially dilutive securities:			
Options to purchase common stock	2,243	1,846	1,905
Unvested restricted stock and restricted stock units	—	53	15
	2,243	1,899	1,920

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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.

New Accounting Pronouncements

In January 2013, the Financial Accounting Standards Board issued an update to clarify the scope of disclosures for offsetting assets and liabilities. The standard is effective for interim and annual periods beginning on or after January 1, 2013 and requires disclosure for all comparative periods. We adopted the provisions of this guidance in 2013.

In February 2013, the Financial Accounting Standards Board issued a new standard to improve the reporting of reclassifications out of accumulated other comprehensive income. The new standard requires the disclosure of significant amounts reclassified from each component of accumulated other comprehensive income and the income statement line items affected by the reclassification. The standard is effective prospectively for interim and annual periods beginning after December 15, 2012. We adopted the provisions of this guidance, including the additional disclosure noted above, in 2013.

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.

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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, 2013, the fair value of the contingent consideration for Enobia was $133,013. Changes in fair value of the consideration for Enobia were $8,602 and $7,411 for the years ended December 31, 2013 and 2012, 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

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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 and 2011 as if the acquisition of Enobia had been completed on January 1, 2011. 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	2011
Revenues	$1,134,114	$783,431
Net income	236,407	124,496
Earnings per common share		
Basic	$1.24	$0.68
Diluted	$1.19	$0.65

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. In addition, during 2013, we made milestone payments of $3,000 related to this acquisition.

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. At December 31, 2013, the fair value of the contingent consideration for Orphatec was $5,704. Changes in fair value of the consideration for Orphatec were $1,181, $2,087 and $350 for the years ended December 31, 2013, 2012 and 2011, 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.

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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, 2013, the fair value of the contingent consideration for Taligen was $3,959. Changes in fair value of the consideration for Taligen were $(5,777), $(2,948) and $1,050 for the years ended December 31, 2013, 2012 and 2011, respectively. Included in the change in fair value for the years 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.

Acquisition-Related Costs

Acquisition-related costs associated with our business combinations for the years ended December 31, 2013, 2012 and 2011 include the following:

	Year Ended December 31,		
	2013	2012	2011
Separately-identifiable employee costs	$248	$3,669	$6,597
Professional fees	775	12,593	5,489
Changes in fair value of contingent consideration	4,006	6,550	1,400
	$5,029	$22,812	$13,486

During the years ended December 31, 2013, 2012 and 2011, we incurred approximately $9,625, $23,673 and $2,039, respectively, in costs related to the Enobia acquisition, which are included in this table above.

3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31, 2013	December 31, 2012
Prepaid taxes	$30,235	$25,920
Forward contract receivable	21,815	17,862
Other	35,243	31,493
	$87,293	$75,275

4. Property, Plant and Equipment, Net

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

	December 31, 2013	December 31, 2012
Land	$692	$692
Buildings and improvements	154,996	147,838
Machinery and laboratory equipment	56,130	49,692
Computer hardware and software	41,704	33,809
Furniture and office equipment	10,119	8,593
Construction-in-progress	41,573	4,996
	305,214	245,620
Less: Accumulated depreciation and amortization	(104,105)	(79,991)

	$201,109	$165,629

Included in construction-in-progress at December 31, 2013 is $32,230 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-

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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 $19,084, $15,192 and $12,236 for the years ended December 31, 2013, 2012 and 2011, respectively.

At December 31, 2013 and 2012, computer software costs included in property, plant and equipment were $9,691 and $9,628, respectively. Depreciation and amortization expense for capitalized computer software costs was $4,503, $4,228 and $3,642 for the years ended December 31, 2013, 2012 and 2011, respectively.

5. Intangible Assets and Goodwill

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

		December 31, 2013			December 31, 2012		
	Estimated Life (months)	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Licenses	72-96	$28,507	$(18,719)	$9,788	$23,688	$(13,152)	$10,536
Patents	84	10,517	(9,100)	1,417	10,517	(6,827)	3,690
Purchased technology	144	—	—	—	5,000	(798)	4,202
Acquired IPR&D	Indefinite	598,514	—	598,514	628,250	—	628,250
Total		$637,538	$(27,819)	$609,719	$667,455	$(20,777)	$646,678
Goodwill	Indefinite	$256,974	$(2,901)	$254,073	$256,546	$(2,901)	$253,645

Amortization of our intangible assets was approximately $8,257, $5,660 and $5,087 for the years ended December 31, 2013, 2012 and 2011, respectively. Assuming no changes in the gross cost basis of intangible assets, the estimated amortization of intangible assets for the next five fiscal years is as follows:

Year	
2014	$11,160
2015	42
2016	3
2017	—
2018	—

As of December 31, 2013, we have recorded indefinite-lived intangible assets of $598,514 of purchased IPR&D from prior business acquisitions. As of December 31, 2013, 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 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. 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 the third quarter of 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

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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, 2011	$79,639
Goodwill resulting from the Enobia acquisition	174,006
Balance at December 31, 2012	253,645
Change in goodwill associated with prior acquisition	428
Balance at December 31, 2013	$254,073

6. 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, 2013 were as follows:

	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated 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, 2013 was $461,634. These investments have been in a continuous unrealized loss position for less than 12 months. As of December 31, 2013 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, 2013
Cash and cash equivalents	$43,780
Marketable securities	983,977
	$1,027,757

The fair values of available-for-sale debt securities at December 31, 2013, by contractual maturity, are summarized as follows:

	December 31, 2013
Due in one year or less	$501,051
Due after one year through three years	526,706
Due after three years through five years	—

	$1,027,757

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

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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, 2013.
We held no marketable securities as of December 31, 2012.

7. Derivative Instruments and Hedging Activities

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

We enter into foreign exchange forward contracts, with durations of up to 36 months, to hedge exposures resulting from portions of our forecasted 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, 2013, we had open contracts with notional amounts totaling $1,084,418 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, 2013 and 2012 were as follows:

	Year Ended December 31,	
	2013	2012
Gain (loss) recognized in AOCI, net of tax	$(1,000)	$14,856
Gain reclassified from AOCI to net product sales (effective portion), net of tax	$18,820	$11,775
Loss reclassified from AOCI to other income and expense (ineffective portion), net of tax	$(837)	$(754)

Assuming no change in foreign exchange rates from market rates at December 31, 2013, $1,197 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, 2013, the notional amount of foreign exchange contracts where hedge accounting is not applied was $138,046.

We recognized a gain of $8,306, $3,518 and $790, in other income and expense, for the years ended December 31, 2013, 2012 and 2011, respectively, associated with the foreign exchange contracts not designated as hedging instruments under the guidance. These amounts were largely offset by gains or losses in monetary assets and liabilities.

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The following tables summarize the fair value of outstanding derivatives at December 31, 2013 and 2012:

	December 31, 2013 Asset Derivatives Balance Sheet Location	Fair Value	Liability Derivatives 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
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	—	Other current liabilities	—
Total fair value of derivative instruments		$31,654		$35,092

	December 31, 2012 Asset Derivatives Balance Sheet Location	Fair Value	Liability Derivatives Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	$15,617	Other current liabilities	$3,529
Foreign exchange forward contracts	Other non-current assets	9,378	Other non-current liabilities	4,521
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	2,245	Other current liabilities	2,010
Total fair value of derivative instruments		$27,240		$10,060

Although we do not offset derivative assets and liabilities within our 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 consolidated balance sheets of offsetting our foreign exchange forward contracts subject to such provisions:

December 31, 2013

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	Gross Amounts Not Offset 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)

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December 31, 2012

				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	$ 27,240	$—	$ 27,240	$(10,060)	$—	$17,180
Derivative liabilities	(10,060)	—	(10,060)	10,060	—	—

8. Accrued Expenses and Other Liabilities

Accrued expenses consist of the following:

	December 31, 2013	December 31, 2012
Royalties	$40,945	$25,450
Payroll and employee benefits	64,950	49,954
Taxes payable	108,907	68,432
Rebates payable	124,297	62,334
Other	63,245	43,617
	$402,344	$249,787

Other current liabilities consist of the following:

	December 31, 2013	December 31, 2012
Contingent consideration	$35,932	$2,668
Forward contract payable	20,228	5,539
Other	528	1,341
	$56,688	$9,548

Other liabilities consist of the following:

	December 31, 2013	December 31, 2012
Taxes	$14,901	$7,066
Forward contract payable	14,864	4,521
Pension liability	14,839	8,478
Other	3,369	2,727
	$47,973	$22,792

9. Debt

On February 7, 2012, we entered into a Credit Agreement (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

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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, 2013 and 2012, the interest rate on our outstanding loans under the Credit Agreement was 1.41% and 1.46%, respectively.
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 Alexion Pharma International Sàrl 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.
In connection with entering into the Credit Agreement, we paid $6,184 in financing costs which are being amortized as interest expense over the life of the debt. Amortization expense associated with deferred financing costs for the years ended December 31, 2013, 2012 and 2011 was approximately $1,351, $3,035 and $283, respectively.
In connection with the acquisition of Enobia in February 2012, we borrowed $240,000 under the term loan facility and $80,000 under the revolving facility, and we used our available cash for the remaining purchase price. During 2012, we repaid the revolving facility in full and made payments of $91,000 against the term loan. As of December 31, 2013, we had $113,000 outstanding on the term loan. As of December 31, 2013, we had open letters of credit of $17,134, and our borrowing availability under the revolving facility was $182,866.
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, 2013 are $5,000 in 2014, $48,000 in 2015 and 2016, and $12,000 in 2017. As of December 31, 2013, 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 2014.

10. Commitments and Contingencies

Commitments

License Agreements

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 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.

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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, vial filling and packaging through third parties. We have various agreements with Lonza, with remaining total commitments of approximately $147,000 through 2019. 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 Alexion Rhode Island Manufacturing Facility (ARIMF).

Contingent Liabilities

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

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 business. However, the amount of such loss or a range of loss, if any, beyond amounts currently accrued, cannot be reasonably estimated.

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 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. We continue to manufacture products, including Soliris, in this facility. While the resolution of 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.

Operating Leases

As of December 31, 2013, we lease our headquarters and primary research and development facilities in Cheshire, Connecticut. The leases are set to expire in 2016 and 2020, and we would be subject to contractual penalties of approximately $3,800 if the leases were to terminate early. 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 $19,094, $16,758 and $10,424 for the years ended December 31, 2013, 2012 and 2011, respectively. Lease expense is being recorded on a straight-line basis over the applicable lease terms.

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In November 2012, we entered into a new operating lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. The construction of the facility began in June 2013 and is expected to be completed in 2015. The term of the new lease will commence upon the landlord's substantial completion of the building and will expire 12 years after the completion date, 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. The lease provides for monthly payments, ranging from $971 to $1,108, over the term of the lease. Upon completion of the new facility, we will relocate our headquarters and Cheshire operations to New Haven.

In November 2012, in connection with the planned construction of facilities in New Haven, Connecticut, 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. 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. It is unlikely that we will be able to realize the full value of the available tax credits, and we are currently exploring alternatives for the disposition of these credits. As of December 31, 2013, we have not received any grant funds or tax credits associated with our agreement with the State of Connecticut.

Aggregate future minimum annual rental payments, exclusive of costs related to our new operating lease for facilities to be constructed in New Haven, Connecticut, which are contingent upon construction of the facility, for the next five years and thereafter under non-cancellable operating leases (including facilities and equipment) as of December 31, 2013 are:

Year	
2014	$17,641
2015	13,484
2016	10,851
2017	7,804
2018	6,694
Thereafter	6,162

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.

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The minimum fixed payments (assuming non-termination of the above agreements) as of December 31, 2013, for each of the next five years are as follows:

Year	License Agreements	Clinical and Manufacturing Development Agreements
2014	$1,963	$71,555
2015	2,212	18,032
2016	713	17,584
2017	663	16,184
2018	3,162	16,184
	$8,713	$139,539

11. Income Taxes

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

	Year Ended December 31,		
	2013	2012	2011
U.S.	$376,067	$294,794	$158,472
Non-U.S.	150,202	102,772	71,196
	$526,269	$397,566	$229,668

The components of the income tax provision are as follows:

	Year Ended December 31,		
	2013	2012	2011
Domestic			
Current	$141,051	$(2,094)	$(904)
Deferred	92,040	114,807	45,463
	233,091	112,713	44,559
Foreign			
Current	34,975	73,287	13,191
Deferred	5,308	(43,256)	(3,397)
	40,283	30,031	9,794
Total			
Current	176,026	71,193	12,287
Deferred	97,348	71,551	42,066
	$273,374	$142,744	$54,353

We continue to maintain a valuation allowance against certain deferred tax assets where realization is not certain. Due to the exhaustion of our U.S. federal net operating losses, we anticipate paying U.S. federal income taxes in the next twelve months. We continue to pay cash taxes in various U.S. states and foreign jurisdictions where we have operations and have utilized all of our net operating losses.

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At December 31, 2013, we have federal and state net operating loss carryforwards of $8,809 and $33,969, respectively. Included in the NOL's are state NOL's of $23,660 attributable to excess tax benefits from the exercise of non-qualified stock options. 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 2021 and 2032. We also have federal and state income tax credit carryforwards of $184,919 and $6,194, respectively. These income tax credits expire between 2014 and 2033. Additionally, included in these income tax credit carryforwards are federal income tax credit carryforwards of $6,049 attributable to excess tax benefits from the exercise of non-qualified stock options.

Certain stock option exercises resulted in tax deductions in excess of previously recorded benefits based on the option value at the time of grant. Although these additional tax benefits or "windfalls" are reflected in net operating loss carryforwards, pursuant to authoritative guidance, the additional tax benefit associated with the windfall is not recognized until the deduction reduces 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 will exempt the Company 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, $3,173 in 2012 and $2,506 in 2011.

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,		
	2013	2012	2011
U.S. federal statutory tax rate	35.0 %	35.0 %	35.0 %
State and local income taxes	3.3 %	1.7 %	2.5 %
Foreign income tax rate differential	(14.1)%	(6.7)%	(9.4)%
Income tax credits	(3.5)%	(0.4)%	(14.1)%
Foreign income subject to U.S. taxation	(10.3)%	0.2 %	3.4 %
Stock option compensation	1.1 %	0.7 %	1.0 %
State tax incentives	— %	(1.1)%	— %
Structuring related costs	— %	4.8 %	— %
Non-deductible acquisition related costs	— %	0.3 %	0.3 %
U.S. deferred taxes on foreign earnings	27.2 %	— %	— %
Other nondeductible and permanent differences	13.2 %	1.8 %	5.0 %
Provision (benefit) attributable to valuation allowances	— %	(0.4)%	— %
Effective income tax rate	51.9 %	35.9 %	23.7 %

As described further below, we recorded $95,800 of tax expense as a result of the centralization of our global supply chain and technical operations in Ireland and the related recognition of deferred tax liabilities.

The U.S. Federal tax credit for research and experimentation expenses 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.

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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.

In September 2011, we completed our assessment of the impact the election to claim federal foreign tax credits and the federal orphan drug credits would have on our historical tax returns. Based on this assessment, management elected to claim both the foreign tax credit for the tax year ended December 31, 2010 and orphan drug credit for the tax years ended December 31, 2010 and 2009. The net federal income tax benefit recorded during 2011 as a result of the election to claim the federal foreign tax credit for 2010 and the federal orphan drug credit for 2010 and 2009 was approximately $15,400.

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, 2013	December 31, 2012
Deferred tax assets:		
Net operating losses	$5,398	$8,519
Income tax credits	4,863	9,279
Stock compensation	33,539	25,140
Accruals and allowances	40,438	21,185
Intangible assets	3,418	639
	87,656	64,762
Valuation allowance	(1,934)	(2,941)
Total deferred tax assets	85,722	61,821
Deferred tax liabilities:		
Depreciable assets	(41,281)	(41,361)
Intangible assets	—	(369)
Unrealized gains	(134)	(1,045)
Investment in foreign partnership	(100,746)	—
Total deferred tax liabilities	(142,161)	(42,775)
Net deferred tax asset (liability)	$(56,439)	$19,046

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:

	2013	2012	2011
Beginning of period balance	$12,393	$9,773	$8,658
Increases for tax positions taken during a prior period	2,571	99	186
Decreases for tax positions taken during a prior period	(812)	(1,931)	(689)
Increases for tax positions taken during the current period	33,056	4,651	1,692
Decreases for tax positions related to settlements	(419)	(199)	(74)

Decreases for tax positions related to lapse of statute	(400)	—	—
	$46,389	$12,393	$9,773

The total amount of accrued interest and penalties was not significant as of December 31, 2013. The total amount of tax expense recorded during 2013 which related to unrecognized tax benefits was $7,897. Amounts recognized during 2012 and 2011 were 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.

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We expect $24,812 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, other than the $24,812 mentioned above, within the next year.

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. 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 unremitted 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.

12. Stock Options and Restricted Stock

At December 31, 2013, 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 vests over four years; however, performance-based restricted stock units have 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,		
	2013	2012	2011
Cost of sales	$3,214	$2,815	$2,375

Research and development	23,905	13,839	9,759
Selling, general and administrative	49,084	37,359	32,629
Total share-based compensation expense	76,203	54,013	44,763
Income tax effect	(28,652)	(20,188)	(17,290)
Total share-based compensation expense, net of tax	$47,551	$33,825	$27,473

Share-based compensation expense capitalized to inventory during the years ended December 31, 2013, 2012 and 2011 was $3,978, $2,838, and $2,954, respectively.

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As of December 31, 2013, there was $169,965 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 2.67 years.

Stock Options

A summary of the status of our stock option plans at December 31, 2013, 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, 2012	9,557	$35.92		
Granted	1,999	97.30		
Exercised	(2,481)	28.74		
Forfeited and canceled	(456)	65.04		
Outstanding at December 31, 2013	8,619	$50.69	6.66	$708,406
Vested and unvested expected to vest at December 31, 2013	8,520	$50.22	6.64	$704,223
Exercisable at December 31, 2013	5,154	$30.26	5.45	$528,955

Total intrinsic value of stock options exercised during the years ended December 31, 2013, 2012 and 2011 was $204,470, $308,009 and $114,712, 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, 2013, 2012 and 2011 was $32,249, $27,301 and $23,485, 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, 2013	December 31, 2012	December 31, 2011
Expected life in years	3.30 - 5.37	3.30 - 4.19	3.53 - 5.84
Interest rate	0.30% - 1.21%	0.45% - 0.78%	0.61% - 1.89%
Volatility	29.81% - 36.93%	29.82% - 38.57%	37.43% - 40.14%
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, 2013, 2012 and 2011 was $23.99, $24.04 and $15.46 per option, respectively.

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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, 2012	1,761	$51.39
Shares granted	967	95.06
Shares forfeited	(199)	68.07
Shares vested	(740)	36.07
Nonvested Restricted Stock at December 31, 2013	1,789	$78.63

Restricted stock awards granted in 2013 include 81 restricted stock units granted to senior management, which have both performance-based and service-based vesting conditions. The weighted average grant date fair value of these awards was $97.07. The number of performance-based restricted stock units granted represents the number of shares earned during the performance period, which ended on December 31, 2013, 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, 2013, 2012 and 2011 was $95.06, $82.13 and $44.25 per share, respectively. The total fair value of restricted stock vested during the years ended December 31, 2013, 2012 and 2011 was $26,679, $18,573 and $13,028, respectively.

13. 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.

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Share Repurchases

In November 2012, our Board of Directors authorized the repurchase of up to $400,000 of our common stock. This repurchase program does not have an expiration date and we are not obligated to acquire a particular number of shares. The program may be discontinued at any time at the Company's discretion. Under the program, we repurchased 758 and 130 shares of our common stock at a cost of $66,136 and $11,553 during the years ended December 31, 2013 and 2012, respectively. At December 31, 2013, there is a total of 322,311 remaining for repurchases under the program.

14. Other Comprehensive Income and Accumulated Other Comprehensive Income

The following table summarizes the changes in AOCI, by component, for the years ended December 31, 2013, 2012 and 2011:

	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, 2010	$(3,018)	$10	$(2,501)	$(1,631)	$(7,140)
Other comprehensive income before reclassifications	(1,386)	(10)	7,121	(1,328)	4,397
Amounts reclassified from other comprehensive income	221	—	6,701	—	6,922
Net other comprehensive income (loss)	(1,165)	(10)	13,822	(1,328)	11,319
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)

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The table below provides details regarding significant reclassifications from AOCI during the years ended December 31, 2013, 2012 and 2011:

Details about Accumulated Other Comprehensive Income Components	Amount Reclassified From Accumulated Other Comprehensive Income during the year ended December 31,			Affected Line Item in the Consolidated Statements of Operations
	2013	2012	2011	
Unrealized Gains (Losses) on Hedging Activity				
Effective portion of foreign exchange contracts	$20,569	$12,869	$(6,558)	Net product sales
Ineffective portion of foreign exchange contracts	(915)	(824)	(766)	Foreign currency loss
	19,654	12,045	(7,324)	
	(1,671)	(1,024)	623	Income tax provision
	$17,983	$11,021	$(6,701)	
Unrealized Gains (Losses) from Marketable Securities				
Realized gains (losses) on sale of securities	$(81)	$—	$—	Investment income
	(81)	—	—	
	30	—	—	Income tax provision
	$(51)	$—	$—	
Defined Benefit Pension Items				
Amortization of prior service costs and actuarial losses	$(421)	$(304)	$(242)	(a)
	(421)	(304)	(242)	
	36	26	21	Income tax provision
	$(385)	$(278)	$(221)	

(a) This AOCI component is included in the computation of net periodic pension benefit cost (see Note 16 for additional details).

15. 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.

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The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2013 and 2012, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

		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

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		Fair Value Measurement at December 31, 2012			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$803,550	$—	$803,550	$—
Other current assets	Foreign exchange forward contracts	$17,862	$—	$17,862	$—
Other assets	Foreign exchange forward contracts	$9,378	$—	$9,378	$—
Other current liabilities	Foreign exchange forward contracts	$5,539	$—	$5,539	$—
Other liabilities	Foreign exchange forward contracts	$4,521	$—	$4,521	$—
Other current liabilities	Acquisition-related contingent consideration	$2,668	$—	$—	$2,668
Contingent consideration	Acquisition-related contingent consideration	$139,002	$—	$—	$139,002

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.

Items 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 and our counterparties' credit risks. Based on these inputs, the derivative assets and liabilities are classified within Level 2 of the valuation hierarchy.

Items classified as Level 3 within the valuation hierarchy, consisting of contingent consideration liabilities related to acquisitions, were 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, 2013, 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 ranging from 5.3% to 6.2% for developmental milestones and a weighted average cost of capital ranging from 14% 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.

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Estimated 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, 2013, the fair value of acquisition-related contingent consideration was $142,676. The following table represents a roll-forward of our acquisition-related contingent consideration:

	December 31, 2013
Balance at beginning of period	$(141,670)
Milestone payments	3,000
Change in fair value	(4,006)
Balance at end of period	$(142,676)

16. Employee Benefit Plans

Deferred Compensation Plan

Effective June 15, 2013, we began sponsoring a nonqualified deferred compensation plan which allows certain highly-compensated employees to make voluntary deferrals of up to 80% of their base salary and incentive bonuses. The plan is designed to work in conjunction with the 401(k) plan and provides for a total combined employer match of up to 6% of an employee's eligible earnings, up to the IRS annual 401(k) contribution limitations. Employee deferrals and employer matching contributions under the plan began in the third quarter of 2013 and were not material for the year ended December 31, 2013.

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. For the years ended December 31, 2013, 2012 and 2011, we recorded matching contributions of approximately $6,360, $3,700, and $2,882 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, 2013	2012
Change in benefit obligation:		
Projected benefit obligation, beginning of year	$24,484	$19,009
Prior service cost	—	—
Service cost	5,413	4,733
Interest cost	504	464
Change in assumptions	2,643	1,064
Recognized actuarial net loss	3,701	496
Foreign currency exchange rate changes	573	221

Net transfers to (from) plan	848	(1,503)
Projected benefit obligation, end of year	$38,166	$24,484
Accumulated benefit obligation, end of year	$30,655	$19,345

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	December 31, 2013	2012
Change in plan assets:		
Fair value of plan assets, beginning of year	$16,006	$12,858
Return on plan assets	244	182
Employer contributions	3,811	2,920
Plan participants' contributions	1,523	1,163
Foreign currency exchange rate changes	895	386
Net transfers to (from) plan	848	(1,503)
Fair value of plan assets, end of year	$23,327	$16,006
Funded status at end of year	$(14,839)	$(8,478)

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, 2013 and the classification of each investment category within the fair value hierarchy with respect to the inputs used to measure fair value:

	December 31, 2013		December 31, 2012	
	Fair Value (Level 2)	as % of total plan assets	Fair Value (Level 2)	as % of total plan assets
Cash and cash equivalents	$1,470	6 %	$1,192	7 %
Equity security funds	9,237	40 %	4,769	30 %
Debt security funds	9,704	42 %	7,943	50 %
Real estate funds	2,916	12 %	2,102	13 %
	$23,327	100 %	$16,006	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, 2013, we have recorded a liability of $14,839 in other non-current liabilities and a charge to accumulated other comprehensive income, net of tax, of $11,502 related to an additional minimum liability.

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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,	
	2013	2012
Weighted average assumptions - Net Periodic Benefit Cost:		
Discount rate	2.0 %	2.3 %
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	2.1 %	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,		
	2013	2012	2011
Service cost	$5,413	$4,733	$4,540
Interest cost	504	464	449
Expected return on plan assets	(633)	(515)	(473)
Employee contributions	(1,523)	(1,163)	(1,056)
Amortization of prior service costs	9	9	9
Amortization and deferral of actuarial gain	410	217	305
Total net periodic benefit cost	$4,180	$3,745	$3,774

Other changes in plan assets and benefit obligations recognized in AOCI are as follows:

Amount included in AOCI - December 31, 2011	$(4,183)
Prior service cost	9
Net gain (loss) arising during the period	(566)
Change in assumptions	(1,074)
Amortization of net gain (loss)	295
Plan assets losses	(336)
Taxes	143
Amount included in AOCI - December 31, 2012	$(5,712)
Prior service cost	9
Net gain (loss) arising during the period	(3,710)
Change in assumptions	(2,657)
Amortization of net gain (loss)	412
Plan assets losses	(391)

Taxes	547
Amount included in AOCI - December 31, 2013	$(11,502)

The amount in accumulated other comprehensive income as of December 31, 2013 that is expected to be recognized as a component of the net periodic pension costs in 2014 is $886.

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We estimate that we will pay employer contributions of approximately $3,886 in 2014. The expected future cash flows to be paid in respect of the pension plans as of December 31, 2013 were as follows:

Year	
2014	$2,140
2015	1,960
2016	1,910
2017	2,020
2018	1,851
2019 to 2023	8,306

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:	2013	2012	2011
United States	$561,405	$400,483	$263,387
Europe	514,987	418,321	340,812
Asia Pacific (primarily Japan)	203,538	161,480	115,377
Other	271,416	153,830	63,855
	$1,551,346	$1,134,114	$783,431

	December 31,	
Long-lived assets (1):	2013	2012
United States	$190,791	$157,019
Europe	5,413	5,988
Other	4,905	2,622
	$201,109	$165,629

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

18. Subsequent Events

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 addition to the option agreement, we purchased $25,000 of preferred equity of Moderna LLC, Moderna's parent company.

In January 2014, we agreed to purchase a vialing facility in Athlone, Ireland. The closing of the acquisition is expected to occur during the first quarter of 2014 upon satisfaction of agreed upon closing conditions. Following closing and refurbishment of the facility, and after successful completion of the appropriate validation processes and regulatory approvals, such facility will become our first company-owned vialing facility for Soliris and other clinical and commercial products.

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19. Quarterly Financial Information (unaudited)

The following condensed quarterly financial information is for the years ended December 31, 2013 and 2012:

	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 (1)	51,552
Operating expenses	186,700	193,023	213,772	252,285 (2)
Operating income	116,972	137,691	135,275	138,072
Net income (loss)	$82,217	$95,885	$93,785	$(18,992)
Earnings (loss) per common share				
Basic	$0.42	$0.49	$0.48	$(0.10)
Diluted	$0.41	$0.48	$0.47	$(0.10)

	March 31	June 30	September 30	December 31
2012:				
Revenues	$244,733	$274,719	$294,136	$320,526
Cost of sales	28,268	31,613	(20,191) (3)	33,147
Operating expenses	146,427 (4)	159,401 (4)	171,608 (4) (5)	179,503 (4)
Operating income	70,038	83,705	142,719	107,876
Net income	$45,413	$36,258	$92,179	$80,972
Earnings per common share				
Basic	$0.24	$0.19	$0.48	$0.42
Diluted	$0.23	$0.18	$0.46	$0.40

(1) Included within cost of sales for the third quarter 2013 is expense of $9,181 resulting from the execution of a settlement agreement with Novartis in October 2013.

(2) 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.

(3) Included within cost of sales for the third quarter 2012 is a positive impact of $53,377 which was recognized to reduced our estimate for probable contingent liabilities as the result of the execution of a settlement and non-exclusive license agreement with a third party in October 2012.

(4) Included within operating expenses for each quarter of 2012 are acquisition-related employee costs and professional fees of $10,765, $2,840, $1,509, and $1,148, respectively, associated with the acquisition of Enobia.

(5) Included within operating expenses for the third quarter of 2012 is an impairment charge of $26,300 to write-down the value of an early stage, preclinical indefinite-lived intangible asset related to the Taligen acquisition.

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