ALEXION PHARMACEUTICALS INC
Form 10-K
February 08, 2016

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, 2015
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.)

100 College Street, New Haven, Connecticut 06510
(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

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, 2015, was $39,491,560,848.(1)

The number of shares of Common Stock outstanding as of February 3, 2016 was 225,291,331.

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 11, 2016, are incorporated by reference into Part III of this report.

1

(1) Excludes 7,551,963 shares of common stock held by directors and executive officers at June 30, 2015. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

Alexion Pharmaceuticals, Inc.
Table of Contents

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®, Strensiq® and Kanuma™ for approved indications and any expanded uses, timing and effect of sales of our products in various markets worldwide, pricing for our products, level of insurance coverage and reimbursement for our products, level of future product sales and collections, timing regarding development and regulatory approvals for our products in additional indications or in additional territories, the medical and commercial potential of additional indications for Soliris, failure to satisfactorily address the issues raised by the U.S. Food and Drug Administration (FDA) in the March 2013 Warning Letter and Form 483s issued by the FDA, 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 our products and our product candidates in the patient, physician and payer communities, the safety and efficacy of our products and our product candidates, estimates of the potential markets and estimated commercialization dates for our products and our product candidates around the world, sales and marketing plans, any changes in the current or anticipated market demand or medical need for our products or our product candidates, status of our ongoing clinical trials for our product candidates, commencement dates for new clinical trials, clinical trial results, evaluation of our clinical trial results by regulatory agencies, the adequacy of our pharmacovigilance and drug safety reporting processes, prospects for regulatory approval of our product candidates, need for additional research and testing, the uncertainties involved in the drug development process and manufacturing, performance and reliance on third party service providers, our future research and development activities, plans for acquired programs, our ability to develop and commercialize products with our collaborators, assessment of competitors and potential competitors, the outcome of challenges and opposition proceedings to our intellectual property, assertion or potential assertion by third parties that the manufacture, use or sale of our products infringes their intellectual property, estimates of the capacity of manufacturing and other service facilities to support our products 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 our products, delay of collection or reduction in reimbursement due to adverse economic conditions or changes in government and private insurer regulations and approaches to reimbursement, uncertainties surrounding government investigations, including our Securities and Exchange Commission (SEC) and U.S. Department of Justice (DOJ) investigations, the short and long term effects of other government healthcare measures, the effect of interest rate increases, and the effect of shifting foreign exchange rates. Words such as “anticipates,” “expects,” “intends,” “plans,” “believes,” “seeks,” “estim 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 SEC.

Item 1. BUSINESS.

(dollars and shares in thousands)

Overview

We are a biopharmaceutical company focused on serving patients with devastating and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products.

In our complement franchise, Soliris is the first and only therapeutic approved for patients with either paroxysmal nocturnal hemoglobinuria (PNH), a life-threatening and ultra-rare genetic blood disorder, or atypical hemolytic uremic syndrome (aHUS), a life-threatening and ultra-rare genetic disease. PNH and aHUS are two severe and ultra-rare disorders resulting from chronic uncontrolled activation of the complement component of the immune system.

In our metabolic franchise, we market Strensiq for the treatment of patients with Hypophosphatasia (HPP) and Kanuma for the treatment of patients with Lysosomal Acid Lipase Deficiency (LAL-D). HPP is a genetic ultra-rare disease characterized by defective bone mineralization that can lead to deformity of bones and other skeletal abnormalities. LAL-D is a serious, life threatening ultra-rare disease in which genetic mutations result in decreased activity of the Lysosomal Acid Lipase (LAL) enzyme leading to marked accumulation of lipids in vital organs, blood vessels and other tissues.

We are also evaluating additional potential indications for eculizumab in other severe and devastating diseases in which uncontrolled complement activation is the underlying mechanism, and we are progressing in various stages of development with additional product candidates as potential treatments for patients with severe and life-threatening rare disorders.

We were incorporated in 1992. In June 2015, we acquired all of the outstanding shares of common stock of Synageva BioPharma Corp. (Synageva), a publicly-held clinical-stage biotechnology company. The acquisition furthered our objective to develop and commercialize life-transforming therapies for an increasing number of patients with devastating and rare diseases.

Products and Development Programs

We focus our product development programs on life-transforming therapeutics for devasting and ultra-rare diseases for which current treatments are either non-existent or inadequate.

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 Registry	Phase IV
Strensiq (asfotase alfa)	Metabolic Disorders	Hypophosphatasia (HPP)	Commercial
		HPP Registry	Phase IV
Kanuma (sebelipase alfa)	Metabolic Disorders	Lysosomal Acid Lipase Deficiency (LAL-D)	Commercial
		LAL-D Registry	Phase IV

Soliris (eculizumab)

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.

Paroxysmal Nocturnal Hemoglobinuria (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). We continue to work with researchers to expand the base of knowledge in PNH and the utility of Soliris to treat patients with PNH. Soliris is approved for the treatment of PNH in the United States, Europe, Japan and in several other territories. 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. In April 2015, the European Commission (EC) approved an update to the European Union (EU) label that supports Soliris treatment for patients with PNH regardless of history of transfusion and additional updates to inform physicians to make treatment decisions based on elevated hemolysis and the presence of common symptoms associated with PNH. Additionally, Soliris has been granted orphan drug designation for the treatment of PNH in the United States, Europe,

Japan and several other territories.

Atypical Hemolytic Uremic Syndrome (aHUS)

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. Soliris is approved for the treatment of pediatric and adult patients with aHUS in the United States, Europe and Japan. In April 2015, the EC approved an update to the EU label for Soliris treatment for patients with aHUS that included new efficacy data which specifies that longer-term treatment with Soliris is associated with a greater proportion of patients achieving clinically significant benefits, including complete TMA response and hematologic normalization, as well as the importance of sustained Soliris therapy. In addition, the FDA and EC have granted Soliris orphan drug designation for the treatment of patients with aHUS.

Strensiq (asfotase alfa)

Hypophosphatasia (HPP)

HPP is an ultra-rare genetic and progressive metabolic disease in which patients experience devastating effects on multiple systems of the body, leading to debilitating or life-threatening complications. HPP is characterized by defective bone mineralization that can lead to deformity of bones and other skeletal abnormalities, as well as systemic complications such as profound muscle weakness, seizures, pain, and respiratory failure leading to premature death in infants.

Strensiq, a targeted enzyme replacement therapy, is the first and only approved therapy for patients with HPP, and is designed to directly address underlying causes of HPP by aiming to restore the genetically defective metabolic process, thereby preventing or reversing the severe and potentially life-threatening complications in patients with HPP. In July 2015, Japan’s Ministry of Health. Labour and Welfare (MHLW) approved Strensiq for the treatment of patients with HPP. On September 1, 2015, we announced that the EC granted marketing authorization for Strensiq for the treatment of patients with pediatric-onset HPP. On October 23, 2015, we announced that the FDA approved Strensiq for patients with perinatal-, infantile- and juvenile-onset HPP.

Kanuma (sebelipase alfa)

Lysosomal Acid Lipase Deficiency (LAL Deficiency or LAL-D)

LAL-D is a serious, life-threatening ultra-rare disease associated with premature mortality and significant morbidity. LAL-D is a chronic disease in which genetic mutations result in decreased activity of the LAL enzyme that leads to marked accumulation of lipids in vital organs, blood vessels, and other tissues, resulting in progressive and systemic organ damage including hepatic fibrosis, cirrhosis, liver failure, accelerated atherosclerosis, cardiovascular disease, and other devastating consequences.

Kanuma, a recombinant form of the human LAL enzyme, is the only enzyme-replacement therapy that is approved for the treatment for patients with LAL-D. On September 1, 2015, Alexion announced that the EC granted marketing authorization of Kanuma for long-term enzyme replacement therapy in patients of all ages with LAL-D. On December 8, 2015, we announced that the FDA approved Kanuma for the treatment of patients with LAL-D. In addition, a New Drug Application (NDA) for Kanuma has been submitted to Japan’s MHLW.

Clinical Development Program

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

Product	Development Area	Indication	Development Stage
Soliris (eculizumab)	Neurology	Myasthenia Gravis (MG)	Phase III
		Neuromyelitis Optica Spectrum Disorder (NMOSD)	Phase III
	Transplant	Delayed Kidney Transplant Graft Function (DGF)	Phase III
		Antibody Mediated Rejection (AMR) Presensitized Renal Transplant - Living Donor	Phase II
		Antibody Mediated Rejection (AMR) Presensitized Renal Transplant - Deceased Donor	Phase II
		Treatment of Antibody Mediated Rejection (AMR) Following Renal Transplantation*	Phase II
cPMP (ALXN 1101)	Metabolic Disorders	MoCD Type A	Phase II / III
ALXN 1007	Inflammatory Disorders	GI Graft versus Host Disease	Phase II
		Anti-phospholipid Syndrome	Phase II
SBC-103	Metabolic Disorders	Mucopolysaccharidoses IIIB (MPS IIIB)	Phase I / II
ALXN 1210	Next Generation Complement Inhibitor	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Phase I / II
ALXN 5500	Next Generation Complement Inhibitor		Phase I

* Investigator Initiated Trial

Soliris (eculizumab)

Neurology

Myasthenia Gravis (MG)

MG is an ultra-rare autoimmune syndrome characterized by complement activation leading to the failure of neuromuscular transmission. We have completed enrollment of patients in a Phase III multinational, placebo-controlled registration trial of eculizumab in patients with refractory generalized MG, and dosing continues. The FDA, EC and MHLW have granted orphan drug designation for eculizumab as a treatment for patients with MG.

Neuromyelitis Optica Spectrum Disorder (NMOSD)

NMOSD is a severe and ultra-rare autoimmune disease of the central nervous system (CNS) that primarily affects the optic nerves and spinal cord. Enrollment and dosing are ongoing in a global, randomized, double-blind, placebo-controlled to evaluate eculizumab as a treatment for patients with relapsing NMOSD. The FDA, EC, and MHLW have each granted orphan designation for eculizumab as a treatment for patients with NMOSD.

Transplant

Delayed Kidney Transplant Graft Function (DGF)

DGF is the term used to describe the failure of a kidney or other organs to function immediately after transplantation due to ischemia-reperfusion and immunological injury. Enrollment is complete in a single, multinational, placebo-controlled DGF registration trial and patient follow-up is ongoing. Eculizumab has been granted orphan drug designation for DGF by the FDA and the EC granted orphan drug designation to eculizumab for prevention of DGF after solid organ transplantation.

7

Antibody Mediated Rejection (AMR) in Presensitized Kidney Transplant Patients

AMR is the term used to describe a type of transplant rejection that occurs when the recipient has antibodies to the donor organ. Enrollment in a multi-national, multi-center controlled clinical trial of eculizumab in presensitized kidney transplant patients at elevated risk for AMR who received kidneys from deceased organ donors was completed in March 2013 and patient follow-up in the trial is continuing. In September 2013, researchers presented positive preliminary data from the eculizumab deceased-donor AMR kidney transplant study. In May 2015, new data from the Phase II single-arm deceased-donor transplant trial of eculizumab in prevention of acute AMR was presented and was consistent with previous positive reports.

In January 2015, we reported results from a randomized, open-label, multicenter Phase II clinical trial of eculizumab presensitized kidney transplant patients at an elevated risk of AMR who received kidneys from living donors. The primary composite endpoint of the trial did not reach statistical significance. Patient follow-up and data analyses are ongoing and based on discussions with regulators, we are developing plans for next steps for eculizumab in AMR. The EC granted orphan drug designation to eculizumab for the prevention of graft rejection following solid organ transplantation.

cPMP (ALXN 1101)

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

MoCD Type A is an ultra-rare metabolic disorder characterized by severe and rapidly progressive neurologic damage and death in newborns. MoCD Type A results from a genetic deficiency in cyclic Pyranopterin Monophosphate (cPMP), a molecule that enables the function of certain enzymes and the absence of which allows neurotoxic sulfite to accumulate in the brain. To date, there is no approved therapy available for MoCD Type A. There has been some early clinical experience with the recombinant cPMP replacement therapy in a small number of children with MoCD Type A, and we have completed enrollment in 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 form of cPMP replacement therapy in a Phase I healthy volunteer study is complete. In addition, we completed enrollment in a multi-center, multinational open-label clinical trial of synthetic cPMP in patients with MoCD Type A switched from treatment with recombinant cPMP. Activities have commenced for the Phase II/III pivotal open-label, single-arm trial of ALXN1101 for treatment-naïve neonates with MoCD Type A.

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. A proof-of-concept study in patients with an ultra-rare disorder, gastrointestinal graft versus host disease (GI-GVHD), is ongoing. Acute GI-GVHD is an immune-mediated disease and a complication of stem cell transplantation occurring in 10-12 percent of allogenic hematopoietic stem cell transplants. Patients with severe acute GI-GVHD have a 30-40 percent mortality rate within the first six months post-transplant. The study is evaluating patients with GI-GVHD following bone marrow or hematopoietic stem cell transplant experience engrafted hematopoietic cells that attack host gastrointestinal tissues in the first 100 days post-transplant causing damage to the GI tract, liver and skin. In December 2015, we announced that interim data from a Phase II study showed an overall 28 day acute GI-GVHD response rate of 80 percent, which supports the continued advancement of ALXN 1007 in GI-GVHD.

In addition, enrollment in a Phase II proof-of-concept study in patients with non-criteria manifestations of anti-phospholipid syndrome (APS) was discontinued early due to recruitment difficulties. The study is ongoing for initially enrolled patients. APS is an ultra-rare autoimmune, hypercoagulable state caused by antiphospholipid antibodies.

SBC-103

Mucopolysaccharidosis IIIB (MPS IIIB)

MPS IIIB is a rare, devastating and life-threatening disease which typically presents in children during the first few years of life. Genetic mutations result in decreased activity of the alpha-N-acetyl-glucosaminidase (NAGLU) enzyme, which leads to a buildup of abnormal amounts of heparan sulfate (HS) in the brain and throughout the body. Over time, this unrelenting systemic accumulation of HS causes progressive and severe cognitive decline, behavioral problems, speech loss, increasing loss

of mobility, and premature death. Current treatments are palliative for the behavioral problems, sleep disturbances, seizures, and other complications, and these treatments do not address the root cause of MPS IIIB or stop disease progression.

SBC-103, a recombinant form of natural human NAGLU is designed to replace the missing (or deficient) NAGLU enzyme. SBC-103 was granted orphan drug designation by the FDA in April 2013 and by the European Medicines Agency (EMA) in June 2013. It received Fast Track designation by the FDA in January 2015. In June 2015, the first-in-human trial of patients with MPS IIIB reached its targeted enrollment of nine patients, and the trial is ongoing. In December 2015, we announced interim data in the Phase I/II trial showing a dose-dependent reduction of heparin sulfate in cerebrospinal fluid across three dosing cohorts. Escalated dosing of SBC-103 will commence in the first half of 2016.

ALXN 1210

ALXN 1210 is a next-generation complement inhibitor in development for PNH and other indications. Phase I data from the first-in-human single-ascending dose study of ALXN 1210 was published in the journal Blood in December 2015. Results showed that ALXN 1210 was well-tolerated in healthy volunteers and the mean terminal half-life was extended to 32 days, compared to Soliris, which has a terminal half-life of 9 days. Based upon longer terminal half-life and healthy volunteer studies, ALXN 1210 is suitable for longer dosing intervals than Soliris. A multiple-ascending dose study of ALXN 1210 is ongoing to further evaluate the safety and efficacy of ALXN 1210. In addition, we have two ongoing clinical studies of ALXN 1210 in patients with PNH. Preliminary data in a Phase I/II dose-escalating study showed a rapid reduction of lactate dehydrogenase (LDH) following the initial dose. Alexion also has initiated an open-label, multi-dose Phase II study of ALXN 1210 in patients with PNH that is designed to measure change in LDH levels and safety in several dosing cohorts and intervals.

Manufacturing

We currently rely on internal manufacturing facilities and third party contract manufacturers, including Lonza Group AG and its affiliates (Lonza) to supply clinical and commercial quantities of our commercial products and product candidates. Our internal manufacturing facilities include our Rhode Island manufacturing facility (ARIMF), and facilities in Massachusetts and Georgia. We also utilize third party contract manufacturers for other manufacturing services including purification, product filling, finishing, packaging, and labeling.

We have various agreements with Lonza through 2028, with remaining total non-cancellable commitments of approximately $1,156,980. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangements. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at ARIMF and a payment with respect to sales of Soliris manufactured at Lonza facilities. During 2015, we entered into a new supply agreement with Lonza whereby Lonza will construct a new manufacturing facility dedicated to Alexion manufacturing at its existing Portsmouth, New Hampshire facility.

In addition to Lonza, we have non-cancellable commitments of approximately $36,400 through 2019 with other third party manufacturers.

In March 2013, we received a Warning Letter (Warning Letter) from the FDA regarding compliance with current Good Manufacturing Practices (cGMP) at ARIMF. The Warning Letter followed receipt of a Form 483 Inspectional Observations by the FDA in connection with an FDA inspection that concluded in August 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. As previously announced, the FDA issued Form 483s in August 2014 and August 2015 relating to observations at ARIMF. The inspectional observations from the August 2015 letter have since been closed out by the FDA. The observations are inspectional and do not represent a final FDA determination of compliance. We continue to manufacture products, including Soliris, in this facility. While the resolution of the issues raised in the Warning Letter is difficult to predict, we do not currently believe a loss related to this matter is probable or that the potential magnitude of such loss or range of loss, if any, can be reasonably estimated.

In April 2014, we purchased a fill/finish facility in Athlone, Ireland. Following refurbishment of the facility, and after successful completion of the appropriate validation processes and regulatory approvals, the facility will become our first company-owned fill/finish facility for our commercial and clinical products. In November 2015, the construction of office, laboratory and packaging facilities in Dublin, Ireland was completed. In May 2015, we announced plans to

construct a new biologics manufacturing facility on our existing property in Dublin, Ireland, which is expected to be completed by 2020.

Sales and Marketing

We have established a commercial organization to support current and future sales of our products in the United States, Europe, Japan, Asia Pacific countries, and other territories. Our sales force is small compared to that of other drugs with similar revenues; however, we believe that a relatively smaller sales force is appropriate to effectively market our products due to the incidence and prevalence of rare diseases. If we receive regulatory approval in new territories or for new products or indications, we may expand our own commercial organizations in such territories and market and sell our products through our own sales force in these territories. However, we evaluate each jurisdiction on a country-by-country basis, and, in certain territories, we promote our products 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 our products to governments and government agencies.

During 2015 and 2014, sales to our largest customer accounted for 18% of net product sales.

Because of factors such as the pricing of our products, the limited number of patients, the short period from product sale to patient use and the lack of contractual return rights, 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 18 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. During the period of market exclusivity an innovative product generally realizes most of its commercial value.

Patents provide the owner with a right to exclude others from practicing an invention. In our business, 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 for such delay certain countries will extend a patent’s term, subject to a number of factors and caps.

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

Soliris Exclusivity

With respect to Soliris, we own an issued U.S. patent that covers the eculizumab composition of matter and will expire in 2021, taking into account patent term extension. Soliris is also protected in the U.S. by regulatory data exclusivity until 2019

10

and by orphan drug exclusivity for treating aHUS until 2018. In Europe we have supplementary protection certificates that extend rights associated with a composition of matter patent until 2020 in certain countries. Soliris is also protected in Europe by orphan drug exclusivity until 2019 for PNH and until 2023 for aHUS. In addition to the foregoing patent and regulatory protections, we own pending patent applications that are directed to various aspects of using and making eculizumab and which may provide additional protection for Soliris.

Strensiq Exclusivity

With respect to Strensiq, we own an issued U.S. patent that covers the asfotase alfa composition of matter and will expire in 2026. We are applying for an extension of the U.S. patent term. Strensiq is also protected in the U.S. by orphan drug exclusivity until 2022 and by regulatory data exclusivity until 2027. In Europe, we own two issued patents that cover the asfotase alfa composition of matter and will expire in 2025 and 2028. We are applying for supplementary protection certificates in the European countries. Strensiq is also protected in Europe by orphan drug exclusivity and regulatory data exclusivity until 2025. In other countries we own corresponding patents that will expire between 2025 and 2028, not including possible extensions.

Kanuma Exclusivity

With respect to Kanuma, we own issued patents in the U.S., Europe adn other countries that cover methods of using the product to treat LAL-D and will expire in 2031. The European patent is under challenge in an administrative opposition proceeding. An exclusively licensed composition of matter patent also protects Kanuma in certain European countries until it expires in 2021, though we are also applying for supplementary protection certificates in those countries. In the U.S. Kanuma also is protected by orphan drug exclusivity until 2022 and by regulatory data exclusivity until 2027. In Europe it is protected by orphan drug exclusivity and regulatory data exclusivity until 2025.

Soliris, Strensiq, and Kanuma Regulatory Protection

As noted above, for each of Soliris, Strensiq and Kanuma 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.

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.

License and Collaboration Agreements

In March 2015, we entered into an agreement with a third party that allowed us to exercise an option with another third party for exclusive, worldwide, perpetual license rights to a specialized technology and other intellectual property, and we simultaneously exercised the option. Due to the early stage of these assets, we recorded expense for the payments of $47,000 during the first quarter 2015.

In March 2015, we entered into a collaboration agreement with a third party that allows us to identify and optimize drug candidates. Alexion will have the exclusive worldwide rights to develop and commercialize products arising from the collaboration. Due to the early stage of the assets we are licensing in connection with the collaboration, we recorded expense for the upfront payment of $15,000 during the first quarter 2015. In addition, we could be required to pay up to an additional $250,750 if certain development, regulatory, and commercial milestones are met over time, as well as royalties on commercial sales.

In January 2015, we entered into a license agreement with a third party to obtain an exclusive research, development and commercial license for specific therapeutic molecules. Due to the early stage of these assets, we recorded expense for the upfront payment of $50,000 during the first quarter 2015. In addition, we could be required to pay up to an additional $822,000 if certain development, regulatory, and commercial milestones are met over time, as well as royalties on commercial sales.

In December 2014, we entered into an agreement with X-Chem Pharmaceuticals (X-Chem) that allows us to identify novel drug candidates from X-Chem's proprietary drug discovery engine. Alexion will have the exclusive worldwide rights to develop and commercialize up to three targets arising from the collaboration. Due to the early stage of these

assets, we recorded expense for an upfront payment of $8,000. In addition, for each drug target, to a maximum of three targets, we could be

required to make additional payments upon the achievement of specified research, development and regulatory milestones up to $75,000, as well as royalties on commercial sales.

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

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

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

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®, Strensiq® and Kanuma™, 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. Our three approved products are regulated by the FDA as biologics. Biologics require the submission of a Biologics License Application (BLA) and approval by the FDA prior to being marketed in the United States. In the case of Kanuma, which is derived from egg whites from select hens, we also submitted a New Animal Drug Application (NADA) for approval by the FDA. Manufacturers of biologics and drugs derived from animal origin 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 investigational new drug (IND) application for human clinical testing, which must become effective before human clinical trials may commence;

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

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

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

(6) FDA review and approval of the BLA or supplemental BLA.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological animal studies to assess the potential safety and efficacy of the product candidate. Preclinical safety tests

intended for submission to FDA must be conducted in compliance with FDA's Good Laboratory Practice (GLP) regulations and the United States Department of Agriculture's Animal Welfare Act. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application 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. FDA may stop the clinical trials by placing them on "clinical hold" because of concerns about the safety of the product being tested, or for other reasons.

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

Clinical trials are typically conducted in three sequential phases, but the phases may overlap and different trials may be initiated with the same drug candidate within the same phase of development in similar or differing patient populations. Phase I studies may be conducted in a limited number of patients, but are usually conducted in healthy volunteer subjects. The drug is usually tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmaco-dynamics and pharmaco-kinetics. Phase II usually involves studies in a larger, but still limited patient population to evaluate preliminarily the efficacy of the drug candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible short-term adverse effects and safety risks. Phase III trials are undertaken to gather additional information to evaluate the product's overall risk-benefit profile, and to provide a basis for physician labeling. Phase III trials evaluate clinical efficacy of a specific endpoint and test further for safety within an expanded patient population at geographically dispersed clinical study sites. Phase I, Phase II or Phase III testing might not be completed successfully within any specific time period, if at all, with respect to any of our product candidates. Results from one trial are not necessarily predictive of results from later trials. Furthermore, the FDA, sponsor or institutional review board may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

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

There are proposals to expand these registration requirements to additional studies.

The results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the product and proposed labeling for the product, are submitted to the FDA as part of a BLA requesting approval to market the product candidate for a proposed indication. Under the Prescription Drug User Fee Act, as amended, the fees payable to the FDA for reviewing a BLA, as well as annual fees for commercial manufacturing establishments and for approved products, can be substantial. The BLA review fee alone can exceed $2,000 subject to certain

limited deferrals, waivers and reductions that may be available. Each BLA submitted to the FDA for approval is typically reviewed for administrative completeness and reviewability within 60 days following submission of the application. If the FDA finds the BLA sufficiently complete, the FDA will “file” the BLA, thus triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. FDA performance goals provide for action on an application within 12 months of submission. The FDA, however, may not approve a drug within these established goals and its review goals are subject to change from time to time because the review process is often significantly extended by FDA requests for additional information or clarification. As part of its review, the FDA may refer the BLA to an advisory committee composed of outside experts for evaluation and a recommendation as to whether the application should be approved. Although the FDA is not bound by the recommendation of an advisory committee, the agency usually has followed such recommendations. Further, the outcome of the review, even if generally favorable, may not be an actual approval but instead a “complete response letter” communicating the FDA's decision not to approve the application, outlining the deficiencies in the BLA, and identifying what information and/or data (including additional pre-clinical or clinical data) is required before the application can be approved. Even if such additional information and data are submitted, the FDA may decide that the BLA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we do.

Before approving a BLA, the FDA typically will inspect the facilities at which the product is manufactured and will not approve the product unless the facilities comply with the FDA’s cGMP requirements. The FDA may deny approval of a BLA if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can delay the approval process. FDA approval of any application may include many delays or never be granted. If a product is approved, the approval will impose limitations on the indicated uses for which the product may be marketed, may require that warning statements be included in the product labeling, and may require that additional studies be conducted following approval as a condition of the approval. FDA also may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a Risk Evaluation Mitigation Strategies (REMS), or otherwise limit the scope of any approval. A REMS may include various elements, ranging from a medication guide to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. To market a product for other indicated uses, or to make certain manufacturing or other changes, requires FDA review and approval of a BLA Supplement or new BLA and the payment of applicable review fees. 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. 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. Under the BPCI, innovator manufacturers of original reference biological products are granted 12 years of exclusive use before biosimilar versions of such products can be licensed for marketing in the United States. This means that the FDA may not approve an application for a biosimilar version of a reference biological product until 12 years after the date of approval of the reference biological product (with a potential six-month extension of exclusivity if certain pediatric studies are conducted and the results reported to FDA), although a biosimilar application may be submitted four years after the date of licensure of the reference biological product. Additionally, the BPCI establishes procedures by which the biosimilar applicant must provide information about its application and product to the reference product sponsor, and by which information about potentially relevant patents is shared and litigation over patents may proceed in advance of approval. The BPCI also provides a period of exclusivity for the first biosimilar to be determined by the FDA to be interchangeable with the reference product.

FDA has released guidance documents interpreting the BPCI in each of the last four years. These guidance documents, among other things, elaborate on the definition of a biosimilar as a biological product that is highly similar to an already approved biological product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biosimilar and the approved biological product in

terms of the safety, purity, and potency. More recently, FDA has released guidance on the assignment of nonproprietary, clearly distinguishable product names for both biologic and biosimilar products.

The FDA approved the first biosimilar product under the BPCI in 2015, and the agency continues to refine the procedures and standards it will apply in implementing this approval pathway. We anticipate that contours of the BPCI will continue to be defined as the statute is implemented over a period of years. This likely will be accomplished by a variety of means, including

FDA issuance of guidance documents, proposed regulations, and decisions in the course of considering specific applications. 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, and in the case of Kanuma, the NADA, 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 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 take regulatory action, including fines, recalls, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Accordingly, manufacturers must continue to spend time, money, and effort to maintain cGMP compliance.

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

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

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

Medicinal products: (a) that are used to treat or prevent life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the European Union; or (b) that are used to treat or prevent life-threatening or chronically debilitating conditions and that, for economic reasons, would be unlikely to be developed without incentives; and (c) where no satisfactory method of diagnosis, prevention or treatment of the condition concerned exists, or, if such a method exists, the medicinal product would be of significant benefit to those affected by the condition, may be granted an orphan designation in the European Union. The application for orphan designation must be submitted to the EMA and approved before an application is made for marketing authorization for the product. Once authorized, orphan medicinal products are entitled to ten years of market exclusivity. During this ten year period, with a limited number of exceptions, neither the competent authorities of the

European Union member states, the EMA, or the European Commission are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this latter product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity. Soliris has received orphan drug designation for (a) the treatment of PNH and aHUS in the United States, the European Union, and in several other territories; (b) the prevention of delayed graft function in renal transplant patients in the United States; (c) the treatment of patients with myasthenia gravis in the United States, Japan, and the European Union; and (d) the prevention of graft rejection and delayed graft rejection following solid organ transplantation in the European Union. In 2008, Strensiq received orphan drug designation for the treatment of patients with HPP in the United States and the European Union, and in Japan in November 2014. Furthermore, in 2010, Kanuma received orphan drug designation for the treatment of LAL-D in the United States and the European Union. Orphan drug designation provides certain regulatory and filing fee advantages, including market exclusivity, except in limited circumstances, for several years after approval.

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 Strensiq for HPP in perinatal-, infant-, and juvenile-onset patients; for Kanuma in the treatment of LAL-D presenting in infants; and for 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 including governing human clinical trials, marketing approval, and post-marketing regulation for drugs. The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above, as well as additional country-specific regulations. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The approval process varies from country to country, can involve additional testing beyond that required by FDA, and may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country.

Under the European Union regulatory system, we may submit applications for marketing authorizations either under a centralized, decentralized, or mutual recognition marketing authorization procedure. The centralized procedure provides for the grant of a single marketing authorization for a medicinal product by the European Commission on the basis of a positive opinion by the EMA. A centralized marketing authorization is valid for all European Union member states and three of the four EFTA States (Iceland, Liechtenstein and Norway). The decentralized procedure

and the mutual recognition procedure apply between European Union member states. The decentralized marketing authorization procedure involves the submission of an application for marketing authorization to the competent authority of all European Union member states in which the product is to be marketed. One national competent authority, selected by the applicant, assesses the application for marketing authorization. The competent authorities of the other European Union member states are subsequently required to grant marketing authorization for their territory on the basis of this assessment, except where grounds of potential serious risk to

public health require this authorization to be refused. The mutual recognition procedure provides for mutual recognition of marketing authorizations delivered by the national competent authorities of European Union member states by the competent authorities of other European Union member states. The holder of a national marketing authorization may submit an application to the competent authority of a European Union member state requesting that this authority recognize the marketing authorization delivered by the competent authority of another European Union member state for the same medicinal product.

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

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

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

Pharmaceutical Pricing and Reimbursement

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

Medicare is a U.S. federal government insurance program that covers individuals aged 65 years or older, as well as individuals of any age with certain disabilities, and individuals with End-Stage Renal Disease. The primary Medicare programs that may affect reimbursement for Soliris are Medicare Part B, which covers physician services and outpatient care, and Medicare Part D, which provides a voluntary outpatient prescription drug benefit. Medicare Part B provides limited coverage of certain outpatient drugs and biologicals that are reasonable and necessary for diagnosis or treatment of an illness or injury. Under Part B, reimbursement for most drugs is based on a fixed percentage above the applicable product’s average sales price (ASP). Manufacturers calculate ASP based on a statutory formula and must report ASP information to the Centers for Medicare and Medicaid Services (CMS), the federal agency that administers Medicare and the Medicaid Drug Rebate Program, on a quarterly basis. The current reimbursement rate for drugs and biologicals 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 is a prescription drug benefit available to all Medicare beneficiaries. It is a voluntary benefit that is implemented through private plans under contractual arrangements with the federal government. Similar to pharmaceutical coverage through private health insurance, Part D plans negotiate discounts from drug manufacturers. Medicare Part D coverage is available through private plans, and the list of prescription drugs covered by Part D plans varies by plan. However,

individual plans are required by statute to cover certain therapeutic categories and classes of drugs or biologicals and to have at least two drugs in each unique therapeutic category or class, with certain exceptions.

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

Beginning April 1, 2013, the Budget Control Act of 2011, Pub. L. No. 112-25, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240, required Medicare payments for all items and services, including drugs and biologicals, to be reduced by 2% under sequestration (i.e., automatic spending reductions). Subsequent legislation extended the 2% reduction, on average, to 2025. This 2% reduction in Medicare payments affects all Parts of the Medicare program and could impact sales of our products.

Medicaid is a government health insurance program for low-income children, families, pregnant women, and people with disabilities. It is jointly funded by the federal and state governments, and it is administered by individual states within parameters established by the federal government. Coverage and reimbursement for drugs and 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, under which we are required to pay a rebate to each state Medicaid program for quantities of our products that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our products under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS. These data include the average manufacturer price and the best price for each product we sell. As further described below under "U.S. Healthcare Reform and Other U.S. Healthcare Laws," the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the PPACA), made significant changes to the Medicaid Drug Rebate Program that could negatively impact our results of operations.

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

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

beneficiaries. The rebates are calculated as the difference between Annual Non-FAMP and FCP.

Payers also are increasingly considering new metrics as the basis for reimbursement rates, such as ASP, average manufacturer price, and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug

Acquisition Cost, or NADAC, files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payers to cover our products.

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

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

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

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. Moreover, the requirements governing drug pricing and reimbursement 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. Some 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 reference pricing, basing the price or reimbursement level in their territory either, on the pricing and reimbursement levels in other countries, or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Furthermore, some European Union member states impose direct or indirect controls on the profitability of the company placing the medicinal product on the market.

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 national healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA may 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 between European Union member states in pricing and reimbursement decisions and negatively impact price in at least some European Union member states.

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

Fraud and Abuse

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

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully soliciting, offering, receiving, or paying any remuneration, directly or indirectly, in cash or in kind, to induce or reward purchasing, ordering or arranging for or recommending the purchase or order of any item or service for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. Liability may be established without a person or entity having actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. This statute has been interpreted to apply broadly to arrangements between pharmaceutical manufacturers on the one hand and prescribers, patients, purchasers and formulary managers on the other. In addition, PPACA amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. A conviction for violation of the Anti-kickback Statute requires mandatory exclusion from participation in federal health care programs. 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 those activities may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor.

- The federal civil False Claims Act (FCA) prohibits, among other things, knowingly presenting, or causing to be presented claims for payment of government funds that are false or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to such a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. This statute also 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 investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as 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; engaging in promotion for “off-label” uses; and submitting inflated best price information to the Medicaid Rebate Program.

- The federal False Statements Statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using

any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items, or services.

- The federal Civil Monetary Penalties Law authorizes the imposition of substantial civil monetary penalties against an entity, such as a pharmaceutical manufacturer, that engages in activities including, among others (1) knowingly

presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment.

- The majority of states also have statutes similar to the federal anti-kickback law and false claims laws that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

- The federal Open Payments program requires manufacturers of products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, to track and report annually to the federal government (for disclosure to the public) certain payments and other transfers of value made to physicians and teaching hospitals. In addition, several U.S. states and localities have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, and/or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Other state laws prohibit certain marketing-related activities including the provision of gifts, meals or other items to certain health care providers. Many of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.
- Sanctions under federal and state fraud and abuse laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, monetary damages, criminal fines, and imprisonment.
- Federal and state authorities are continuing to devote significant attention and resources to enforcement of fraud and abuse laws within the pharmaceutical industry, and private individuals have been active in alleging violations of the law and bringing suits on behalf of the government under the FCA. For example, federal enforcement agencies recently have investigated certain pharmaceutical companies' product and patient assistance programs, including manufacturer reimbursement support services and relationships with specialty pharmacies. Some of these investigations have resulted in significant civil and criminal settlements. Moreover, the Office of Inspector General for the U.S. Department of Health and Human Services has refined its guidance with respect to manufacturer grants to independent charitable foundations that provide financial support to financially needy patients, and has issued new or revised advisory opinions containing updated guidance on the government's view of such programs. Efforts to ensure that our business arrangements continue to comply with applicable healthcare laws and regulations could be costly.

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

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

PPACA contains several provisions that have or could potentially impact our business. PPACA made significant changes to the Medicaid Drug Rebate Program. Effective March 23, 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. With regard to the amount of the rebates owed, PPACA increased the minimum Medicaid rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, PPACA and subsequent legislation changed the definition of average manufacturer price. On January 21, 2016, CMS issued final regulations to implement the changes to the

Medicaid Drug Rebate Program under PPACA. These regulations become effective on April 1, 2016. We are evaluating the impact of these regulations on our business and operations. . Finally, PPACA requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2016 (and set to increase in ensuing years), based on the dollar value of its branded prescription drug sales to certain

federal programs identified in the law. Sales of “orphan drugs” are excluded from this fee. “Orphan drugs” are specifically defined for purposes of the fee. For each indication approved by the FDA for the drug, such indication must have been designated as orphan by the FDA under section 526 of the FDCA, an orphan drug tax credit under section 45C of the Internal Revenue Code must have been claimed with respect to such indication, and such tax credit must not have been disallowed by the Internal Revenue Service. Finally, the FDA must not have approved the drug for any indication other than an orphan indication for which a section 45C orphan drug tax credit was claimed (and not disallowed).

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

PPACA also expanded the Public Health Service’s 340B drug pricing discount program. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. PPACA expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by PPACA. PPACA exempts “orphan drugs”-those designated under section 526 of the FDCA, such as our products-from the ceiling price requirements for these newly-eligible entities.

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

Other Regulations

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

Recent years have seen a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the DOJ and the SEC, increased enforcement activity by non-U.S. regulators, and increases in criminal and civil proceedings brought against companies and individuals. Increasing regulatory scrutiny of the promotional activities of pharmaceutical companies also has been observed in a number of EU member states.

Similar strict restrictions are imposed on the promotion and marketing of drug products in the EU, where a large portion of our non-U.S. business is conducted, and other territories. Laws in the EU, including in the individual EU

member states, require promotional materials and advertising for drug products to comply with the product's Summary of Product Characteristics (SmPC), which is approved by the competent authorities. Promotion of a medicinal product which does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the EU and in other territories. The promotion of medicinal products that are not subject to a marketing authorization is also prohibited in the EU. Laws in the EU, including in the individual EU member states, also prohibit the

direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU and in other territories could be penalized by administrative measures, fines and imprisonment.

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

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

Soliris is currently the only approved therapy for the treatment of PNH and aHUS. We are in advanced clinical studies of Soliris for the treatment of other indications, and there are currently no competitors for the patient segments we target. Strensiq is currently the only product approved for the treatment of HPP and Kanuma is the only product approved for the treatment of LAL-D. Many pharmaceutical and biotech companies have publicly announced intention to establish or develop rare disease programs that may be competitive with ours. We also experience competition in drug development from universities and other research institutions, and pharmaceutical companies compete with us to attract universities and academic research institutions as drug development partners, including for licensing their proprietary technology. Some of these entities may have:

- greater financial and other resources;
- larger research and development staffs;
- lower labor costs; and/or
- more extensive marketing and manufacturing organizations.

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

We compete with large pharmaceutical companies that produce and market synthetic compounds and with specialized biotechnology firms in the United States, Europe and in other countries and regions, as well as a growing number of large pharmaceutical companies that are developing biotechnology products. A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us. Other companies have initiated clinical studies for the treatment of PNH, aHUS, AMR, DGF, MG and NMOSD, and we are aware of companies that are planning to initiate studies for diseases we are also targeting. In the future, our products may also compete with biosimilars.

Several biotechnology and pharmaceutical companies 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 or have had programs to develop complement inhibitor therapies. Soliris is the only therapy that has demonstrated to be safe and effective in two clinical indications by regulators in many jurisdictions around the world.

Employees

As of December 31, 2015, we had 2,924 full-time, world-wide employees, of which 1,200 were engaged in research, product development, manufacturing, and clinical development, 1,131 in sales and marketing, and 593 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, 2016 are as follows:

Name	Age	Position with Alexion
David L. Hallal	49	Chief Executive Officer
Clare Carmichael	56	Executive Vice President and Chief Human Resources Officer
Saqib Islam	46	Executive Vice President and Chief Strategy and Portfolio Officer
Martin Mackay	59	Executive Vice President and Global Head of Research and Development
John B. Moriarty, J.D.	48	Executive Vice President and General Counsel
Julie O'Neill	49	Executive Vice President of Global Operations
Vikas Sinha, M.B.A., C.A., C.P.A.	52	Executive Vice President and Chief Financial Officer
Carsten Thiel, Ph.D.	52	Executive Vice President and Chief Commercial Officer
Edward Miller	51	Senior Vice President and Global Chief Compliance Officer
Heidi L. Wagner, J.D.	51	Senior Vice President, Global Governmental Affairs

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

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

Saqib Islam has been at Alexion since April 2013 and has served as Executive Vice President, Chief Strategy and Portfolio Officer since February 2015. From April 2013 to February 2015 Mr. Islam served as Senior Vice President, Chief Strategy and Portfolio Officer. 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.

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

and key related R&D functions. From April 1995 to May 2010, he held various positions of increasing responsibility at Pfizer, including President, Head of Pfizer Pharmatherapeutics, R&D, where he oversaw all aspects of small molecule discovery and development across multiple therapeutic areas. Dr. Mackay has also worked in the CIBA organization, now Novartis, and held positions within academia. Dr. Mackay received a Microbiology First Class Honors Degree from Heriot-Watt University, Scotland, and a Ph.D. in Molecular Genetics from the University of Edinburgh, Scotland.

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

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

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

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

Edward Miller has been Senior Vice President and Global Chief Compliance Officer since joining Alexion in September 2014. Prior to joining Alexion, Mr. Miller served in various compliance and legal leadership positions at

Boehringer Ingelheim from 2000 to August 2014, including Vice President, Associate General Counsel, Global Head of Litigation and Government Investigations; Vice President and Acting Global Compliance Officer and Vice President, Chief Compliance Officer and Head of Litigation. Prior to Boehringer Ingelheim, Mr. Miller was a Senior Trial Attorney at the U. S. Department of Justice in Washington, D.C. Mr. Miller received a Bachelor's Degree from Princeton University and his J.D. from Rutgers University School of Law.

Heidi L. Wagner, J.D., has been with Alexion since September 2009 and has served as Senior Vice President, Global Governmental Affairs since September 2012. From September 2009 to September 2012, Ms. Wagner served as Vice President, Global Government Affairs. Prior to joining Alexion, Ms. Wagner was the Sr. Director of Governmental Affairs for Genentech,

and also consulted for a variety of health plans, biopharmaceutical and other health care-related companies. Ms. Wagner received a Bachelor of Science degree in Journalism and Mass Communication from the University of Colorado in Boulder, and a law degree from the George Mason University School of Law in Virginia.

Available Information

Our internet website address is http://www.alexion.com. Through our website, we make available, free of charge, our Annual Reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, any amendments to those reports, proxy and registration statements, and all of our insider Section 16 reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission (SEC). These SEC reports can be accessed through the “Investors” section of our website. The information found on our website is not part of this or any other report we file with, or furnish to, the SEC. Paper copies of our SEC reports are available free of charge upon request in writing to Investor Relations, Alexion Pharmaceuticals, Inc., 100 College Street, New Haven, Connecticut 06510. In addition, any document we file may be inspected, without charge, at the SEC’s public reference room at 100 F Street NE, Washington, DC 20549, or at the SEC’s internet address at http://www.sec.gov. (This website address is not intended to function as a hyperlink, and the information contained in the SEC’s website is not intended to be a part of this filing). Information related to the operation of the SEC’s public reference room may be obtained by calling the SEC at 800-SEC-0330 (800-732-0330).

Item 1A. Risk Factors.
(amounts in thousands, except percentages)
You should carefully consider the following risk factors before you decide to invest in Alexion and our business because these risk factors may have a significant impact on our business, operating results, financial condition, and cash flows. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of the following risks actually occurs, our business, financial condition and results of operations could be materially and adversely affected.
Risks Related to Our Products
We depend heavily on the success of our lead product, Soliris. If we are unable to increase sales of Soliris, or sales of Soliris are adversely affected, our business may be materially harmed.
Currently, our ability to generate revenues depends primarily on the commercial success of Soliris and whether physicians, patients and health care payers view Soliris as therapeutically effective and safe relative to cost. Since we launched Soliris in the United States in 2007, essentially all of our revenue has been attributed to sales of Soliris. In 2015, we received marketing approval in the United States, the European Union and Japan, of our second marketed product, Strensiq, for the treatment of HPP. We also received marketing approval in 2015 in the United States and the European Union for our third product, Kanuma, for the treatment of LAL-D. However, we anticipate that Soliris product sales will continue to contribute a significant percentage of our total revenue over the next several years.
The commercial success of Soliris and our ability to generate and increase revenues depends on several factors, as discussed in greater detail below, including safety and efficacy of Soliris, coverage or reimbursement by government or third-party payers, pricing, manufacturing and uninterrupted supply, the introduction of and success of competing products, the size of patient populations and the number of patients diagnosed who may be treated with Soliris, adverse legal, administrative, regulatory or legislative developments, and our ability to develop, register and commercialize Soliris for new indications.
If we are not able to increase revenues from sales of Soliris, or our revenues do not grow as anticipated, our results of operations and stock price could be adversely affected.
Our future commercial success depends on gaining regulatory approval for new products and obtaining approvals for existing products for new indications.
Our long-term success and revenue growth will depend upon the successful development of new products and technologies from our research and development activities, including those licensed or acquired from third parties and approval of additional indications for our existing products. Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. 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. Our ability to grow revenues would be adversely affected if we are delayed or unable to successfully develop the products in our pipeline, including Soliris for additional indications, obtain marketing approval for Strensiq and Kanuma in additional territories or acquire or license products and technologies from third parties.
We dedicate significant resources to the worldwide development, manufacture and commercialization of our products. We cannot guarantee that any marketing application for our product candidates will be approved or maintained in any country where we seek marketing authorization. If we do not obtain regulatory approval of new products or additional indications for existing products, or are significantly delayed or limited in doing so, our revenue growth will be adversely affected, we may experience surplus inventory, our business may be materially harmed and we may need to significantly curtail operations.

Sales of our products depend on reimbursement government health administration authorities, private health insurers and other organizations. If we are unable to obtain, or maintain at anticipated levels, reimbursement for our products, or coverage is reduced, 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 our products on a profitable basis or our profitability may be reduced if we are required to sell our products at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. Our products are significantly more expensive than traditional drug treatments and almost all patients require some form of third party coverage

to afford its cost. We depend, to a significant extent, on governmental payers, such as Medicare and Medicaid in the United States or country specific governmental organizations in foreign countries, and private third-party payers to defray the cost of our products to patients. These entities may refuse to provide coverage and reimbursement, 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 certain countries where we sell or are seeking or may seek to commercialize our products, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control. We may be unable to timely or successfully negotiate coverage, pricing, and reimbursement on terms that are favorable to us, or such coverage, pricing, and reimbursement may differ in separate regions in the same country. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. As discussed above in the subsection entitled “Pharmaceutical Pricing and Reimbursement,” the requirements governing drug pricing vary widely from country to country, which may include a combination of distinct potential payers, including private insurance and governmental payers and a HTA assessment of medicinal products for pricing and reimbursement methodologies. Therefore, we may not successfully conclude the necessary processes and commercialize our products in every, or even most countries in which we seek to sell our products.

A significant reduction in the amount of reimbursement or pricing for our products in one or more countries may reduce our profitability and adversely affect our financial condition. 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. 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. In the U.S. for example, the price of drugs has come under intense scrutiny by the U.S. Congress. Third party payers decide which drugs they will pay for and establish reimbursement and co-payment levels. Government and other third-party payers are increasingly challenging the prices charged for health care products, examining the cost effectiveness of drugs in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement for prescription drugs. See additional discussion below under the headings "Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy and government initiatives that affect coverage and reimbursement of drug products may impact our business in ways that we cannot currently predict and these changes could adversely affect our business and financial condition" and "The credit and financial market conditions may aggravate certain risks affecting our business."

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. To the extent we are successful in developing Soliris for indications other than PNH and aHUS, the potential increase in the number of patients receiving Soliris may cause third-party payers to refuse coverage or reimbursement for Soliris for the treatment of PNH, aHUS or for any other approved indication, or provide a lower level of coverage or reimbursement than anticipated or currently in effect.

As discussed above in the subsection entitled "pharmaceutical Pricing and Reimbursement," 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 products may be subject to payer-driven restrictions. Additionally, U.S. payers are increasingly considering new metrics as the basis for reimbursement rates.

In countries where patients have access to insurance, their insurance co-payment amounts or other benefit limits may represent a barrier to obtaining or continuing Soliris. We have financially supported non-profit organizations that assist patients in accessing treatment for PNH and aHUS, including Soliris. Such organizations assist patients whose insurance coverage imposes 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 our products without

charge to patients who have no insurance coverage for drugs through related charitable purposes. We are not able to predict the financial impact of the support we may provide for these and other charitable purposes; however, substantial support could have a material adverse effect on our profitability in the future.

Our commercial success depends on obtaining and maintaining reimbursement at anticipated levels reimbursement for our products. It may be difficult to project the impact of evolving reimbursement mechanics on the willingness of payers to cover our products. If we are unable to obtain or maintain coverage, or coverage is reduced in one or more countries, our pricing may be affected or our product sales, results of operations or financial condition could be harmed.

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

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

If our products fail 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.

Manufacturing issues at our facilities or the facilities of our third party service providers could cause product shortages, stop or delay commercialization of our products, disrupt, delay our clinical trials or regulatory approvals, and adversely affect our business.

The manufacture of our products and our product candidates is highly regulated, complex and difficult, requiring a multi-step controlled process and even minor problems or deviations could result in defects or failures. We have limited experience manufacturing commercial quantities of Strensiq and Kanuma. Only a small number of companies have the ability and capacity to manufacture our products for our development and commercialization needs. Due to the highly technical requirements of manufacturing our products and the strict quality and control specifications, we and our third party providers may be unable to manufacture or supply our products despite our and their efforts. Failure to produce sufficient quantities of our products and product candidates could result in lost revenue, diminish our profitability, delay the development of our product candidates, or result in supply shortages for our patients, which may lead to lawsuits or could accelerate introduction of competing products to the market.

The manufacture of our products and product candidates is at high risk of product loss due to contamination, equipment malfunctions, human error, or raw material shortages. Deviations from established manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or manufacturing facilities, we may need to close our manufacturing facilities for an extended period of time to investigate and remediate the contaminant. The occurrence of any such event could adversely affect our ability to satisfy demand for any of our products, which could materially and adversely affect our operating results.

Many additional factors could cause production interruptions at our facilities or at the facilities of our third party providers, including natural disasters, labor disputes, acts of terrorism or war. 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 expect that the demand for Soliris will increase. We may underestimate demand for Soliris or any of our products, or experience product interruptions at Alexion's internal manufacturing facilities or a facility of a third party provider, including as a result of risks and uncertainties described in this report.

We and our third party providers are required to maintain compliance with cGMP and other stringent requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to supply our products and product candidates. Significant

noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.

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

we rely on two animal facilities to produce the starting material, and a single manufacturing facility to manufacture the drug product.

We depend on a very limited number of third party providers for supply chain services with respect to our clinical and commercial product requirements, including product filling, finishing, packaging, and labeling. Our third party providers operate as independent entities and we do not have control over any third party provider's compliance with our internal or external specifications or the rules and regulations of regulatory agencies, including the FDA, competent authorities or any other applicable regulations or standards.

Any difficulties or delays in our third party manufacturing, 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 our products from customers, cause us to lose revenue or incur penalties for failure to deliver product, make us postpone or cancel clinical trials, or cause our products to be recalled or withdrawn, such as the voluntary recalls that we initiated in 2013 and 2014 due to the presence of visible particles in a limited number of vials in specific lots. Even if we are able to find alternatives they may ultimately be insufficient for our needs. No guarantee can be made that regulators will approve additional third party providers in a timely manner or at all, or that any third party providers will be able to perform services for sufficient product volumes for any country or territory. Further, 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.

It can take longer than five years to build and validate a new manufacturing facility and it can take longer than three years to qualify and validate a new contract manufacturer. We are currently completing the build-out of a fill-finish facility in Ireland to support global distribution of Soliris and Alexion's other clinical and commercial products. To date, we have relied entirely on third party fill-finish providers and have never operated our own fill-finish facility. We also completed construction of a new facility in Dublin, Ireland in the fourth quarter of 2015, which is comprised of laboratories, packaging and warehousing operations and we intend to make significant further investment in this facility for the manufacture our products. We cannot guarantee that we will be able to successfully and timely complete the appropriate validation processes or obtain the necessary regulatory approvals, or that we will be able to perform the intended supply chain services at either of these facilities for commercial or clinical use.

Certain of the raw materials required in the manufacture and the formulation of our products are derived from biological sources. Such raw materials are difficult to procure and may be subject to contamination or recall. Access to and supply of sufficient quantities of raw materials which meet the technical specifications for the production process is challenging, and often limited to single-source suppliers. Finding an alternative supplier could take a significant amount of time and involve significant expense due to the nature of the products and the need to obtain regulatory approvals. The failure of these single-source suppliers to supply adequate quantities of raw materials for the production process in a timely manner may impact our ability to produce sufficient quantities of our products for clinical or commercial requirements. A material shortage, contamination, recall, or restriction on the use of certain biologically derived substances or any raw material used in the manufacture of our products could adversely impact or disrupt manufacturing.

In addition, Kanuma is a transgenic product. It is produced in the egg whites of genetically modified chickens who receive copies of the human lysosomal acid lipase gene to produce recombinant human lysosomal acid lipase. The facilities on which we rely to produce raw material for recombinant lyosomal acid lipase are the only animal facilities in the world that produces the necessary egg whites from transgenic chickens. Natural disasters, disease, such as exotic Newcastle disease or avian influenza, or other catastrophic events could have a significant impact on the supply of unpurified Kanuma, or destroy Alexion’s animal operations altogether. If our animal operations are disrupted or destroyed, it will be extremely difficult to set up another animal facility to supply the unpurified Kanuma. This would adversely affect our ability to satisfy demand for Kanuma, which could materially and adversely affect our operating results.

Any adverse developments affecting our manufacturing operations or the operations of our third-party providers could result in a product shortage of clinical or commercial requirements, withdrawal of our product candidates or any

approved products, shipment delays, lot failures, or product withdrawals or recalls. We may also have to write-off inventory and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Such manufacturing issues could increase our cost of goods, cause us to lose revenue, reduce our profitability or damage our reputation.

We operate in a highly regulated industry and if we or our third party providers fail to comply with United States and foreign regulations, we or our third party providers could lose our approvals to market our products or our product candidates, and our business would be seriously harmed.

We and our current and future partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by governmental authorities around the world, including the FDA, EMA, the competent authorities of the European Union member states, and MHLW. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or in the case of Kanuma, problems with animal operations, a regulatory agency may impose restrictions on that product, the manufacturing facility or us. For example, in March 2013, we received a Warning Letter from the FDA relating to compliance with FDA's cGMP requirements at ARIMF. We are working with the FDA to resolve the issues identified in the Warning Letter. Failure to address the FDA's concerns may lead the FDA or other regulatory authorities to take regulatory action, including fines, civil penalties, recalls, seizure of product, suspension of manufacturing operations, operating restrictions, injunctions, withdrawal of FDA approval, and/or criminal prosecution.

If we do not resolve outstanding concerns expressed by the FDA in the Warning Letter and the Form 483s to the satisfaction of the FDA, EMA or any other regulatory agency, or we or our third-party providers, including our product fill-finish providers, packagers and labelers, fail to comply fully with applicable regulations, then we may be required to initiate a recall or withdrawal of our products. Like our contract manufacturers' manufacturing operations, our animal operations will also be subject to FDA inspection to evaluate whether our animal husbandry, containment, personnel, and record keeping practices are sufficient to ensure safety and security of our transgenic chickens and animal products (e.g., eggs, waste, etc.). Our animal operations may also be subject to inspection by the United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA APHIS), the agency responsible for administering the Animal Welfare Act. Any failure to ensure safety and security of our transgenic chickens and/or animal products could result in regulatory action by the FDA or another regulatory body, including USDA APHIS.

The safety profile of any product continues to be closely monitored by the FDA and other foreign regulatory authorities after approval. Regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, finishing, filling, labeling, advertising, promotion, risk mitigation, adverse event reporting requirements, and export of biologics. For example, the risk management program established in 2007 upon the FDA's approval of Soliris for the treatment of PNH was replaced with a Risk Evaluation and Mitigation Strategy (REMS) program, approved by the FDA in 2010, and further revised in December 2015 concerning presecribing information regarding the level of fever needed to seek medical attention and reporting adverse events. Future changes to the Soliris REMS could be costly and burdensome to implement.

We are required to report any serious and unexpected adverse experiences and certain quality problems with our products to the FDA, the EMA, and other health agencies. We or any health agency may have to notify health care providers of any such developments. Non-compliance with safety reporting requirements could result in regulatory action that may include civil action or criminal penalties. Regulatory agencies inspect our pharmacovigilance processes, including our adverse event reporting. If regulatory agencies determine that we or other parties, including clinical trial investigators, have not complied with the applicable reporting or other pharmacovigilance requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including monetary fines, marketing authorization withdrawal and other penalties.

As a condition of approval for marketing our products, governmental authorities may require us to conduct additional studies. In connection with the approval of Soliris in the United States, EU 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. 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. Furthermore, in connection with the approval of Strensiq in the United States, we agreed to conduct a prospective observational study in treated patients to assess the long-term safety of Strensiq therapy and to develop complementary assays. Similarly, in connection with the approval of Kanuma in the United States, we have agreed to

conduct a long-term observational study of treated patients, either as a standalone study or as a component of the existing LAL Registry. In the EU, in connection with the grant of authorization for Strensiq, we agreed to conduct a multicenter, randomized, open-label, Phase 2a study of Strensiq in patients with HPP and to extend the studies ENB-008-10 and ENB-009-10 to provide efficacy data in patients 13 to 18 year-old of age. We also agreed to set up an observational, longitudinal, prospective, long-term registry of patients with HPP to collect information on the epidemiology of the disease, including clinical outcomes and quality of life, and to evaluate safety and effectiveness data in patients treated with Strensiq. In the United States, the FDA can also 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.

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

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

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

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

Our products and our product candidates treat patients with ultra-rare diseases. We generally test our products in only a small number of patients. For example, 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. As more patients use our products, 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 may also be discovered in connection with unapproved uses of our products, which may include administration of our products 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 our products 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, or as our products are 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, reformulate our products or make changes and obtain new approvals for our and our suppliers' manufacturing facilities. We may also experience a significant drop in potential sales, experience harm to our reputation and the reputation of our products in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales or substantially increase the costs and expenses of commercializing and marketing our products.

We may be sued by people who use our products, whether as a prescribed therapy, during a clinical trial, during an investigator initiated study, or otherwise. Many patients who use our products are already very ill. Any informed

consents or waivers obtained from people who enroll in our trials or use our products 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 our products or a product candidate, or to a product liability claim, may make it more difficult, or impossible, for us to market and sell. 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 our products already often have severe and advanced stages of disease and known as well as unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our products. Some patients treated with our products,

including patients who have participated in our clinical trials, have died or suffered potentially life-threatening diseases either during or after ending their treatments. Patients who delay or miss a dose or discontinue treatment may also experience complications, including death. 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 our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, 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 that our products receive or maintain.

For example, use of C5 Inhibitors, such as Soliris, is associated with an increased risk for certain types of infection, including meningococcal infection. 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. 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 our products could have a material adverse effect on our ability to sell our products.

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 our products.

We are marketing and selling our products ourselves in the United States, Europe, Japan and several other territories. Strensiq and Kanuma were approved in 2015, are in the early stages of commercial launch and are the second and third new product launches in Alexion's history. If we are unable to establish and/or expand our capabilities to sell, market and distribute our products, 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 our products. 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 our products. Establishing and maintaining sales, marketing and distribution capabilities are competitive, 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. Our competitors may also develop, manufacture and market products that are more effective or less expensive than ours, or reach the market first. We cannot guarantee that we will be successful in commercializing any of our products.

If we fail to comply with laws or regulations, we may be subject to investigations and civil or criminal penalties and our business could be adversely affected.

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 (FCA), the anti-kickback provisions of the federal Social Security Act, and other related federal laws and regulations. As discussed above in the subsection entitled “Fraud and Abuse,” the federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind to induce, or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any health care item or service reimbursable under

Medicare, Medicaid, or other federal health care programs. Liability may be established without a person or entity having actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. A conviction for violation of the Anti-kickback Statute requires mandatory exclusion from participation in federal health care programs. The majority of states also have statutes similar to the federal Anti-Kickback Statute and false claims laws that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. 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 scrutiny on a case-by-case basis. As discussed above in subsection entitled “Fraud and Abuse,” the FCA prohibits any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly

making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim. Pharmaceutical companies have been investigated and have reached substantial financial settlements with the Federal government under the FCA for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for uses that the FDA has not approved, or "off-label" uses; and submitting inflated best price information to the Medicaid Rebate Program. We seek to comply with the FCA laws, but we cannot assure that our compliance program, policies and procedures will always protect Alexion from acts committed by its employees or third-party distributors or service providers. Violations of U.S. federal and state fraud and abuse laws may result in criminal, civil and administrative sanctions, including fines, damages, civil monetary penalties and exclusion from federal healthcare programs (including Medicare and Medicaid).

Although physicians in the United States 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 our products for their approved uses. Although we believe our marketing materials and training programs for physicians do not constitute off-label promotion, 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 any of our products, it could request that we modify our training or promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal or state enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false or fraudulent claims for payment of government funds.

As discussed above in subsection entitled "Other Regulations," the EU imposes similar strict restrictions on the promotion and marketing of drug products. The off-label promotion of medicinal products is prohibited in the EU and in other territories. The promotion of medicinal products that are not subject to a marketing authorization is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU and in other territories could be penalized by administrative measures, fines and imprisonment.

As discussed above in the subsection entitled "Other Regulations," we are subject to FCPA, the U.K. Bribery Act, and other anti-corruption laws and regulations that generally prohibit companies and their intermediaries from making improper payments to government officials and/or other persons for the purpose of obtaining or retaining business and we operate in countries that are recognized as having a greater potential for governmental and commercial corruption. We cannot assure that our compliance program, policies and procedures will always protect Alexion from acts committed by its employees or third-party distributors or service providers.

In May 2015, we received a subpoena in connection with an investigation by the Enforcement Division of the SEC requesting information related to our grant-making activities and compliance with the FCPA in various countries. The SEC also seeks information related to Alexion's recalls of specific lots of Soliris and related securities disclosures. In addition, in October 2015, Alexion received a request from the U.S. Department of Justice (DOJ) for the voluntary production of documents and other information pertaining to Alexion's compliance with the FCPA. Alexion is cooperating with these investigations. At this time, Alexion is unable to predict the duration, scope or outcome of these investigations.

Any determination that our operations or activities are not, or were not, in compliance with existing United States or foreign laws or regulations, including by the SEC or DOJ pursuant to its investigation of our compliance with the FCPA and other matters, could result in the imposition of a broad range of civil and criminal sanctions against Alexion and certain of our directors, officers and/or employees, including injunctive relief, disgorgement, substantial fines or penalties, imprisonment, and other legal or equitable sanctions. Additionally, we could experience interruptions of business, harm to our reputation, debarment from government contracts, loss of supplier, vendor or other third-party relationships, and necessary licenses and permits could be terminated. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence. Cooperating with and responding to the SEC and the DOJ in connection with its investigation of our

FCPA practices and other matters, as well as responding to any future U.S. or foreign governmental investigation or whistleblower lawsuit, could result in substantial expenses, and could divert management's attention from other business concerns and could have a material adverse effect on our business and financial condition and growth prospects.

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

interpretations that could delay, limit or prevent regulatory approval. If the design or results achieved in our clinical trials are insufficient to proceed to further trials or to regulatory approval of our product candidates, our company could be materially adversely affected. Failure of a clinical trial to achieve its pre-specified primary endpoint, such as the Phase II Soliris trial for AMR that we announced in January 2015, generally increases the likelihood that additional studies or trials will be required if we determine to continue development of the product candidate, reduces the likelihood of timely development of and regulatory approval to market the product candidate, and may decrease the chances for successfully achieving the primary endpoint in scientifically similar indications.

Our clinical studies may be costly and lengthy, and 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 making patient enrollment difficult. 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 or a study 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. We may open clinical sites and enroll patients in countries where we have little experience. We rely on a small number of clinical research organizations to carry out our clinical trial related activities, and one CRO is responsible for many of our studies. We rely on such parties to accurately report their results. Our reliance on CROs may impact our ability to control the timing, conduct, expense and quality of our clinical trials.

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.

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.

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.

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. Our products and product 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 products from copycat products.

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

In 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 biopharmaceutical 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 products. If we cannot obtain a license, we may be prevented from the manufacture, sale or development of our products, which would adversely affect our business.

Parts of our technology, techniques, proprietary compounds and potential product 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 certain third parties filed civil lawsuits against us claiming infringement of their intellectual property rights. Each of those matters was resolved. However, additional third parties may claim that the manufacture, use or sale of our products or product candidates infringes patents owned or granted to such third parties. 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 our products or product 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 our products or investigational compounds. In respect to some of these patents, we have obtained licenses, or expect to obtain licenses. However, with regard to other patents, we have determined in our judgment that:

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

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 products. 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 our products, 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 our products 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 our products is based upon patent rights and certain regulatory forms of exclusivity. The scope of our product 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 our products 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. 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 includes an approval pathway for biosimilar versions of innovative biological products. Under the 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 for a full biologic license application. After an innovator has marketed its product for four years, other manufacturers may apply for approval of a biosimilar version of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not actually approve a biosimilar version until 12 years after the innovative product received its approval. The law also provides a mechanism for innovators to enforce their patents that protect their products and for biosimilar applicants to challenge the patents. Such litigation may begin as early as four years after the innovative biological product is first approved by the FDA. Pathways for biosimilar products also exist in many other markets, including Europe and Japan.

Risks Related to Our Operations

We may not accurately forecast demand for our products, including our new products, which may cause our operating results to fluctuate, and 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.

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. Our quarterly revenues, expenses and net income (loss) may fluctuate, even significantly, due to the risks described in these "Risk Factors" as well as the timing of charges and expenses that we may take. We believe that we formulate our annual operating budgets with reasonable assumptions and targets, however we may not generate sufficient revenues or control expenses to achieve our financial goals, including continued profitability. We may not be able to sustain or increase profitability on a quarterly or annual basis. You should not consider our financial performance, including our revenue growth, in recent periods as indicative of our future performance. We may not accurately forecast demand for our products, especially Strensiq and Kanuma. Strensiq and Kanuma are in the early stages of commercial launch having each received marketing approval in 2015, and both products treat rare diseases for which there was no existing therapy in a new therapeutic area for us. Product demand is dependent on a number of factors. Our investors may have widely varying expectations that may be materially higher or lower than actual revenues and if our revenues are different from these expectations, our stock price may experience significant volatility. Our revenues are also subject to foreign exchange rate fluctuations due to the global nature of our operations and our results of operations could be adversely affected due to unfavorable foreign exchange rates. Although we use derivative instruments to manage foreign currency risk, our efforts to reduce currency exchange losses may not be successful.

We have significant debt service obligations as a result of the debt we incurred to finance the acquisition of Synageva. Changes in interest rates related to this debt could significantly increase our annual interest expense. As we advance

our most robust pipeline in our history and launch our second and third products worldwide, 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 worldwide, some of which could be delayed, scaled-back or eliminated to achieve our financial objectives.

We have also recorded, or may be required to record, charges that include inventory write-downs for failed quality specifications or recalls, impairments with respect to investments, fixed assets and long-lived assets, outcomes of litigation and

other legal or administrative proceedings, regulatory matters and tax matters, and payments in connection with acquisitions and other business development activities, such as milestone payments.

Each of our products is currently the only approved drug for the disease(s) the product treats. If a competitive product is approved for sale, including a biosimilar or generic product, our market share and our revenues could decline, particularly if the competitive product is perceived to be more effective or is less expensive than our product.

We operate in a highly competitive environment. Soliris is currently the only approved therapy for the treatment of PNH and aHUS. We are in advanced clinical studies of Soliris for the treatment of other diseases, and there are currently no approved drugs for any of these other diseases. Strensiq is currently the only product approved to treat HPP and Kanuma is the only product approved to treat LAL-D. In the future, Soliris may compete with new drugs currently in development, and Strensiq and Kanuma may also experience competition. Other companies have initiated clinical studies for the treatment of PNH and NMO, and we are aware of companies that are planning to initiate studies for diseases that we are also targeting.

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 financial, technical and marketing resources than us, may commercialize products that are cheaper, more effective, safer, or easier to administer than our products. In the future, our products may also compete with biosimilars or generics. We experience competition in drug development from universities and other research institutions, and pharmaceutical companies compete with us to attract universities and academic research institutions as drug development partners, including for licensing their 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 a company announces successful clinical trial results for a product that may be competitive with one of our products or product candidates, receives marketing approval of a competitive product, or gets to the market before we do with a competitive product, our business may be harmed or our stock price may decline.

If we fail to attract and retain highly qualified personnel, we may not be able to successfully develop, manufacture or commercialize our products or products candidates.

The success of our business is dependent in large part on our continued ability to attract and retain our senior management, and other highly qualified personnel in our scientific, clinical, manufacturing and commercial organizations. There is intense competition in the biopharmaceutical industry for these types of personnel. Our business is specialized and global and we must attract and retain highly qualified individuals across many geographies. We may not be able to continue to attract and retain the highly qualified personnel necessary for developing, manufacturing and commercializing our products and product candidates. If we are unsuccessful in our recruitment and retention efforts, our business may be harmed.

If we fail to satisfy our debt service obligations or obtain the capital necessary to fund our operations, we may be unable to commercialize our products or continue or complete our product development.

In June 2015, we acquired Synageva and used a substantial portion of our cash on hand and incurred significant debt under the terms of a senior secured credit facility to finance the acquisition. In addition, we have substantial contingent liabilities, including milestone and royalty obligations under earlier acquisitions and strategic transactions. Our increased indebtedness, including increased interest expense, together with our significant contingent liabilities, could, among other things:

- make us more vulnerable to economic or industry downturns and competitive pressures;
- make it difficult for us to make payments on the credit facilities and require us to use cash flow from operations to satisfy our debt obligations, which would reduce the availability of our cash flow for other purposes, including business development efforts, research and development and mergers and acquisitions;
- limit our ability to incur additional debt or access the capital markets; and
- limit our flexibility in planning for, or reacting to changes in, our business.

The Credit Agreement requires us to comply with certain financial covenants on a quarterly basis and 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, and engage in certain investment, acquisition and

disposition transactions. 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.

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

We may not be able to access the capital and credit markets on terms that are favorable to us.

We may need to raise additional capital to supplement our existing funds and cash generated from operations for working capital, capital expenditure and debt service requirements, and other business activities. Funding needs may shift and the amount of capital we may need depends on many factors, including, the cost of any acquisition or any new collaborative, licensing or other commercial relationships that we may establish, the time and cost necessary to build our manufacturing facilities or enhance our manufacturing operations, the cost of obtaining and maintaining the necessary regulatory approvals for our manufacturing facilities, and the progress, timing and scope of our preclinical studies and clinical trials. The capital and credit markets have experienced extreme volatility and disruption. We may not receive additional funding when we need it or funding may only be available on unfavorable terms. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back or eliminate certain research, development, manufacturing or commercial activities.

Our business involves environmental risks and potential exposure to environmental liabilities.

As a biopharmaceutical company, our business involves the use of certain hazardous materials in our research, development, manufacturing, and other activities. We and our third party providers are subject to various federal, state and local environmental laws and regulations concerning 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. We also are subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment and a current or previous owner or operator of property may be liable for the costs of remediating its property or locations, without regard to whether the owner or operator knew of or caused the contamination. If an accident or environmental discharge occurs, or if we discover contamination caused by prior owners and operators of properties we acquire, we could be liable for remediation obligations, damages and fines that could exceed our insurance coverage and financial resources. Such obligations and liabilities, which to date have not been material, could have a material impact on our business and financial condition. Additionally, the cost of compliance with environmental and safety laws and regulations may increase in the future, and we may be required dedicate more resources to comply with such developments or purchase supplemental insurance coverage.

We are seeking to expand our business through strategic initiatives. Our efforts to identify opportunities or complete transactions that satisfy our strategic criteria may not be successful, and we not realize the anticipated benefits of any completed acquisition or other strategic transaction.

Our business strategy includes expanding our products and capabilities. We regularly evaluate potential merger, acquisition, partnering and in-license opportunities that we expect will expand our pipeline or product offerings, and enhance our research platforms. 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;
- failure of any acquired businesses or products or in-licensed products to achieve the scientific, medical, commercial or other results anticipated;
- diverting our management's attention away from other business concerns;
- the potential loss of our key employees or key employees of the acquired companies; and
- risks of entering markets in which we have limited or no direct experience.

A substantial portion of our strategic efforts are focused on opportunities for rare disorders and life-saving therapies and the availability of such opportunities is limited. We may not be able to identify opportunities that satisfy our strategic criteria or are acceptable to us or our stockholders. Several companies have publicly announced intentions to establish or develop rare disease programs and we may compete with these companies for the same opportunities. For these and other reasons, we may not be able to acquire the rights to additional product candidates or approved products on terms that we or our stockholders find acceptable, or at all.

Even if we are able to successfully identify and complete acquisitions and other strategic transactions, we may not be able to integrate them or take full advantage of them. An acquisition or other strategic transaction may not result in

short-term or long-term benefits to us. We may also incorrectly judge the value or worth of an acquired company or business or an acquired or in-licensed product.

To effectively manage our current and future potential growth, we must continue to effectively enhance and develop our global employee base, and our operational and financial processes. Supporting our growth strategy will require significant capital expenditures and management resources, including investments in research, development, sales and marketing, manufacturing and other areas of our operations. 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.

We may be required to recognize impairment charges for our goodwill and other intangible assets.

As of December 31, 2015, the net carrying value of our goodwill and other intangible assets totaled $9,755,799. As required by generally accepted accounting principles, we periodically assess these assets to determine if they are impaired. Impairment of intangible assets may be triggered by developments both within and outside our control. Deteriorating economic conditions, technological changes, disruptions to our business, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in use of the assets, intensified competition, divestitures, market capitalization declines and other factors may impair our goodwill and other intangible assets. Any charges relating to such impairments could adversely affect our results of operations in the periods an impairment is recognized.

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. As previously disclosed, in May 2015, we received a subpoena in connection with an investigation by the Enforcement Division of the SEC requesting information related to our grant-making activities and compliance with the FCPA in various countries. The SEC also seeks information related to Alexion’s recalls of specific lots of Soliris and related securities disclosures. In addition, in October 2015, Alexion received a request from the DOJ for the voluntary production of documents and other information pertaining to Alexion's compliance with the FCPA. Legal proceedings, government investigations, including the SEC and DOJ investigations, and enforcement actions can be expensive and time consuming. An adverse outcome could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations.

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

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

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

intended tax consequences, our effective tax rate could increase and harm our financial position and results of operations.

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

These changes and other prospective changes in the United States and other countries in which we and our affiliates operate could increase our effective tax rate, and harm our financial position and results of operations.

Our sales and operations are subject to a variety of risks relating to the conduct and expansion of our international business.

We continue to increase our international presence, including in emerging markets. Our operations in foreign countries subject us to a variety of risks, including:

- difficulties or the inability to obtain necessary foreign regulatory or reimbursement approvals of our products in a timely manner;
- political or economic determinations that adversely impact pricing or reimbursement policies;
- economic problems or political instability;
- fluctuations in currency exchange rates;
- difficulties or inability to obtain financing in markets;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- difficulties enforcing contractual and intellectual property rights;
- compliance with complex import and export control laws;
- 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.

Additionally, our business and marketing methods are subject to the laws and regulations of the countries in which we operate, which may differ significantly from country to country and may conflict with U.S. laws and regulations. The FCPA and anti-bribery laws and regulations are extensive and far-reaching, and we must maintain accurate records and control over the activities of our distributors and third party service providers in countries where we operate. 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. Although we conducted due diligence of Synageva's operations prior to the acquisition, we may discover or identify deficiencies or non-compliance with such laws as we complete the integration of the Synageva business and conduct operations. Failure to comply with the laws and regulations of the countries in which we operate could materially harm our business.

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

We 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 and fluctuations in foreign currency exchange rates affect our operating results. The exposures result from portions of our revenues, as well as the related receivables, and expenses that are denominated in currencies other than the U.S. dollar, including the Euro, Japanese Yen, British Pound, Swiss Franc, and Russian Ruble. As the U.S. dollar strengthens against these foreign currencies, the relative value of sales made in the respective foreign currency decreases. When the U.S. dollar weakens against these currencies, the relative value of such sales increases. 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 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 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. Any significant foreign currency exchange rate fluctuations could adversely affect our financial condition and results of operations. Changes in healthcare laws and policy may affect coverage and reimbursement of our products in ways that we cannot currently predict and these changes could adversely affect our business and financial condition.

In the U.S., there have been a number of legislative and regulatory initiatives focused on containing the cost of health care. The Patient Protection and Affordable Care Act (PPACA) was enacted in the United States in March 2010. This law substantially changes the way healthcare is financed by both governmental and private insurers in the U.S., and significantly impacts the pharmaceutical industry. PPACA contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under health insurance exchanges, expansion of the 340B program, expansion of state Medicaid programs, fraud and abuse enforcement and rules governing the approval of biosimilar products. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. On January 21, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate Program under PPACA. These regulations become effective on April 1, 2016. We are evaluating the impact of these regulations on our business and operations. Moreover, in the future, Congress could enact legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate Program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate Program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Governments in countries where we operate have adopted or have shown significant interest in pursuing legislative initiatives to reduce costs of health care. 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 our products, or to what extent, until such laws, rules and regulations are promulgated, implemented and enforced, which could sometimes take many years. 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 our products and materially harm our business, financial condition and results of operations.

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

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer price and best price for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due, and CMS may request or require restatements for earlier periods as well. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug discount program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price, ASP, or best price information to the government, we may be liable for civil monetary penalties in the amount of $100

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

As discussed above in the subsection entitled “Pharmaceutical Pricing and Reimbursement,” federal law requires that a company must participate in the FSS pricing program to be eligible to have its products paid for with federal funds. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

We are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., we may be subject to state security breach notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure and transmission of personal information. Each of these laws are subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by the federal Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA) or for aiding and abetting the violation of HIPAA. Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. European Union member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the European Commission adopted the EU Data Protection Directive, as implemented into national laws by the EU member states, which imposed strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from different EU member states have interpreted the privacy laws differently, which adds to the complexity of processing personal data in the EU, and guidance on implementation and compliance practices are often updated or otherwise revised. Any failure to comply with the rules arising from the EU Data Protection Directive and related national laws of European Union member states could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

In December 2015, a proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, was agreed between the European Parliament, the Council of the European Union and the European Commission. The EU Data Protection Regulation, which will be officially adopted in early 2016, will introduce new data protection requirements in the EU and substantial fines for breaches of the data protection rules. The EU Data Protection Regulation, which will be applicable two years after the date of its publication in the Official Journal for the European Union, will increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules.

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

We are increasingly dependent on our information technology systems and infrastructure for our business. We collect, store, and transmit sensitive information including intellectual property, proprietary business information and personal information in connection with business operations. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack by third parties with a wide range of motives and expertise, including organized criminal groups, “hactivists,” patient groups, disgruntled current or former employees, and others. Cyber-attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance. We have implemented information security measures to protect patients’ personal information against the risk of inappropriate and unauthorized external use and disclosure.

However, despite these measures, and due to the ever changing information cyber-threat landscape, we may be subject to data breaches through cyber-attacks. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. If our systems become compromised, we may not promptly discover the intrusion. Like other companies in our industry, we have experienced attacks to our data and systems, including malware and computer viruses. If our systems failed or were breached or disrupted, we could lose product sales, and suffer reputational damage and loss of customer confidence. Such incidents would result in notification obligations to affected individuals and government agencies, legal claims or proceedings, and liability under federal and state laws that protect the privacy and security of personal information. Any one of these events could cause our business to be materially harmed and our results of operations would be adversely impacted.

Negative public opinion and increased regulatory scrutiny of recombinant and transgenic products, genetically modified products, and genetically modified animals generally may damage public perception of our current and future products or adversely affect our ability to conduct our business and obtain regulatory approvals we may seek. Kanuma is a transgenic product produced in the egg whites of genetically modified chickens who receive copies of the human lysosomal acid lipase gene to produce recombinant human lysosomal acid lipase. The success of Kanuma will depend in part on public attitudes of the use of genetic engineering. Public attitudes may be influenced by claims and perceptions that these types of activities or products are unsafe, and our products may not gain sufficient acceptance by, or fall out of favor with, the public or the medical community. Negative public attitudes to genetic engineering activities in general could result in more restrictive legislation or regulations and could impede our ability to conduct our business, delay preclinical or clinical studies, or otherwise prevent us from commercializing our product.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

The trading price of our common stock has been extremely volatile and may continue to be volatile in the future. Many factors could have an impact on our stock price, including fluctuations in our or our competitors' operating results, clinical trial results or adverse events associated with our products, product development by us or our competitors, changes in laws, including healthcare, tax or intellectual property laws, intellectual property developments, changes in reimbursement or drug pricing, the existence or outcome of litigation or government proceedings, including the SEC/DOJ investigation, failure to resolve, delays in resolving or other developments with respect to the issues raised in the Warning Letter, acquisitions or other strategic transactions, and the perceptions of our investors that we are not performing or meeting expectations. 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.

Anti-takeover provisions in our charter and bylaws could make a third-party acquisition of us difficult and may frustrate any attempt to remove or replace our current management.

Our corporate charter and by-law provisions may discourage certain types of transactions involving an actual or potential change of control that might be beneficial to us or our stockholders. Our bylaws provide that special meetings of our stockholders may be called only by the Chairman of the Board, the President, the Secretary, or a majority of the Board of Directors, or upon the written request of stockholders who together own of record 25% 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.

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.

Item 1B. UNRESOLVED STAFF COMMENTS.

None.

Item 2. PROPERTIES.

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

Location	Operations Conducted	Approximate Square Feet	Lease Expiration Dates
New Haven, Connecticut	Corporate headquarters and executive, sales, research and development offices	514,000	2030
Dublin, Ireland	Global supply chain, distribution, and administration offices	215,000	Owned
Lexington, Massachusetts	Research and development offices	81,000	2019
Bogart, Georgia	Commercial, research and development manufacturing	70,000	2024
Smithfield, Rhode Island	Commercial, research and development manufacturing	67,000	Owned
Zurich, Switzerland	Regional executive and sales offices	69,000	2025

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 in foreign countries to support our operations as a global organization.

As of December 31, 2015, we also leased approximately 254,000 square feet in Cheshire, Connecticut, which was the previous location of our corporate headquarters and executive, sales, research and development offices. In December 2015, we entered into an early termination of this lease and will occupy this space through May 2016.

In April 2014, we purchased a fill/finish facility in Athlone, Ireland. Following refurbishment of the facility, and after successful completion of the appropriate validation processes and regulatory approvals, the facility will become our first company-owned fill/finish and packaging facility for our commercial and clinical products. In May 2015, we announced plans to construct a new biologics manufacturing facility on our existing property in Dublin Ireland, which is expected to be completed by 2020.

Item 3. LEGAL PROCEEDINGS.

In May 2015, we received a subpoena in connection with an investigation by the Enforcement Division of the SEC requesting information related to our grant-making activities and compliance with the FCPA in various countries. The SEC also seeks information related to Alexion’s recalls of specific lots of Soliris and related securities disclosures. In addition, in October 2015, Alexion received a request from the DOJ for the voluntary production of documents and other information pertaining to Alexion's compliance with the FCPA. Alexion is cooperating with these investigations. At this time, Alexion is unable to predict the duration, scope or outcome of these investigations. Given the ongoing nature of these investigations, management does not currently believe a loss related to these matters is probable or that the potential magnitude of such loss or range of loss, if any, can be reasonably estimated.

Item 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Our common stock is quoted on The NASDAQ Stock Market, LLC under the symbol "ALXN." The following table sets forth the range of high and low sales prices for our common stock on The NASDAQ Stock Market, LLC for the periods indicated since January 1, 2014.

Fiscal 2014	High	Low
First Quarter (January 1, 2014 to March 31, 2014)	$185.43	$126.76
Second Quarter (April 1, 2014 to June 30, 2014)	$172.50	$136.37
Third Quarter (July 1, 2014 to September 30, 2014)	$173.70	$154.38
Fourth Quarter (October 1, 2014 to December 31, 2014)	$203.30	$155.01
Fiscal 2015		
First Quarter (January 1, 2015 to March 31, 2015)	$193.27	$171.08
Second Quarter (April 1, 2015 to June 30, 2015)	$191.00	$150.06
Third Quarter (July 1, 2015 to September 30, 2015)	$208.88	$142.02
Fourth Quarter (October 1, 2015 to December 31, 2015)	$193.45	$150.69

As of January 28, 2016, we had approximately 108 stockholders of record of our common stock and an estimated 144,340 beneficial owners. The closing sale price of our common stock on January 28, 2016 was $145.61 per share.

DIVIDEND POLICY

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

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

The following table summarizes our common stock repurchase activity during the fourth quarter of 2015:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Dollar Value of Shares that May Yet Be Purchased Under the Programs
October 1-31, 2015	766	158.69	766	786,625
November 1-30, 2015	105	175.79	105	768,226
December 1-31, 2015	70	175.59	70	755,864
Total	941	161.86	941	

In November 2012, our Board of Directors authorized a share repurchase program. The repurchase program does not have an expiration date and we are not obligated to acquire a particular number of shares. In May 2015, our Board of Directors increased the authorization of shares up to $1,000,000 for future purchases under the repurchase program,

which superseded all prior repurchase programs.

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 (1)	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 (2)
Equity compensation plans approved by stockholders	6,221	$110.15	6.96	10,005
Equity compensation plans not approved by stockholders	—	$—	—	—

(1) Reflects number of shares of common stock to be issued upon exercise of outstanding options under all our equity compensation plans, including our Amended and Restated 2004 Incentive Plan. Does not include 2,040 restricted shares outstanding that were issued under the Amended and Restated 2004 Incentive Plan.

(2) Of these shares, 9,040 remain available for future issuance under the Amended and Restated 2004 Incentive Plan and 965 remain available under the 2015 Employee Stock Purchase 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, 2010 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

	12/10	12/11	12/12	12/13	12/14	12/15
Alexion Pharmaceuticals, Inc.	100.00	177.53	232.75	329.94	459.42	473.62
NASDAQ Composite	100.00	100.53	116.92	166.19	188.78	199.95
NASDAQ Biotechnology	100.00	113.92	153.97	263.29	348.49	369.06

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,				
	2015	2014	2013	2012	2011
Net product sales [1]	$2,602,532	$2,233,733	$1,551,346	$1,134,114	$783,431
Other revenue	1,515	—	—	—	—
Total revenues	2,604,047	2,233,733	1,551,346	1,134,114	783,431
Cost of sales:					
Cost of sales	233,089	173,862	168,375	126,214	93,140
Change in contingent liability from intellectual property settlements	—	—	9,181	(53,377)	—
Total cost of sales	233,089	173,862	177,556	72,837	93,140
Operating expenses:					
Research and development	709,472	513,782	317,093	222,732	137,421
Selling, general and administrative	862,595	630,209	489,720	384,678	308,176
Amortization of purchased intangible assets [2]	116,584	—	417	417	382
Change in fair value of contingent consideration	64,257	20,295	4,006	6,550	1,400
Acquisition-related costs	39,210	—	1,023	16,262	12,086
Restructuring expenses	42,169	15,365	—	—	—
Impairment of intangible assets	—	11,514	33,521	26,300	—
Total operating expenses	1,834,287	1,191,165	845,780	656,939	459,465
Operating income	536,671	868,706	528,010	404,338	230,826
Other income (expense)	(38,529)	3,401	(1,741)	(6,772)	(1,158)
Income before income taxes	498,142	872,107	526,269	397,566	229,668
Income tax provision [3] [4]	353,757	215,195	273,374	142,744	54,353
Net income	$144,385	$656,912	$252,895	$254,822	$175,315
Earnings per common share					
Basic	$0.68	$3.32	$1.29	$1.34	$0.96
Diluted	$0.67	$3.26	$1.27	$1.28	$0.91
Shares used in computing earnings per common share					
Basic	213,431	198,103	195,532	190,461	183,220
Diluted	215,933	201,623	199,712	198,501	191,806

Consolidated Balance Sheet Data:

	As of December 31,				
	2015	2014	2013	2012	2011
Cash, cash equivalents and marketable securities	$1,385,015	$1,961,566	$1,514,851	$989,501	$540,865
Total assets [5]	13,133,230	4,201,962	3,317,696	2,613,560	1,394,751
Long-term debt and convertible notes (current and noncurrent) [6]	3,456,250	57,500	113,000	149,000	—
Contingent consideration (current and noncurrent)	177,228	162,971	142,676	141,670	18,120
Facility lease obligation	151,307	107,099	32,230	—	—
Total stockholders' equity[7]	8,258,616	3,302,018	2,382,079	1,970,850	1,134,492

In addition to the following notes, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Consolidated Financial Statements and accompanying notes and previously filed Annual Reports on Form 10-K for further information regarding our consolidated results of operations and financial position for periods reported therein.

[1] In March 2014, we entered into an agreement with the French government which positively impacted prospective reimbursement of Soliris and also provided for reimbursement for shipments made in years prior to January 1, 2014. As a result of the agreement, in 2014 we recognized $87,830 of net product sales from Soliris in France relating to years prior to January 1, 2014.
[2] In the third quarter 2015, we received regulatory approval for Strensiq and Kanuma. As a result, we began amortizing intangible assets associated with Strensiq and Kanuma.
[3] In connection with the integration of the Synageva business with and into the Alexion business, we incurred a one-time tax expense of $315,569 in the third quarter 2015. This tax expense is attributable to the change in our deferred tax liability for the outside basis difference resulting from the movement of assets into our captive foreign partnership.
[4] In 2013, we recognized tax expense of approximately $95,800 resulting from the centralization of our global supply chain and technical operations in Ireland.
[5] In connection with the acquisition of Synageva, we acquired $4,236,000 of intangible assets and $4,793,812 of goodwill.
[6] In connection with the acquisition of Synageva, we borrowed $3,500,000 under our term loan under a new credit facility.
[7] In connection with the acquisition of Synageva, we issued $4,917,810 of common stock to former Synageva stockholders.

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 devastating and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products.

In our complement franchise, Soliris is the first and only therapeutic approved for patients with either PNH, a life-threatening and ultra-rare genetic blood disorder defined by chronic uncontrolled complement activation leading to destruction of red blood cells, and aHUS, a life-threatening and ultra-rare genetic disease characterized by chronic, uncontrolled complement activation and thrombotic microangiopathy. PNH and aHUS are two severe and ultra-rare disorders resulting from chronic uncontrolled activation of the complement component of the immune system.
In our metabolic franchise, we market Strensiq for the treatment of patients with HPP and Kanuma for the treatment of patients with LAL-D. HPP is a genetic ultra-rare disease characterized by defective bone mineralization that can lead to deformity of bones and other skeletal abnormalities. LAL-D is a serious, life threatening ultra-rare disease in which genetic

mutations result in decreased activity of the LAL enzyme leading to marked accumulation of lipids in vital organs, blood vessels and other tissues.

We are also evaluating additional potential indications for eculizumab in other severe and devastating diseases in which uncontrolled complement activation is the underlying mechanism, and we are progressing in various stages of development with additional product candidates as potential treatments for patients with severe and life-threatening rare disorders.

Business Highlights

In June 2015, we acquired all of the outstanding shares of common stock of Synageva BioPharma Corp. (Synageva), a publicly-held clinical-stage biotechnology company, in a transaction accounted for under the acquisition method of accounting for business combinations. The merger consideration consisted of shares of our common stock and cash, which we financed with existing cash and proceeds from a new credit facility.

In 2015, the FDA approved Strensiq for patients with perinatal-, infantile- and juvenile-onset HPP, the EC granted marketing authorization for Strensiq for the treatment of patients with pediatric-onset HPP and Japan's MHLW approved Strensiq for the treatment of patients with HPP.

In 2015, the FDA approved Kanuma for the treatment of patients of all ages with LAL-D and EC granted marketing authorization of Kanuma for long-term enzyme replacement therapy in patients of all ages with LAL-D.

Critical Accounting Policies and the Use of Estimates

The significant accounting policies and basis of preparation of our consolidated financial statements are described in Note 1, "Business Overview and Summary of Significant Accounting Policies" of the Consolidated Financial Statements included in this Annual Report on Form 10-K. Under accounting principles generally accepted in the United States, we are required to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingent assets and liabilities in our financial statements. Actual results could differ from those estimates.

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

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

Revenue Recognition

Net Product Sales

Our principal source of revenue is product sales. We recognize revenue from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and we have no further performance obligations. Depending on these criteria, revenue is usually recorded upon receipt of the product by the end customer, which is typically a hospital, physician's office, private or government pharmacy or other health care facility. On a regular basis, we review revenue arrangements, such as distributor relationships, to determine whether changes in these criteria have an impact on revenue recognition. Amounts collected from customers and remitted to governmental authorities, such as value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in our consolidated statements of operations and do not impact net product sales.

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

Because of factors such as the price of our products, the limited number of patients, the short period from product sale to patient infusion and the lack of contractual return rights, 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

51

demand, contractual terms and financial strength of distributors. In certain countries, exact quantities of inventory in the channel are not precisely known, requiring us to estimate these amounts. If actual amounts of inventory differ from these estimates, these adjustments could have an impact in the period in which these estimates change.

In addition to sales in countries where product is commercially available, we have also recorded revenue on sales for patients receiving 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 product has not received final approval for commercial sale.

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

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

We have provided balances and activity in the rebates payable account for the years ended December 31, 2015, 2014 and 2013 as follows:

	Rebates Payable
Balance at December 31, 2012	$62,334
Current provisions relating to sales in current year	149,247
Adjustments relating to prior years	(2,180)
Payments/credits relating to sales in current year	(29,574)
Payments/credits relating to sales in prior years	(55,530)
Balance at December 31, 2013	$124,297
Current provisions relating to sales in current year	62,478
Adjustments relating to prior years	(87,004)
Payments/credits relating to sales in current year	(33,922)
Payments/credits relating to sales in prior years	(29,022)
Balance at December 31, 2014	$36,827
Current provisions relating to sales in current year	89,329
Adjustments relating to prior years	(1,821)
Payments/credits relating to sales in current year	(42,839)
Payments/credits relating to sales in prior years	(25,893)
Balance at December 31, 2015	$55,603

In 2015 compared to 2014, current provisions relating to sales in the current year increased by $26,851 primarily due to increased unit volumes in the United States and Europe which were subject to rebates.

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

We record distribution and other fees paid to our customers as a reduction of revenue, unless we receive an identifiable and separate benefit for the consideration and we can reasonably estimate the fair value of the benefit received. If both

conditions are met, we record the consideration paid to the customer as an operating expense. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

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

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

We continue to monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. For additional information related to our concentration of credit risk associated with certain international accounts receivable balances, refer to the "Financial Condition, Liquidity and Capital Resources" section below.

Contingent liabilities

We are currently involved in various claims 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 and liquidity.

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, 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 product utilized for both commercial and clinical programs is identical and, as a result, the inventory has an "alternative future use" as defined in authoritative guidance. Raw materials and purchased drug product associated with clinical development programs are included in inventory and charged to research and development expense when the product enters the research and development process and no longer can be used for

commercial purposes and, therefore, does not have an "alternative future use".

For products which are under development and have not yet been approved by regulatory authorities, purchased drug product is charged to research and development expense when the inventory passes quality inspection and ownership transfers

to us. Nonrefundable advance payments for research and development activities, including production of purchased drug product, are deferred and capitalized until the goods are delivered. We also recognize expense for raw materials purchased when the raw materials pass quality inspection, and we have an obligation to pay for the materials.

We analyze our inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of our product is subject to strict quality control, certain batches or units of product may no longer meet quality specifications or may expire, which would require adjustments to our inventory values. We also apply judgment related to the results of quality tests that we perform throughout the production process, as well as our understanding of regulatory guidelines, to determine if it is probable that inventory will be saleable. These quality tests are performed throughout the pre- and post-production process, and we continually gather information regarding product quality for periods after the manufacturing date. Our products currently have a maximum estimated life range of 36 to 48 months and, based on our sales forecasts, we expect to realize the carrying value of the product inventory. In the future, reduced demand, quality issues or excess supply beyond those anticipated by management may result in a material adjustment to inventory levels, which would be recorded as an increase to cost of sales.

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

Share-Based Compensation

We have two share-based compensation plans pursuant to which awards are currently being made: (i) the Amended and Restated 2004 Incentive Plan (2004 Plan) and (ii) the 2015 Employee Stock Purchase Plan (ESPP). Under the 2004 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. Under the ESPP, eligible employees can purchase shares of common stock at a discount semi-annually through payroll deductions. To date, share-based compensation issued under the plans consists of incentive and non-qualified stock options, restricted stock and restricted stock units, including restricted stock units with market and non-market performance conditions, and shares issued under our ESPP. Stock-related awards are also outstanding under other share-based compensation plans, but we have not granted awards under these plans since 2004.

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

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

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

The purchase price of common stock under our ESPP is equal to 85% of the lower of (i) the market value per share of the common stock on the first business day of an offering period or (ii) the market value per share of the common

stock on the purchase date. The fair value of the discounted purchases made under our ESPP is calculated using the Black-Scholes model. The fair value of the look-back provision plus the 15% discount is recognized as compensation expense over the 6 month purchase period.

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

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

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

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

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

Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events occur.

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. Impairment testing is performed at least annually or when a triggering event occurs that could indicate a potential impairment. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized over a period that best reflects the economic benefits provided by these assets.

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.

Valuation of Contingent Consideration

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

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

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

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

Income Taxes

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

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

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

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2017 and allows for adoption using a full retrospective method, or a modified retrospective method. Entities may elect to early adopt the standard for annual periods beginning after December 15, 2016. We are currently assessing the method of adoption and the expected impact the new standard has on our financial position and results of operations.

In April 2015, the FASB issued a new standard simplifying the presentation of debt issuance costs. The new standard aligns the treatment of debt issuance costs with debt discounts and premiums and requires debt issuance costs be presented as a direct deduction from the carrying amount of the related debt. The standard is effective for interim and annual periods beginning after December 15, 2015, with early adoption permitted, and requires a retrospective method of adoption. We will adopt the provisions of the new standard for the balance sheet disclosures of debt issuance costs beginning in the first quarter 2016.

In September 2015, the FASB issued a new standard simplifying the accounting for measurement-period adjustments. The new standard eliminates the requirement to restate prior period financial statements for measurement period adjustments. The new standard requires that the cumulative impact of a measurement period adjustment (including the impact on prior periods) be recognized in the reporting period in which the adjustment is identified. The standard is effective for interim and annual periods beginning after December 15, 2015 and is not expected to have a material impact on our financial condition or results of operations.

56

In November 2015, the FASB issued a new standard simplifying the classification of deferred tax assets and liabilities. The new standard requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. The standard is effective for interim and annual periods beginning after December 15, 2016 and allows for early adoption using a full retrospective method or a prospective method. We have elected to early adopt the provisions of this new standard using a prospective method. As a result, all deferred taxes as of December 31, 2015 are classified as noncurrent in our consolidated balance sheet, while prior periods remain as previously reported.

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,		
	2015	2014	2013
Net product sales	$2,602,532	$2,233,733	$1,551,346
Other revenue	1,515	—	—
Total revenues	2,604,047	2,233,733	1,551,346
Cost of sales:			
Cost of sales	233,089	173,862	168,375
Change in contingent liability from intellectual property settlements	—	—	9,181
Total cost of sales	233,089	173,862	177,556
Operating expenses:			
Research and development	709,472	513,782	317,093
Selling, general and administrative	862,595	630,209	489,720
Amortization of purchased intangible assets	116,584	—	417
Change in fair value of contingent consideration	64,257	20,295	4,006
Acquisition-related costs	39,210	—	1,023
Restructuring expenses	42,169	15,365	—
Impairment of intangible assets	—	11,514	33,521
Total operating expenses	1,834,287	1,191,165	845,780
Operating income	536,671	868,706	528,010
Other (expense) income	(38,529)	3,401	(1,741)
Income before income taxes	498,142	872,107	526,269
Income tax provision	353,757	215,195	273,374
Net income	$144,385	$656,912	$252,895
Earnings per common share:			
Basic	$0.68	$3.32	$1.29
Diluted	$0.67	$3.26	$1.27

Comparison of the Year Ended December 31, 2015 to the Year Ended December 31, 2014

Net Product Sales

Net product sales by significant geographic region are as follows:

	Year Ended December 31,			
	2015	2014	% Change	
Net product sales:				
United States	$951,307	$730,089	30	%
Europe (1)	840,465	836,134	1	%
Asia Pacific	276,350	244,059	13	%
Other	534,410	423,451	26	%
	$2,602,532	$2,233,733	17	%

Net product sales by product are as follows:

	Year Ended December 31,			
	2015	2014	% Change	
Net product sales:				
Soliris (1)	2,590,197	2,233,733	16	%
Strensiq	11,969	—	N/A	
Kanuma	366	—	N/A	
	$2,602,532	$2,233,733	17	%

(1) In March 2014, we entered into an agreement with the French government which positively impacts prospective reimbursement of Soliris and also provides for reimbursement for shipments made in years prior to January 1, 2014. As a result of the agreement, in the first quarter of 2014, we recognized $87,830 of net product sales from Soliris in France relating to years prior to January 1, 2014. Exclusive of the $87,830, net product sales in Europe increased 12% for the year ended December 31, 2015 compared to the year ended December 31, 2014.

The components of the increase in net product sales for the year ended December 31, 2015, exclusive of the $87,830 recognized in 2014 related to prior years, are as follows:

	Year Ended December 31, 2015	
Components of change:		
Price	—	%
Volume	29	%
Foreign exchange	(8	)%
Total change in net product sales	21	%

The increase in net product sales for fiscal year 2015 as compared to the same period in 2014, was primarily due to an increase in unit volumes of 29% due to increased demand globally for Soliris therapy for patients with PNH or aHUS during the respective periods.

The positive impact of volume on net product sales was offset by the negative impact on foreign exchange of 8%, for the year ended December 31, 2015, as compared to the same period in 2014. The negative impact on foreign exchange of $165,280, or 8%, was due to changes in foreign currency exchange rates (inclusive of hedging activity) versus the U.S. dollar for the year ended December 31, 2014. The negative impact was primarily due to the weakening of the Euro, Japanese Yen and Russian Ruble. We recorded a gain in revenue of $117,915 and $18,873 related to our foreign currency cash flow hedging program, for the years ended December 31, 2015 and 2014, respectively. We expect the strong dollar compared to other currencies to continue to have a negative impact on revenue into 2016.

Cost of Sales

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

The following table summarizes cost of sales for the year ended December 31, 2015 and 2014:

	Year Ended December 31,					
	2015		2014		% Change	
Cost of sales	$233,089		$173,862		$59,227	
Cost of sales as a percentage of net product sales	9	%	8	%	1	%

We recorded an expense of $24,352 in the first quarter of 2015 associated with a portion of a single manufacturing campaign at a third party manufacturer for Strensiq. The costs are comprised of raw materials, internal overhead and external production costs. We do not expect this expense will impact the clinical supply of inventory or the commercial launch of Strensiq, and we do not expect further material financial impact related to this campaign. Exclusive of the item mentioned above, cost of sales as a percentage of net product sales was 8% for the years ended December 31, 2015 and 2014.

Research and Development Expense

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

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

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

The following table provides information regarding research and development expenses:

	Year Ended December 31, 2015	Year Ended December 31, 2014	$ Change	% Change	
Clinical development	$155,162	$116,314	$38,848	33	%
Product development	120,316	58,356	61,960	106	%
Licensing agreements	129,750	109,925	19,825	18	%
Discovery research	44,478	13,403	31,075	232	%
Total external direct expenses	449,706	297,998	151,708	51	%
Payroll and benefits	218,919	190,669	28,250	15	%
Facilities and other costs	40,847	25,115	15,732	63	%
Total other R&D expenses	259,766	215,784	43,982	20	%
Research and development expense	$709,472	$513,782	$195,690	38	%

During the year ended December 31, 2015, we incurred research and development expenses of $709,472, an increase of $195,690, or 38%, versus the $513,782 incurred during the year ended December 31, 2014. The increase was primarily related to the following:

59

- Increase of $38,848 in external clinical development expenses related primarily to an expansion of studies for eculizumab, ALXN 1007, ALXN 1210, and other programs (see table below).
- Increase of $61,960 in external product development expenses related primarily to an increase in costs associated with the manufacturing of material for increased clinical research activities and clinical studies.
- Increase of $19,825 in licensing agreement expenses related to the achievement of additional license milestones.
- Increase of $31,075 in discovery research expenses primarily related to increases in external research expenses associated with our Moderna agreement and other external research expenses.
- Increase of $28,250 R&D payroll and benefit expense related to the additional headcount acquired as part of the Synageva acquisition in the second quarter 2015 and the continued global expansion of staff supporting our increasing number of clinical and development programs.
- Increases of $15,732 in R&D facilities and other costs related to the additional R&D facilities as part of the Synageva acquisition in the second quarter 2015 and the additional costs associated with the continued expansion of global supply chain facilities and support services.

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

	Year Ended December 31, 2015	Year Ended December 31, 2014	Accumulated Expenditures
External direct expenses			
Eculizumab	$77,859	$67,744	(a)
Asfotase alfa	21,845	26,893	$67,153
cPMP	7,886	7,961	24,382
ALXN 1007	14,243	3,172	21,276
Sebelipase alfa	4,774	—	4,774
ALXN 1210	8,091	1,135	9,308
Other programs	13,657	2,995	27,074
Unallocated	6,807	6,414	(b)
	$155,162	$116,314	$153,967

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

(b) External costs shared across various development programs.

The successful development of our drug candidates is uncertain and subject to a number of risks. We cannot guarantee that results of clinical trials will be favorable or sufficient to support regulatory approvals for our other programs. We could decide to abandon development or be required to spend considerable resources not otherwise contemplated. For additional discussion regarding the risks and uncertainties regarding our development programs, please refer to Item 1A "Risk Factors" in this Annual Report on Form 10-K.

We expect our research and development expenses to increase in 2016 due to clinical development and manufacturing costs related to our expanding development programs. For additional information on these programs, please refer to “Product and Development Programs” in Item I "Business" of this Annual Report on Form 10-K.

Selling, General and Administrative Expense

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

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

	Year Ended December 31, 2015	Year Ended December 31, 2014	$ Change
Salary, benefits and other labor expense	$549,944	$388,738	$161,206
External selling, general and administrative expense	312,651	241,471	71,180
Total selling, general and administrative expense	$862,595	$630,209	$232,386

During the year ended December 31, 2015, we incurred selling, general and administrative expenses of $862,595, an increase of $232,386, or 37%, versus the $630,209 incurred during the year ended December 31, 2014. The increase was primarily related to the following:

- Increase in salary, benefits and other labor expenses of $161,206. The increase was a result of increased staff costs related to commercial development activities and increases in payroll and benefits within our general and administrative functions to support our infrastructure growth as a global commercial entity. The increase was also attributable to additional global commercial staff costs due to our acquisition of Synageva in the second quarter 2015 and additional stock-based compensation expense of $29,634 related to the acceleration of Alexion stock awards for former Synageva employees.
- Increase in external selling, general and administrative expenses of $71,180. The increase was primarily due to an increase in external marketing costs to support the global launches of Strensiq and Kanuma and professional services to support the continuing growth of the company.

We expect our selling, general and administrative expenses to increase, at a lower rate than our revenue, in 2016, reflecting our continued growth as a commercial organization throughout the world.

Amortization of Purchase Intangible Assets

In the third quarter 2015, we received regulatory approval for Strensiq and Kanuma. As a result, for the year ended December 31, 2015, we recorded amortization expense of $116,584 associated with intangible assets related to Strensiq and Kanuma.

Acquisition-related Costs

For the years ended December 31, 2015 and 2014, acquisition-related costs associated with our business combinations included the following:

	Year Ended December 31, 2015	Year Ended December 31, 2014
Transaction costs [(1)]	$26,955	$—
Integration costs	12,255	—
	$39,210	$—

(1) Transaction costs include investment advisory, legal, and accounting fees

The increase in acquisition related costs was due to the Synageva acquisition that occurred during 2015.

Change in Fair Value of Contingent Consideration

For the years ended December 31, 2015 and 2014, the change in fair value of contingent consideration expense associated with our prior business combinations was $64,257 and $20,295, respectively. The increase in the fair value of contingent

consideration for the year ended December 31, 2015 as compared the prior year was primarily due to increases in the likelihood of payments for contingent consideration and a net decrease in discount rates.

Restructuring Expenses

In connection with the relocation of our corporate headquarters to New Haven, Connecticut, we entered into a lease termination agreement in December 2015 for the previous corporate headquarters located in Cheshire, Connecticut. We recorded contract termination fees of $11,236 in restructuring expense in the fourth quarter of 2015.

In conjunction with the acquisition and integration of Synageva we recorded restructuring expense of $13,335 primarily related to employee costs during 2015. We expect to pay all remaining accrued amounts related to this restructuring activity by the end of 2016.

In the fourth quarter of 2014 we announced plans to move the European headquarters from Lausanne, Switzerland to Zurich, Switzerland resulting in restructuring expenses of $15,365. The relocation of the European headquarters supports our growing operational needs based on current business forecasts. During the year ended December 31, 2015, we incurred additional restructuring costs of $17,598. We expect to pay all remaining accrued amounts related to this restructuring activity by the end of 2016.

Impairment of Intangible Asset

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

Other Income and Expense

The following table provides information regarding other income and expense:

	Year Ended December 31, 2015	Year Ended December 31, 2014	$ Change
Investment income	$8,519	$8,373	$146
Interest expense	(47,744)	(2,982)	(44,762)
Foreign currency gain (loss)	696	(1,990)	2,686
Total other income (expense)	$(38,529)	$3,401	$(41,930)

The increase in interest expense for the year ended December 31, 2015 as compared to the prior year was due to us borrowing $3,500,000 under a term loan facility in conjunction with the acquisition of Synageva.

Income Taxes

During the year ended December 31, 2015, we recorded an income tax provision of $353,757 and an effective tax rate of 71.0%, compared to an income tax provision of $215,195 and an effective tax rate of 24.7% for the year ended December 31, 2014. The increase in the effective tax rate is primarily attributable to the integration of Synageva assets into our captive foreign partnership. This one-time charge increased our effective tax rate in 2015 by approximately 63.0%. Exclusive of such one-time charges, we expect to continue to benefit from a reduced tax ratecompared to periods prior to January 1, 2014 as a result of centralizing our global supply chain and technical operations in Ireland in the fourth quarter 2013.

The income tax provision for 2015 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations, as well as the tax impact associated with integration of the Synageva business with and into the Alexion business.

In the third quarter 2015, we contributed certain supply chain assets, commercial operation rights and intellectual property acquired in the Synageva acquisition to our captive foreign partnership. This contribution resulted in a revaluation of our captive foreign partnership, an increase to the outside basis difference our U.S. parent company has in the captive foreign partnership, and a corresponding one-time deferred tax expense of $315,569. There was no cash tax payment associated with this deferred expense.

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

We continue to maintain a valuation allowance against certain other 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.

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

Net Product Sales

Net product sales by significant geographic region are as follows:

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

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

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

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

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

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

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

63

Cost of Sales

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

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

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

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

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

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

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

Research and Development Expense

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

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

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

The following table provides information regarding research and development expenses:

	Year Ended December 31, 2014	Year Ended December 31, 2013	$ Change	% Change
Clinical development	$116,314	$74,595	$41,719	56 %
Product development	58,356	60,518	(2,162)	(4)%
Licensing agreements	109,925	14,500	95,425	658 %
Discovery research	13,403	5,546	7,857	142 %
Total external direct expenses	297,998	155,159	142,839	92 %
Payroll and benefits	190,669	144,034	46,635	32 %
Operating and occupancy	11,050	7,765	3,285	42 %
Depreciation and amortization	14,065	10,135	3,930	39 %
Total other R&D expenses	215,784	161,934	53,850	33 %
Research and development expense	$513,782	$317,093	$196,689	62 %

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

- Increase of $41,719 in external clinical development expenses related primarily to an expansion of studies for eculizumab and asfotase alfa (see table below).
- Increase of $95,425 in licensing agreement costs primarily due to the upfront payment of $100,000 on the option agreement entered into with Moderna Therapeutics, Inc. in the first quarter of 2014.
- Increase of $7,857 in discovery research expenses primarily related to increases in external research expenses associated with our Moderna agreement and other external research expenses.
- Increase of $46,635 in R&D payroll and benefit expense related primarily to the continued global expansion of staff supporting our increasing number of clinical and development programs.
- Increases of $3,285 and $3,930 in R&D operating and occupancy and depreciation and amortization expenses. respectively, related primarily to the continued expansion of global supply chain facilities and support services.

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

	Year Ended December 31, 2014	Year Ended December 31, 2013
External direct expenses		
Eculizumab	$67,744	$44,725
Asfotase alfa	26,893	13,615
cPMP	7,961	6,391
Other programs	7,302	6,739
Unallocated	6,414	3,125
	$116,314	$74,595

The successful development of our drug candidates is uncertain and subject to a number of risks. We cannot guarantee that results of clinical trials will be favorable or sufficient to support regulatory approvals for our other programs. We could decide to abandon development or be required to spend considerable resources not otherwise contemplated. For additional discussion regarding the risks and uncertainties regarding our development programs, please refer to Item 1A "Risk Factors" in this Annual Report on Form 10-K.

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

Selling, General and Administrative Expense

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

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

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

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

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

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

Contingent Consideration

For the years ended December 31, 2014 and 2013 the change in fair value of contingent consideration associated with our prior business combinations was $20,295 and $4,006, respectively. The change in the fair value of contingent consideration for the year ended December 31, 2014 as compared the prior year was primarily due to increases in the likelihood of payments for contingent consideration and a decrease in discount rates.

Restructuring Expenses

In the fourth quarter of 2014 we announced plans to move the European headquarters from Lausanne, Switzerland to Zurich, Switzerland resulting in restructuring expenses of $15,365. The relocation of the European headquarters will support our growing operational needs based on current business forecasts.

Impairment of Intangible Asset

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

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

Other Income and Expense

The following table provides information regarding other income and expense:

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

Income Taxes

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

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

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

We were granted an incentive tax holiday in the Canton of Vaud in Switzerland effective January 1, 2010. This tax holiday had exempted us from most local corporate income taxes in Switzerland through the end of 2014 and was renewable for an additional 5 years with final expiration in 2019. During 2013, we undertook a restructuring which significantly changed our business model in Switzerland and we converted from a principal company to a distribution and service company. As a result of the significant change to our business activities in Switzerland, the Canton of Vaud in Switzerland provided final notification to us in December 2014 that our structure no longer complied with the conditions of the incentive tax holiday. In the fourth quarter of 2014, we made a payment of $22,817 in satisfaction of the clawback of previously exempted cantonal income taxes for tax years 2010 through 2013. This amount was fully accrued on our balance sheet as of December 31, 2013. Prospectively, our federal and cantonal tax will be based on the current enacted tax rates in Switzerland.

The U.S. Federal tax credit for research and experimentation expenses expired December 31, 2013. In connection with this expiration, our 2014 tax expense for the first three quarters of the year did not include any benefit from the U.S. Federal tax credit for research and experimentation. In December 2014, the Tax Increase Prevention Act of 2014, which retroactively extended the tax credit for research and experimentation back to January 1, 2014 through

the end of 2014, was signed into law. The effects of a change in tax law is recognized in the period that includes the date of enactment and, therefore, our tax benefit

attributable to the 2014 U.S. Federal tax credit of $3,222 for research and experimentation was recorded in the fourth quarter of 2014.

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

Financial Condition, Liquidity and Capital Resources

The following table summarizes the components of our financial condition as of December 31, 2015 and 2014:

	December 31, 2015	December 31, 2014	$ Change
Cash and cash equivalents	$1,010,111	$943,999	$66,112
Marketable securities	374,904	1,017,567	(642,663)
Long-term debt (includes current portion)	3,456,250	57,500	3,398,750
Current assets	$2,425,349	$2,796,029	$(370,680)
Current liabilities	718,250	606,740	111,510
Working capital	$1,707,099	$2,189,289	$(482,190)

The increase in cash and cash equivalents was primarily attributable to cash generated from operations, proceeds from the maturity or sale of available-for-sale securities, and net proceeds from the exercise of stock options. Offsetting these increases in cash were purchases of marketable securities, payments on our outstanding term loan, purchases of property, plant and equipment, and the repurchase of common stock. The decrease in marketable securities was primarily attributable to sales of marketable securities used to partially fund our acquisition of Synageva in 2015. The increase in long-term debt was attributable to the borrowing of $3,500,000 in connection with the acquisition of Synageva in 2015.

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

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

Financial Instruments

Until required for use in the business, we may invest our cash reserves in money market funds, bank deposits, and 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, 2015, three customers accounted for 51% of the accounts receivable balance, with these individual customers accounting for 14% to 22% of the accounts receivable balance. At December 31, 2014, four customers accounted for 58% of the accounts receivable balance, with individual customers accounting for 10% to 23% of the accounts receivable balance. For the year ended December 31, 2015, 3 customers accounted for 38% of our product sales, with these individual customers ranging from 10% to 18% of product sales. For the year ended December 31, 2014, one customer accounted for 18% of our product sales.

We continue to monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. A substantial portion of our accounts receivable due from these countries are due from or backed by sovereign or local governments, and the amount of non-sovereign accounts receivable is not material. Although collection of our accounts receivables from certain countries may extend

beyond our credit terms, we do not expect any such delays to have a material impact on our financial condition or results of operations.

We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. As of December 31, 2015, we have foreign exchange forward contracts with notional amounts totaling $2,535,490. These outstanding foreign exchange forward contracts had a net fair value of $147,633, of which an unrealized gain of $158,054 is included in other assets, offset by an unrealized loss of $10,421 included in other liabilities. The counterparties to these foreign exchange forward contracts are large domestic and multinational commercial banks, and we believe the risk of nonperformance is not material.

At December 31, 2015, our financial assets and liabilities were recorded at fair value. We have classified our financial assets and liabilities as Level 1, 2 or 3 within the fair value hierarchy. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Our Level 1 assets consist of mutual fund investments. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, but substantially the full term of the financial instrument. Our Level 2 assets consist primarily of institutional money market funds, commercial paper, municipal bonds, U.S. and foreign government-related debt, corporate debt securities, certificates of deposit and foreign exchange forward contracts. Our Level 2 liabilities consist also of foreign exchange forward contracts. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. Our Level 3 liabilities consist of contingent consideration related to acquisitions.

Business Combinations and Contingent Consideration Obligations

The purchase agreements for our business combinations include contingent payments totaling up to $826,000 that will become payable if and when certain development and commercial milestones are achieved. Of these milestone amounts, $511,000 and $315,000 of the contingent payments relate to development and commercial milestones, respectively. We do not expect these amounts to have an impact on our liquidity in the near-term, and, during the next 12 months, we expect to make milestone payments of approximately $60,000 associated with our prior business combinations. As additional future payments become probable, we will evaluate methods of funding payments, which could be made from available cash and marketable securities, cash generated from operations or proceeds from other financing.

Financing Lease Obligations

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, 2015, we recorded a construction-in-process asset of $226,696, inclusive of the landlord's costs as well as costs incurred by Alexion, and an offsetting facility lease obligation of $132,866, associated with the new facility.

During the third quarter 2015, we entered into a new agreement with Lonza Group AG and its affiliates (Lonza) whereby Lonza will construct a new manufacturing facility dedicated to Alexion at its existing Portsmouth, New Hampshire facility. As a result of our contractual right to full capacity of the new manufacturing facility, a portion of the payments under the agreement are considered to be lease payments and a portion as payment for the supply of inventory. Although we will not legally own the premises, we are deemed to be the owner of the manufacturing facility during the construction period based on applicable accounting guidance for build-to-suit leases due to our involvement during the construction period. As of December 31, 2015, we recorded a construction-in-process asset $19,259 associated with the manufacturing facility and an offsetting facility lease obligation of $15,229.

License Agreements

In March 2015, we entered into a collaboration agreement with a third party that allows us to identify and optimize drug candidates. Alexion will have the exclusive worldwide rights to develop and commercialize products arising from the collaboration. Due to the early stage of the assets we are licensing in connection with the collaboration, we recorded expense for the upfront payment of $15,000 during the first quarter 2015. In addition, we could be required to pay up to an additional $250,750 if certain development, regulatory, and commercial milestones are met over time, as well as royalties on commercial sales.

In January 2015, we entered into a license agreement with a third party to obtain an exclusive research, development and commercial license for specific therapeutic molecules. Due to the early stage of these assets, we recorded expense for the

upfront payment of $50,000 during the first quarter 2015. In addition, we could be required to pay up to an additional $822,000 if certain development, regulatory, and commercial milestones are met over time, as well as royalties on commercial sales.

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

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

In addition, we have entered into other license agreements under which we would be required to pay up to an additional $785,500 if certain development, regulatory and commercial milestones are met.

Our license agreements include contingent payments that will become payable if and when certain development, regulatory and commercial milestones are achieved. We do not expect the payments associated with these milestones to have a significant impact on our liquidity in the near-term. During the next 12 months, we expect to make milestone payments related to our license agreements of approximately $26,400.

Long-term Debt

On June 22, 2015, Alexion entered into a credit agreement (the Credit Agreement) with a syndicate of banks, which provides for a $3,500,000 term loan facility and a $500,000 revolving facility. Borrowings under the term loan facility are payable in quarterly installments equal to 1.25% of the original loan amount, beginning December 31, 2015. Final repayment of the term loan and any draw down of revolving credit loans are due on June 22, 2020. In addition to borrowings in which prior notice is required, the revolving credit facility includes a sublimit of $100,000 in the form of letters of credit and borrowings on same-day notice, referred to as swingline loans, of up to $25,000. Borrowings can be used for working capital requirements, acquisitions and other general corporate purposes.

In connection with the acquisition of Synageva in June 2015, we borrowed $3,500,000 under the term loan facility and $200,000 under the revolving facility, and we used our available cash for the remaining cash consideration. In June 2015, we repaid the revolving facility in full. As of December 31, 2015, we had $3,456,250 outstanding on the term loan. As of December 31, 2015, we had open letters of credit of $13,784, and our borrowing availability under the revolving facility was $486,216.

Manufacturing Obligations

We have supply agreements with Lonza through 2028 relating to the manufacture of eculizumab and asfotase alfa, which requires payments to Lonza at the inception of contract and upon the initiation and completion of product manufactured. On an ongoing basis, we evaluate our plans for future levels of manufacturing by Lonza, which depends upon our commercial requirements, the progress of our clinical development programs and the production levels of ARIMF.

We have various agreements with Lonza, with remaining total non-cancellable commitments of approximately $1,156,980 through 2028. Certain commitments may be canceled only in limited circumstances. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at ARIMF and a payment with respect to sales of Soliris manufactured at Lonza facilities.

In addition to Lonza, we have non-cancellable commitments of approximately $36,400 through 2019 with other third party manufacturers.

Taxes

We do not record U.S. tax expense on the undistributed earnings of our controlled foreign corporation (CFC) subsidiaries. These earnings relate to ongoing operations and were approximately $1,012,000 at December 31, 2015. We intend to reinvest these earnings permanently outside the U.S. or repatriate the earnings only when it is tax efficient to do so. Accordingly, we believe that U.S. tax on any earnings that might be repatriated would be substantially offset by realizing the benefit of tax attributes, such as U.S. Foreign tax credits or by utilizing deficits in the foreign earnings and profits account.

During the fourth quarter of 2013, in connection with the centralization of our global supply chain and technical operations in Ireland, our U.S. parent company became a direct partner in a foreign partnership subsidiary. To the extent that our U.S. parent company receives its allocation of partnership taxable income, the amounts will be taxable in the U.S., and therefore the permanent reinvestment assertion will no longer apply.

We do not have any present or anticipated future need for cash held by our CFCs, as cash generated in the U.S., as well as borrowings, are expected to be sufficient to meet U.S. liquidity needs for the foreseeable future. At December 31, 2015, approximately $758,000 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. These subsidiaries will settle any outstanding intercompany trade payables prior to having excess cash available which could be repatriated to our entities in the United States. While we intend to reinvest CFC earnings permanently outside the U.S. or repatriate the earnings only when it is tax efficient to do so, certain unforeseen future events could impact our permanent reinvestment assertion. Such events include acquisitions, corporate restructurings or tax law changes not currently contemplated.

Common Stock Repurchase Program

In November 2012, our Board of Directors authorized a share repurchase program. In May 2015, our Board of Directors increased the authorization of shares up to $1,000,000 for future purchases under the repurchase program, which superseded all prior repurchase programs. The repurchase program does not have an expiration date, and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at the Company's discretion. We expect that cash generated from operations and our existing available cash and cash equivalents will be sufficient to fund any share repurchases.

Under the program, we repurchased 1,963 and 1,903 shares of our common stock at a cost of $327,699 and $302,599 during the years ended December 31, 2015 and 2014, respectively. The Company did not repurchase any shares during the pendency of the Synageva acquisition, and the Company began repurchasing shares again in the third quarter 2015.

Subsequent to December 31, 2015, we repurchased 648 shares of our common stock under our repurchase program at a cost of $98,206. As of February 8, 2016, there is a total of $657,658 remaining for repurchases under the repurchase program.

Cash Flows

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

	Year Ended December 31,		
	2015	2014	$ Change
Net cash provided by operating activities	$675,199	$640,075	$35,124
Net cash used in investing activities	(3,585,173)	(222,869)	(3,362,304)
Net cash provided by financing activities	2,985,077	7,126	2,977,951
Effect of exchange rate changes on cash	(8,991)	(10,190)	1,199
Net change in cash and cash equivalents	$66,112	$414,142	$(348,030)

Operating Activities

Cash flows provided by operations in 2015 was $675,199 compared to $640,075 in 2014. The increase was primarily due to the following:

- Increase in gross margin on product sales of $309,572 resulting primarily from an increase in global demand for Soliris.

Partially offset by the following:

- Additional cash needs associated with the Synageva acquisition, including approximately $98,314 of additional operating expenses, $39,210 of acquisition costs and $13,335 of restructuring costs, as well as an increase in interest expense of $42,968 on our new credit facility.
- Increase in cash outflows related to our licensing arrangements, which totaled $129,750 and $109,925 for the years ended December 31, 2015 and 2014, respectively.

In 2016, we expect increases in cash flow from operations which will be highly dependent on sales levels, and the related cash collections from sales of our products. We also expect cash outflows of approximately $26,400 related to milestone payments on our license agreements.

Investing Activities

Cash used for investing activities in 2015 was $3,585,173 compared to $222,869 in 2014. The increase was primarily due to the following:

- Payment of $3,939,307 during 2015 related to the Synageva acquisition.
- Purchases of property, plant and equipment of $286,335 during the year ended December 31, 2015, compared to $136,650 for the year ended December 31, 2014 due to increased capital spending associated with the construction of our New Haven headquarters and our two facilities in Ireland.

Partially offset by the following:

- Purchases of available-for-sale marketable securities of $519,723 for the year ended December 31, 2015, compared to $664,228 for the year ended December 31, 2014.
- Proceeds from the maturity or sale of available-for-sale marketable securities of $1,159,459 for the year ended December 31, 2015, which were used to fund the acquisition of Synageva. Proceeds from the maturity or sale of available-for-sale marketable securities were $619,447 for the year ended December 31, 2014.

We expect to continue to have significant spending on property, plant and equipment in 2016 related to the construction of our new biologics manufacturing facility in Ireland.

Financing Activities

Cash flows provided by financing activities in 2015 was $2,985,077 compared to $7,126 in 2014. The increase was primarily due to the following:

- Proceeds from our new term loan facility of $3,500,000 during the year ended December 31, 2015.
- Proceeds from the issuance of stock for share-based compensation arrangements of $81,982 for the year ended December 31, 2015, compared to and $114,350 in 2014.

Partially offset by the following:

- Change in 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 of $(89,655) for the year ended December 31, 2015, compared to $251,136 in 2014, due to our election to deduct, rather than capitalize research and development expenses pursuant to Internal Revenue Code section 59(e) on our 2014 federal income tax return, and higher 2014 excess tax benefit deductions from stock option exercises and restricted stock vestings.
- Milestone payments of $50,000 during the year ended December 31, 2015 associated with business combinations completed in prior years.
- Payments of debt issuance costs of $45,492 during the year ended December 31, 2015 in connection with our new debt facility.
- Principal payments of $43,750 related to our new credit facility.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2015 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	$3,456,250	$175,000	$350,000	$2,931,250	$—
Interest expense (1)	274,818	67,134	123,874	83,810	—
Pension obligations	14,639	1,521	3,214	3,028	6,876
Facility lease obligation (2)	239,120	14,391	30,038	31,162	163,529
Operating leases	89,635	25,223	31,986	15,002	17,424
Total contractual obligations	$4,074,462	$283,269	$539,112	$3,064,252	$187,829
Commercial commitments:					
Clinical and manufacturing development (3)	$1,193,380	$160,820	$360,370	$224,190	$448,000
Total commercial commitments	$1,193,380	$160,820	$360,370	$224,190	$448,000

(1) Interest on variable rate debt calculated based on interest rates at December 31, 2015.

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

(3) Clinical and manufacturing development commitments include only non-cancellable commitments, including all Lonza agreements, at December 31, 2015.

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

The table above also does not include a liability for unrecognized tax benefits related to various federal, state and foreign income tax matters of $113,945 at December 31, 2015. The timing of the settlement of these amounts was not reasonably estimable at December 31, 2015. 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 or license agreements, as the timing of payment for these amounts was not reasonably estimable at December 31, 2015. Contingent payments associated with these business combinations total up to $826,000 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 of approximately $60,000 associated with our prior business combinations. License commitments include contingent payments that will become payable if and when certain development, regulatory and commercial milestones are achieved under which we would be required to pay additional amounts if certain development, regulatory and commercial milestones are met. During the next 12 months, we expect to make milestone payments related to our license agreements of approximately $26,400.

Credit Facilities

On June 22, 2015, Alexion entered into a credit agreement (Credit Agreement) with a syndicate of banks, which provides for a $3,500,000 term loan facility and a $500,000 revolving credit facility maturing in five years.

Borrowings under the term loan are payable in quarterly installments equal to 1.25% of the original loan amount, beginning December 31, 2015. Final repayment of the term loan and revolving credit loans are due on June 22, 2020. In addition to borrowings in which prior notice is required, the revolving credit facility includes a sublimit of $100,000 in the form of letters of credit and borrowings on same-

day notice, referred to as swingline loans, of up to $25,000. 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 in an amount that does not cause our consolidated net leverage ratio to exceed the maximum allowable amount.

Under the Credit Agreement we may elect that the loans under the Credit Agreement bear interest at a rate per annum equal to either a base rate or a Eurodollar rate plus, in each case, an applicable margin. The applicable margins on base rate loans range from 0.25% to 1.00% and the applicable margins on Eurodollar loans range from 1.25% to 2.00%, in each case depending upon our consolidated net leverage ratio (as calculated in accordance with the Credit Agreement).

Our obligations under the credit facilities are guaranteed by certain of Alexion's foreign and domestic subsidiaries and secured by liens on certain of Alexion's and its subsidiaries' equity interests, subject to certain exceptions.

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, and engage in certain investment, acquisition and disposition transactions. 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 previous headquarters and research and development facility in Cheshire, Connecticut, as well as office space at our regional executive and sales offices in Zurich, Switzerland. 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.

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. Our commitments with Lonza do not include amounts for estimated CPI adjustments.

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

(amounts in thousands, except percentages)

Interest Rate Risk

As of December 31, 2015, we invested our cash in a variety of financial instruments, principally money market funds, corporate bonds, municipal bonds, commercial paper and government-related obligations. Most of our interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate. Our investment portfolio is comprised of marketable securities of highly rated financial institutions and investment-grade debt instruments, and we have guidelines to limit the term-to-maturity of our investments. Based on the type of securities we hold, we do not believe a change in interest rates would have a material impact on our financial statements. If interest rates were to increase or decrease by 1%, the fair value of our investment portfolio would (decrease) increase by approximately $(4,805) and $4,593, respectively.

In June 2015, we entered into the Credit Agreement with interest at a rate per annum equal to either a base rate or a Eurodollar rate plus, in each case, an applicable margin. The applicable margins on base rate loans range from 0.25% to 1.00% and the applicable margins on Eurodollar loans range from 1.25% to 2.00%, in each case depending upon our consolidated net leverage ratio (as calculated in accordance with the Credit Agreement). Changes in interest rates

related to the Credit Agreement could have a material effect on our financial statements. As of December 31, 2015, we had approximately

$3,456,250 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 $34,563.

Foreign Exchange Market Risk

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

Our monetary exposures on our balance sheet arise primarily from cash, accounts receivable, intercompany receivables and payables denominated in foreign currencies. Approximately 52.4% of our product sales were denominated in foreign currencies during 2015, and our revenues are also exposed to fluctuations in the foreign currency exchange rates over time. In certain foreign countries, we may sell in U.S. Dollar, but our customers may be impacted adversely in fluctuations in foreign currency exchange rates which may also impact the timing and amount of our revenue.

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

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

As of December 31, 2015 and 2014, we held foreign exchange forward contracts with notional amounts totaling $2,535,490 and $1,748,931, respectively. The increase in outstanding foreign exchange forward contracts resulted primarily from increases in forecasted revenues and, for certain currencies, extended duration of hedges. As of December 31, 2015 and 2014, our outstanding foreign exchange forward contracts had a net fair value of $147,633 and $135,166, respectively. The increase in the net fair value of outstanding foreign exchange forward contracts is primarily due to the strengthening of the U.S. dollar in 2014.

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

Based on our foreign currency exchange rate exposures at December 31, 2015, 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 $183,713 at December 31, 2015. The resulting loss on these forward contracts would be offset by the gain on the underlying transactions and therefore would have minimal impact on future anticipated earnings and cash flows. Similarly, adverse fluctuations in exchange rates that would decrease the fair value of our foreign exchange forward contracts that are not designated as hedge instruments would be offset by a positive impact of the underlying monetary assets and liabilities.

Credit Risk

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

our financial condition or results of operations.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

Item 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act,) as of December 31, 2015. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2015, 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 conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2015 based on the framework in Internal Control-Integrated Framework (2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission. The scope of such assessment did not include the Synageva BioPharma Corp. (Synageva) business, which was acquired on June 22, 2015 and accounted for under the acquisition method of accounting for business combinations. Total assets and revenue of the Synageva business represented approximately 1% and less than 1%, respectively, of the accompanying consolidated financial statement amounts as of an for the year ended December 31, 2015. Based on the evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2015.

The effectiveness of our internal control over financial reporting as of December 31, 2015 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, 2015 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 September 2015 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)
2.4	Agreement and Plan of Reorganization, dated May 5, 2015, among Alexion Pharmaceuticals, Inc., Pulsar Merger Sub Inc., Galaxy Merger Sub LLC and Synageva BioPharma Corp. (4)
3.1	Certificate of Incorporation, as amended.(5)
3.2	Certificate of Amendment of the Certificate of Incorporation.(6)
3.3	Bylaws, as amended.(7)
4.1	Specimen Common Stock Certificate.(8)
10.1	Consulting Agreement, by and between Alexion Pharmaceuticals, Inc. and Dr. Leonard Bell, dated April 1, 2015.(9)
10.2	Letter Agreement, by and between Alexion Pharmaceuticals, Inc. and Dr. Leonard Bell, dated April 1, 2015.(9)
10.5	Employment Agreement, dated as of February 14, 2006, between Alexion and Vikas Sinha.(10)**
10.6	Amendment No. 1 to the Employment Agreement, dated as of December 23, 2009, between Alexion and Vikas Sinha.(11)**

10.7	Form of Employment Agreement (Senior Vice Presidents).(10)**
10.8	Form of Amendment No. 1 to Employment Agreements (Senior Vice Presidents). (11)**
10.9	Form of Indemnification Agreement for Officers and Directors. (12)
10.10	Agreement of Lease, dated May 9, 2000, between Alexion and WE Knotter L.L.C.(13)+
10.11	Lease, dated November 15, 2012, between Alexion and WE Route 34, LLC.(14)
10.12	Alexion's 2000 Stock Option Plan, as amended.(15)**
10.13	Alexion's 1992 Outside Directors Stock Option Plan, as amended.(16)**
10.14	Alexion's Amended and Restated 2004 Incentive Plan.(17)**
10.15	License Agreement dated March 27, 1996 between Alexion and Medical Research Council.(18)+
10.16	Master Manufacturing and Supply Agreement, dated December 16, 2014 between Alexion Pharma International Trading, Alexion Pharmaceuticals, Inc, Lonza Group AG, Lonza Biologics Tuas PTE LTD and Lonza Sales AG. (24)*
10.17	Form of Stock Option Agreement for Directors.(20)**

10.18	Form of Stock Option Agreement for Executive Officers (Form A).(21)**
10.19	Form of Stock Option Agreement for Executive Officers (Form B).(21)**
10.20	Form of Restricted Stock Award Agreement for Executive Officers (Form A).(22)**
10.21	Form of Stock Option Agreement (Incentive Stock Options).(19)
10.22	Form of Stock Option Agreement (Nonqualified Stock Options).(19)
10.23	Form of Restricted Stock Award Agreement.(19)
10.24	Form of Restricted Stock Unit Award Agreement.(23)
10.25	Form of Stock Option Agreement for Participants in France.(19)**
10.26	Form of Restricted Stock Unit Agreement for Participants in France.(19)**
10.27	Credit Agreement, dated as of June 22, 2015, by and among Alexion Pharmaceuticals, Inc, as administrative borrower, the guarantors referred to therein, the lenders referred to therein and Bank of America, N.A., as administrative agent. (25)
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, 2015 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 Report on Form 8-K, filed on May 6, 2015
(5)

Incorporated by reference to our Registration Statement on Form S-3 (Reg. No. 333-128085), filed on September 2, 2005.

(6) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

(7) Incorporated by reference to our Report on Form 8-K, filed on January 8, 2016.

(8) Incorporated by reference to our Registration Statement on Form S-1 (Reg. No. 333-00202).

(9) Incorporated by reference to our Report on Form 8-K, filed April 7, 2015.

(10) Incorporated by reference to our Report on Form 8-K filed on February 16, 2006.

(11) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

(12) Incorporated by reference to our Report on Form 8-K, filed on September 17, 2010.

(13) Incorporated by reference to our Registration Statement on Form S-3 (Reg. No. 333-36738) filed on May 10, 2000.

(14) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013.

(15) Incorporated by reference to our quarterly report on Form 10-Q for the quarter ended January 31, 2004.

(16) Incorporated by reference to our Registration Statement on Form S-8 (Reg. No. 333-71879) filed on February 5, 1999.

(17) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

(18) Incorporated by reference to our Annual Report on Form 10-K/A for the fiscal year ended July 31, 1996.

(19) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

(20) Incorporated by reference to our report on Form 8-K, filed on December 16, 2004.

(21) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2005.

(22) Incorporated by reference to our report on Form 8-K, filed on March 14, 2005.
(23) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2010.
(24) Incorporated by reference to our Report on Form 10-K for the fiscal year ended December 31, 2014.
(25) Incorporated by reference to our report on Form 8-K, filed on June 23, 2015.

+ Confidential treatment was granted for portions of such exhibit.

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

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

Item 15(b) Exhibits
See (a) (3) above.

Item 15(c) Financial Statement Schedules
See (a) (2) above.

SIGNATURES

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

ALEXION PHARMACEUTICALS, INC.

By: /s/ David Hallal
David Hallal
Chief Executive Officer (principal executive officer)

Dated: February 8, 2016

By: /s/ Vikas Sinha
Vikas Sinha, M.B.A., C.A. Executive Vice President and Chief Financial Officer
(principal financial officer)
Dated: February 8, 2016

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/ David Hallal David Hallal	Chief Executive Officer and Director (principal executive officer)	February 8, 2016
/s/ Vikas Sinha Vikas Sinha, M.B.A., C.A., C.P.A.	Executive Vice President and Chief Financial Officer (principal financial officer)	February 8, 2016
/s/ Daniel A. Bazarko Daniel A. Bazarko, C.P.A.	Senior Vice President and Chief Accounting Officer (principal accounting officer)	February 8, 2016
/s/ Leonard Bell Leonard Bell, M.D.	Chairman	February 8, 2016
/s/ Felix J. Baker Felix J. Baker, Ph.D.	Director	February 8, 2016
/s/ David R. Brennan David R. Brennan	Director	February 8, 2016
/s/ M. Michele Burns M. Michele Burns	Director	February 8, 2016
/s/ Christopher J. Coughlin Christopher J. Coughlin	Director	February 8, 2016
/s/ John T. Mollen John T. Mollen	Director	February 8, 2016

/s/ R. Douglas Norby R. Douglas Norby	Director	February 8, 2016
/s/ Alvin S. Parven Alvin S. Parven	Director	February 8, 2016
/s/ Andreas Rummelt Andreas Rummelt, Ph.D.	Director	February 8, 2016
/s/ Ann M. Veneman Ann M. Veneman	Director	February 8, 2016

Alexion Pharmaceuticals, Inc.
Contents
For the Years Ended December 31, 2015, 2014 and 2013

Report of Independent Registered Public Accounting Firm
To Board of Directors and Stockholders
of Alexion Pharmaceuticals, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, comprehensive income, changes in stockholders' equity and cash flows present fairly, in all material respects, the financial position of Alexion Pharmaceuticals, Inc. and its subsidiaries at December 31, 2015 and December 31, 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting. 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.

As described in Management's Report on Internal Control over Financial Reporting, management has excluded Synageva BioPharma Corp. from its assessment of internal control over financial reporting as of December 31, 2015 because it was acquired by the Company in a purchase business combination during 2015. We have also excluded Synageva BioPharma Corp. from our audit of internal control over financial reporting. Synageva BioPharma Corp. is a wholly-owned subsidiary whose total assets and total revenues represent 1% and less than 1%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2015.

/s/ PricewaterhouseCoopers LLP

Hartford, Connecticut

February 8, 2016

F-2

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

	December 31, 2015	2014
Assets		
Current Assets:		
Cash and cash equivalents	$1,010,111	$943,999
Marketable securities	374,904	1,017,567
Trade accounts receivable, net	532,832	432,888
Inventories	289,874	176,441
Prepaid expenses and other current assets	217,628	225,134
Total current assets	2,425,349	2,796,029
Property, plant and equipment, net	697,025	392,248
Intangible assets, net	4,707,914	587,046
Goodwill	5,047,885	254,073
Other assets	255,057	172,566
Total assets	$13,133,230	$4,201,962
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$57,360	$44,016
Accrued expenses	403,348	395,232
Deferred revenue	20,504	58,837
Current portion of long-term debt	175,000	48,000
Other current liabilities	62,038	60,655
Total current liabilities	718,250	606,740
Long-term debt, less current portion	3,281,250	9,500
Contingent consideration	121,424	116,425
Facility lease obligation	151,307	107,099
Deferred tax liabilities	528,990	7,046
Other liabilities	73,393	53,134
Total liabilities	4,874,614	899,944
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; 230,498 and 201,944 shares issued at December 31, 2015 and 2014, respectively	23	20
Additional paid-in capital	7,726,560	2,592,167
Treasury stock, at cost, 4,851 and 2,888 shares at December 31, 2015 and 2014, respectively	(710,663)	(382,964)
Accumulated other comprehensive income	62,301	56,785
Retained earnings	1,180,395	1,036,010
Total stockholders' equity	8,258,616	3,302,018
Total liabilities and stockholders' equity	$13,133,230	$4,201,962

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,		
	2015	2014	2013
Net product sales	$2,602,532	$2,233,733	$1,551,346
Other revenue	1,515	—	—
Total revenues	2,604,047	2,233,733	1,551,346
Cost of sales:			
Cost of sales	233,089	173,862	168,375
Change in contingent liability from intellectual property settlements	—	—	9,181
Total cost of sales	233,089	173,862	177,556
Operating expenses:			
Research and development	709,472	513,782	317,093
Selling, general and administrative	862,595	630,209	489,720
Amortization of purchased intangible assets	116,584	—	417
Change in fair value of contingent consideration	64,257	20,295	4,006
Acquisition-related costs	39,210	—	1,023
Restructuring expenses	42,169	15,365	—
Impairment of intangible assets	—	11,514	33,521
Total operating expenses	1,834,287	1,191,165	845,780
Operating income	536,671	868,706	528,010
Other income and expense:			
Investment income	8,519	8,373	3,346
Interest expense	(47,744)	(2,982)	(4,112)
Foreign currency gain (loss)	696	(1,990)	(975)
Income before income taxes	498,142	872,107	526,269
Income tax provision	353,757	215,195	273,374
Net income	$144,385	$656,912	$252,895
Earnings per common share			
Basic	$0.68	$3.32	$1.29
Diluted	$0.67	$3.26	$1.27
Shares used in computing earnings per common share			
Basic	213,431	198,103	195,532
Diluted	215,933	201,623	199,712

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,		
	2015	2014	2013
Net income	$144,385	$656,912	$252,895
Other comprehensive income (loss), net of tax:			
Foreign currency translation	(6,276)	(6,337)	(4,573)
Unrealized losses on marketable securities	(551)	(88)	(146)
Unrealized gains (losses) on pension obligation	6,981	(5,068)	(5,790)
Unrealized gains (losses) on hedging activities, net of tax of $5,643, $45,448 and $(871), respectively	5,362	91,135	(18,983)
Other comprehensive income (loss), net of tax	5,516	79,642	(29,492)
Comprehensive income	$149,901	$736,554	$223,403

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, 2012	194,918	$20	$1,852,221	227	$(14,229)	$ 6,635	$126,203	$1,970,850
Repurchase of common stock	—	—	—	758	(66,136)	—	—	(66,136)
Issuance of common stock from exercise of options	2,481	—	71,281	—	—	—	—	71,281
Issuance of restricted common stock	542	—	—	—	—	—	—	—
Excess tax benefit from stock options	—	—	105,714	—	—	—	—	105,714
Share-based compensation expense	—	—	76,967	—	—	—	—	76,967
Net income	—	—	—	—	—	—	252,895	252,895
Other comprehensive loss	—	—	$—	—	—	(29,492)	—	$(29,492)
Balances, December 31, 2013	197,941	$20	$2,106,183	985	$(80,365)	$ (22,857)	$379,098	$2,382,079
Repurchase of common stock	—	—	—	1,903	(302,599)	—	—	(302,599)
Issuance of common stock from exercise of options	3,408	—	114,350	—	—	—	—	114,350
Issuance of restricted common stock	595	—	—	—	—	—	—	—
Excess tax benefit from stock options	—	—	251,136	—	—	—	—	251,136
Share-based compensation expense	—	—	120,498	—	—	—	—	120,498
Net income	—	—	—	—	—	—	656,912	656,912
Other comprehensive loss	—	—	—	—	—	79,642	—	79,642
Balances, December 31, 2014	201,944	$20	$2,592,167	2,888	$(382,964)	$ 56,785	$1,036,010	$3,302,018
Repurchase of common stock	—	—	—	1,963	(327,699)	—	—	(327,699)
Issuance of common stock, net of issuance costs of $4,053	26,125	3	4,913,754	—	—	—	—	4,913,757
Issuance of common stock under stock option and stock purchase plans	1,363	—	81,982	—	—	—	—	81,982
Issuance of restricted common stock	1,066	—	—	—	—	—	—	—
Excess tax benefit from stock options	—	—	(89,655)	—	—	—	—	(89,655)

Share-based compensation expense	—	—	228,312	—	—	—	—	228,312
Net income	—	—	—	—	—	—	144,385	144,385
Other comprehensive loss	—	—	—	—	—	5,516	—	5,516
Balances, December 31, 2015	230,498	$23	$7,726,560	4,851	$(710,663)	$ 62,301	$1,180,395	$8,258,616

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,		
	2015	2014	2013
Cash flows from operating activities:			
Net income	$144,385	$656,912	$252,895
Adjustments to reconcile net income to net cash flows from operating activities:			
Depreciation and amortization	166,621	46,939	28,693
Impairment of intangible assets	—	11,514	33,521
Change in fair value of contingent consideration	64,257	20,295	4,006
Share-based compensation expense	227,133	114,461	76,203
Premium amortization of available-for-sale securities	6,782	15,519	3,235
Deferred taxes	395,495	(153,905)	92,831
Change in excess tax benefit from stock options	89,655	(251,136)	(105,714)
Other	(3,958)	22,046	2,040
Changes in operating assets and liabilities, excluding the effect of acquisitions:			
Accounts receivable	(115,812)	(28,137)	(116,439)
Inventories	(88,375)	(66,812)	126
Prepaid expenses and other assets	(57,168)	(18,392)	(39,879)
Accounts payable, accrued expenses and other liabilities	(115,938)	264,572	242,355
Deferred revenue	(37,878)	6,199	23,476
Net cash provided by operating activities	675,199	640,075	497,349
Cash flows from investing activities:			
Purchases of available-for-sale securities	(519,723)	(664,228)	(1,048,429)
Proceeds from maturity or sale of available-for-sale securities	1,159,459	619,447	60,917
Purchases of trading securities	(14,980)	(3,431)	(985)
Proceeds from sale of trading securities	10,239	186	—
Purchases of property, plant and equipment	(286,335)	(136,650)	(29,329)
Purchases of other investments	—	(37,500)	—
Payments for acquisitions of businesses, net of cash acquired	(3,939,307)	—	—
Other	5,474	(693)	(9,315)
Net cash used in investing activities	(3,585,173)	(222,869)	(1,027,141)
Cash flows from financing activities:			
Debt issuance costs	(45,492)	—	—
Proceeds from revolving credit facility	200,000	—	—
Payments on revolving credit facility	(200,000)	—	—
Proceeds from term loan	3,500,000	—	—
Payments on term loan	(101,250)	(55,500)	(36,000)
Equity issuance costs for shares issued in connection with acquisition of business	(4,053)	—	—
Change in excess tax benefit from stock options	(89,655)	251,136	105,714
Repurchase of common stock	(327,699)	(302,599)	(66,136)
Net proceeds from issuance of stock under share-based compensation arrangements	81,982	114,350	71,281
Payment of contingent consideration	(50,000)	—	(3,000)
Proceeds from development-related grants	26,000	—	—
Other	(4,756)	(261)	(220)

Net cash provided by financing activities	2,985,077	7,126	71,639
Effect of exchange rate changes on cash	(8,991)	(10,190)	(1,491)
Net change in cash and cash equivalents	66,112	414,142	(459,644)
Cash and cash equivalents at beginning of period	943,999	529,857	989,501
Cash and cash equivalents at end of period	$1,010,111	$943,999	$529,857

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,		
	2015	2014	2013
Supplemental cash flow disclosures:			
Cash paid for interest (net of amounts capitalized)	$41,357	$1,910	$2,831
Cash paid for income taxes	$123,171	$91,195	$76,165
Supplemental cash flow disclosures from investing and financing activities:			
Common stock issued in acquisition of business	$4,917,810	$—	$—
Construction in process related to facility lease obligations	$40,996	$74,869	$32,230
Accrued expenses for purchases of property, plant and equipment	$30,067	$17,092	$—

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, 2015, 2014 and 2013
(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 devastating and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products.

In our complement franchise, Soliris® is the first and only therapeutic approved for patients with either paroxysmal nocturnal hemoglobinuria (PNH), a life-threatening and ultra-rare genetic blood disorder, or atypical hemolytic uremic syndrome (aHUS), a life-threatening and ultra-rare genetic disease. PNH and aHUS are two severe and ultra-rare disorders resulting from chronic uncontrolled activation of the complement component of the immune system.

In our metabolic franchise, we market Strensiq® for the treatment of patients with hypophasphatasia (HPP) and Kanuma™ for the treatment of patients with lysosomal acid lipase deficiency (LAL-D). HPP is a genetic ultra-rare disease characterized by defective bone mineralization that can lead to deformity of bones and other skeletal abnormalities. LAL-D is a serious, life threatening ultra-rare disease in which genetic mutations result in decreased activity of the LAL enzyme leading to marked accumulation of lipids in vital organs, blood vessels and other tissues. We initiated sales of these products in the third quarter 2015.

We are also evaluating additional potential indications for eculizumab in other severe and devastating diseases in which uncontrolled complement activation is the underlying mechanism, and we are progressing in various stages of development with additional product candidates as potential treatments for patients with severe and life-threatening rare disorders.

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

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

Foreign Currency Translation

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

Cash and Cash Equivalents

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

Fair Value of Financial Instruments

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

Marketable Securities

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

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

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

Accounts Receivable

Our standard credit terms vary based on the country of sale and range from 30 to 120 days. Our consolidated average days' sales outstanding ranges from 60 to 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

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

the portion of receivables if and when collection becomes doubtful, and we also assess on an ongoing basis whether collectibility is reasonably assured at the time of sale.

Concentration of Credit Risk

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

At December 31, 2015, three customers accounted for 51% of the accounts receivable balance, with these individual customers ranging from 14% to 22% of the accounts receivable balance. At December 31, 2014, four customers accounted for 58% of the accounts receivable balance, with individual customers accounting for 10% and 23%. For the year ended December 31, 2015, three customers accounted for 38% of our product sales, with these individual customers ranging from 10% to 18% of our product sales. For the year ended December 31, 2014, one customer accounted for 18% of our product sales. No other customers accounted for more than 10% of net product sales or accounts receivable.

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

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,	
	2015	2014
Raw materials	$17,924	$14,570
Work-in-process	180,324	107,170
Finished goods	91,626	54,701
	$289,874	$176,441

Capitalization of Inventory Costs

We capitalize inventory produced for commercial sale, which may include costs incurred for certain products awaiting regulatory approval. We capitalize inventory produced in preparation of product launches sufficient to support estimated initial market demand. Capitalization of such inventory begins when we have (i) obtained positive results in clinical trials that we believe are necessary to support regulatory approval, (ii) concluded that uncertainties regarding regulatory approval have been sufficiently reduced, and (iii) determined that the inventory has probable future economic benefit. In evaluating whether these conditions have been met, we consider clinical trial results for the

underlying product candidate, results from meetings with regulatory authorities, and the compilation of the regulatory application. If we are aware of any material risks or contingencies outside of the standard regulatory review and approval process, or if there are any specific negative issues identified relating to the safety, efficacy, manufacturing, marketing or labeling of the product that would have a significant negative impact on its future economic benefits, the related inventory would not be capitalized. At December 31, 2014, we capitalized $22,005 of inventory produced for commercial sale for products awaiting regulatory approval. As a result of regulatory approval, we had no inventory capitalized for products awaiting regulatory approval at December 31, 2015.

Products that have been approved by the U.S. Food and Drug Administration (FDA) or other regulatory authorities 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 the products utilized for both commercial and clinical programs is

identical and, as a result, the inventory has an "alternative future use" as defined in authoritative guidance. Raw materials and purchased drug product associated with clinical development programs are included in inventory and charged to research and development expense when the product enters the research and development process and no longer can be used for commercial purposes and, therefore, does not have an "alternative future use".

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

Inventory Write-Offs

We analyze our inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of our product is subject to strict quality control, certain batches or units of product may no longer meet quality specifications or may expire, which requires adjustments to our inventory values. We also apply judgment related to the results of quality tests that we perform throughout the production process, as well as our understanding of regulatory guidelines, to determine if it is probable that inventory will be saleable. These quality tests are performed throughout the pre-and post-production process, and we continually gather additional information regarding product quality for periods after the manufacture date. Our products currently have a maximum estimated life ranging from 36 to 48 months and, based on our sales forecasts, we expect to realize the carrying value of our inventory. In the future, reduced demand, quality issues or excess supply beyond those anticipated by management may result in a material adjustment to inventory levels, which would be recorded as an increase to cost of sales.

The determination of whether or not inventory costs will be realizable requires estimates by our management. A critical input in this determination is future expected inventory requirements based on internal sales forecasts. We then compare these requirements to the expiry dates of inventory on hand. For inventories that are capitalized in preparation of product launch, we also consider the expected approval date in assessing realizability. To the extent that inventory is expected to expire prior to being sold, we will write down the value of inventory.

Derivative Instruments

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

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

Property, Plant and Equipment

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

- Building and improvements—fifteen to thirty five years

- Machinery and laboratory equipment—five to fifteen years
- Computer hardware and software—three to seven years
- Furniture and office equipment— five to ten 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.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

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 based on their pattern of economic benefit over their estimated useful lives and reviewed periodically for impairment.

Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized over a period that best reflects the economic benefits provided by these assets.

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.

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.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

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.

Contingent Consideration

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

Contingent Liabilities

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

Treasury Stock

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

Revenue Recognition

Our principal source of revenue is product sales. We recognize revenue from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and we have no further performance obligations. Depending on these criteria, revenue is usually recorded upon receipt of the product by the end customer, which is typically a hospital, physician’s office, private or government pharmacy or other health care facility. On a regular basis, we review revenue arrangements, such as distributor relationships, to determine whether changes in these criteria have an impact on revenue recognition. Amounts collected from customers and remitted to governmental authorities, such as value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in our consolidated statements of operations and do not impact net product sales.

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

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

In addition to sales in countries where our products are commercially available, we have also recorded revenue on sales for patients receiving 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 our products have not received final approval for commercial sale.

We record estimated rebates payable under governmental programs, including Medicaid in the United States and other programs outside the United States, as a reduction of revenue at the time of product sale. Our calculations related to these rebate accruals require analysis of historical claim patterns and estimates of customer mix to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period and record any

necessary adjustments, which may have an impact on revenue in the period in which the adjustment is made. Generally, the length of time between product sale and the processing and reporting of the rebates is three to six months.

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

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

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

Research and Development Expenses

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

Share-Based Compensation

We have two share-based compensation plans pursuant to which awards are currently being made: (i) the Amended and Restated 2004 Incentive Plan (2004 Plan) and (ii) the 2015 Employee Stock Purchase Plan (ESPP). Under the 2004 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. Under the ESPP, eligible employees can purchase shares of common stock at a discount semi-annually through payroll deductions. To date, share-based compensation issued under the plans consists of incentive and non-qualified stock options, restricted stock and restricted stock units, including restricted stock units with market and non-market performance conditions, and shares issued under our ESPP.

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

Our estimates of employee stock option values rely on estimates of factors we input into the Black-Scholes model. The key factors involve an estimate of future uncertain events. Significant assumptions include the use of historical

volatility to determine the expected stock price volatility. We also estimate expected term until exercise and the reduction in the expense from expected forfeitures. We currently use historical exercise and cancellation patterns as our best estimate of future estimated life.

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

The purchase price of common stock under our ESPP is equal to 85% of the lower of (i) the market value per share of the common stock on the first business day of an offering period or (ii) the market value per share of the common stock on the

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

purchase date. The fair value of the discounted purchases made under our ESPP is calculated using the Black-Scholes model. The fair value of the look-back provision plus the 15% discount is recognized as compensation expense over the 6 month purchase period.

Earnings Per Common Share

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

The following table summarizes the calculation of basic and diluted EPS for years ended December 31, 2015, 2014 and 2013:

	Year Ended December 31,		
	2015	2014	2013
Net income used for basic and diluted calculation	$144,385	$656,912	$252,895
Shares used in computing earnings per common share—basic	213,431	198,103	195,532
Weighted-average effect of dilutive securities:			
Stock awards	2,502	3,520	4,180
Shares used in computing earnings per common share—diluted	215,933	201,623	199,712
Earnings per common share:			
Basic	$0.68	$3.32	$1.29
Diluted	$0.67	$3.26	$1.27

We exclude from EPS the weighted-average number of securities whose effect is anti-dilutive. Excluded from the calculation of EPS for the years ended December 31, 2015, 2014 and 2013 were 2,450, 1,099, and 2,243 shares of common stock, respectively, because their effect is anti-dilutive.

Income Taxes

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

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

Comprehensive Income

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

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

Other Investments

We invest in companies with securities that are not publicly traded and where fair value is not readily available. Other investments include an investment in the preferred stock of the non-public entity Moderna LLC. During 2014, we purchased $37,500 of preferred equity of Moderna LLC. We recorded our investment at cost within other assets in our condensed consolidated balance sheets. We regularly monitor these investments to evaluate whether there has been an other-than-temporary decline in its fair value, based on the implied value of recent company financings, public market prices of comparable companies, and general market conditions. The carrying value of these investments was not impaired as of December 31, 2015.

Reclassifications and Adjustments

Certain items in the prior year's consolidated financial statements have been reclassified to conform to the current presentation.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2017 and allows for adoption using a full retrospective method, or a modified retrospective method. Entities may elect to early adopt the standard for annual periods beginning after December 15, 2016. We are currently assessing the method of adoption and the expected impact the new standard has on our financial position and results of operations.

In April 2015, the FASB issued a new standard simplifying the presentation of debt issuance costs. The new standard aligns the treatment of debt issuance costs with debt discounts and premiums and requires debt issuance costs be presented as a direct deduction from the carrying amount of the related debt. The standard is effective for interim and annual periods beginning after December 15, 2015, with early adoption permitted, and requires a retrospective method of adoption. We will adopt the provisions of the new standard for the balance sheet disclosures of debt issuance costs beginning in the first quarter 2016.

In September 2015, the FASB issued a new standard simplifying the accounting for measurement-period adjustments. The new standard eliminates the requirement to restate prior period financial statements for measurement period adjustments. The new standard requires that the cumulative impact of a measurement period adjustment (including the impact on prior periods) be recognized in the reporting period in which the adjustment is identified. The standard is effective for interim and annual periods beginning after December 15, 2015 and is not expected to have a material impact on our financial condition or results of operations.

In November 2015, the FASB issued a new standard simplifying the classification of deferred tax assets and liabilities. The new standard requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. The standard is effective for interim and annual periods beginning after December 15, 2016 and allows for early adoption using a full retrospective method or a prospective method. We have elected to early adopt the provisions of this new standard using a prospective method. As a result, all deferred taxes as of December 31, 2015 are classified as noncurrent in our consolidated balance sheet, while prior periods remain as previously reported.

2. Acquisitions

On May 6, 2015, we announced that we entered into a definitive agreement to acquire Synageva BioPharma Corp. (Synageva), a publicly-held clinical-stage biotechnology company based in Lexington, Massachusetts for per share consideration of $115 in cash and 0.6581 shares of Alexion stock. At this date, the announced purchase consideration was estimated at approximately $8,400,000, net of Synageva cash, based on the closing price of Alexion stock on May 5, 2015 of $168.55.

On June 22, 2015, we completed the acquisition of Synageva, 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 from Synageva were recorded as of the acquisition date at their respective fair values. Synageva's results of operations are included in the consolidated financial statements from the date of acquisition. The acquisition furthers our objective to

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

develop and commercialize life-transforming therapies to an increasing number of patients with devastating and rare diseases. Synageva's lead product candidate, Kanuma, is an enzyme replacement therapy for patients suffering with LAL-D, a life-threatening, ultra-rare disease for which there are no approved treatments.

We acquired all of the outstanding shares of common stock of Synageva for $4,565,524 in cash and 26,125 shares of common stock. At closing of the business combination on June 22, 2015, the purchase consideration was approximately $8,860,000, net of Synageva cash, based on Alexion's closing share price on the date of acquisition of 188.24. We financed the cash consideration with existing cash and proceeds from our new credit facility described further in Note 8.

The aggregate consideration to acquire Synageva consisted of:

Stock consideration	$4,917,810
Cash consideration	4,565,524
Total purchase price	$9,483,334

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

Cash	$626,217
Inventory	23,880
In-process research and development (IPR&D)	4,236,000
Deferred tax liabilities, net	(171,638)
Other assets and liabilities	(24,937)
Net assets acquired	4,689,522
Goodwill	4,793,812
Total purchase price	$9,483,334

Our accounting for this acquisition is preliminary. The fair value estimates for the assets acquired and liabilities assumed were based upon preliminary calculations, and our estimates and assumptions are subject to change as we obtain additional information for our estimates during the measurement period (up to one year from the acquisition date). The areas of these preliminary estimates that are not yet finalized relate primarily to tax-related items. During 2015, we recorded approximately $40,744 of adjustments to the amounts initially recorded for the assets acquired and liabilities assumed as of the acquisition date. These adjustments related primarily to the valuation of acquired inventory and the assessment of inventory-related items.

We acquired $23,880 of Kanuma inventory. The estimated fair value of work-in-process and finished goods inventory was determined utilizing the comparative sales method, based on the expected selling price of the inventory, adjusted for incremental costs to complete the manufacturing process and for direct selling efforts, as well as for a reasonable profit allowance. The estimated fair value of raw material inventory was valued at replacement cost, which is equal to the value a market participant would pay to acquire the inventory.

Intangible assets associated with IPR&D projects primarily relate to Synageva's lead product candidate, Kanuma. The estimated fair value of IPR&D assets of $4,236,000 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 Synageva of 10.0%, 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. The goodwill, which is not tax-deductible, has been recorded as a

noncurrent asset and is not amortized, but is subject to an annual review for impairment. The goodwill represents future economic benefits arising from other assets acquired that could not be individually identified and separately recognized and expected synergies that are specific to our business and not available to market participants, including our unique ability to commercialize therapies for rare diseases, our existing relationships with specialty physicians who can identify patients with LAL-D, a global distribution network to facilitate drug delivery and other benefits that we believe will result from combining the operations of Synageva within our operations.

We recorded a net deferred tax liability of $171,638. This amount was primarily comprised of $594,226 and $8,661, of deferred tax liabilities related to the IPR&D and inventory acquired, respectively, offset by $231,585, $177,128, and $22,536 of

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

deferred tax assets related to net operating loss carryforwards (NOLs), tax credits, and other temporary differences, respectively, which we expect to utilize.

For the year ended December 31, 2015, we recorded $96,433 of pre-tax operating losses associated with the continuing operations of Synageva in our consolidated statements of operations.

Pro forma financial information (unaudited)

The following unaudited pro forma information presents the combined results of Alexion and Synageva as if the acquisition of Synageva had been completed on January 1, 2014, with adjustments to give effect to pro forma events that are directly attributable to the acquisition, including the impact of acquisition financing and the related tax effects. The unaudited pro forma results do not reflect operating efficiencies or potential cost savings which may result from the consolidation of operations. Accordingly, the unaudited pro forma financial information is not necessarily indicative of the results of operations that we would have recognized had we completed the transaction on January 1, 2014.

	Year Ended December 31,	
	2015	2014
Revenues	$2,606,255	$2,240,225
Net income	21,104	260,665
Earnings per common share		
Basic	$0.09	$1.16
Diluted	$0.09	$1.14

The unaudited pro forma consolidated results include the following pro forma adjustments related to non-recurring activity:

- Alexion and Synageva expenses of $33,150 and $127,290, respectively, associated with the accelerated vesting of stock based compensation as a result of the acquisition were excluded from net income for the year ended December 31, 2015. These expenses were included in net income for the year ended December 31, 2014;
- Alexion and Synageva acquisition-related and restructuring costs of $52,545 and $62,071, respectively, were excluded from income for the year ended December 31, 2015. These expenses were included in net income for the year ended December 31, 2014.

Acquisition-Related Costs

Acquisition-related costs associated with our business combinations for the years ended December 31, 2015, 2014 and 2013 include the following:

	Year Ended December 31,		
	2015	2014	2013
Transaction costs [1]	$26,955	$—	$—
Integration costs	12,255	—	1,023
	$39,210	$—	$1,023

(1) Transaction costs include investment advisory, legal, and accounting fees

The acquisition of Synageva also resulted in $13,335 of restructuring related charges for the year ended December 31, 2015. See Note 17 for additional details.

3. Property, Plant and Equipment, Net

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

	December 31, 2015	December 31, 2014
Land	$9,130	$9,130
Buildings and improvements	252,467	170,355
Machinery and laboratory equipment	91,958	65,079
Computer hardware and software	83,997	59,927
Furniture and office equipment	15,570	11,371
Construction-in-progress	420,034	214,041
	873,156	529,903
Less: Accumulated depreciation and amortization	(176,131)	(137,655)
	$697,025	$392,248

Included in construction-in-progress at December 31, 2015 and 2014 was $226,696 and $126,566, respectively, of costs associated with the construction of a new facility in New Haven, Connecticut and $19,259 at December 31, 2015 associated with the construction of a new manufacturing facility. Although we will not legally own these premises, we are deemed to be the owner of the buildings during the construction period based on applicable accounting guidance for build-to-suit leases, see Note 9, "Facility Lease Obligations" for additional information.

In connection with the construction of facilities in New Haven, Connecticut, we 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 10 years; (ii) satisfying minimum employment obligations; and (iii) minimum capital spending requirements. In the third quarter 2015, we received $26,000 for the forgivable loan and grants. The proceeds reduce the costs of our construction-in-process asset associated with the project. As of December 31, 2015, we have not received any tax credits associated with our agreement with the State of Connecticut.

Depreciation and amortization of property, plant and equipment was approximately $43,618, $34,901 and $19,084 for the years ended December 31, 2015, 2014 and 2013, respectively.

At December 31, 2015 and 2014, computer software costs included in property, plant and equipment were $19,530 and $16,292, respectively. Depreciation and amortization expense for capitalized computer software costs was $10,037, $7,016 and $4,503 for the years ended December 31, 2015, 2014 and 2013, respectively.

4. Intangible Assets and Goodwill

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

		December 31, 2015			December 31, 2014		
	Estimated Life (years)	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Licenses	6-8	$28,507	$(28,504)	$3	$28,507	$(28,461)	$46
Patents	7	10,517	(10,517)	—	10,517	(10,517)	—
Purchased technology	6-16	4,708,495	(116,584)	4,591,911	—	—	—
Acquired IPR&D	Indefinite	116,000	—	116,000	587,000	—	587,000
Total		$4,863,519	$(155,605)	$4,707,914	$626,024	$(38,978)	$587,046
Goodwill	Indefinite	$5,050,786	$(2,901)	$5,047,885	$256,974	$(2,901)	$254,073

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

In the third quarter 2015 we received regulatory approval for Strensiq and Kanuma. As a result, $587,000 and $4,120,000 of acquired IPR&D assets associated with Strensiq and Kanuma, respectively, were reclassified from acquired IPR&D to purchased technology.

Amortization expense was $116,627, $11,159 and $8,257 for the years ended December 31, 2015, 2014 and 2013, respectively. Assuming no changes in the gross cost basis of intangible assets, the total estimated amortization expense for finite-lived intangible assets is $320,223 for the year ending December 31, 2016 and $320,142 for each of the years ending December 31, 2017 through December 31, 2020.

During the fourth quarter 2014, we reviewed for impairment the value of the early stage, Phase II indefinite-lived intangible asset related to the Orphatec acquisition. We initiated such review as part of our annual impairment testing and increased costs associated with clinical trial studies. The estimated value that can be obtained from a market participant in an arm's length transaction was determined to be de minimis as of December 31, 2014. As a result, in the fourth quarter 2014, we recognized an impairment charge of $8,050 to write-down these assets to fair value. In addition, during the first quarter of 2014, we reviewed for impairment the value of an early stage, Phase I indefinite-lived intangible asset related to our acquisition of Taligen Therapeutics, Inc. We initiated such review based on a reassessment of scientific findings associated with this acquired asset. As a result, we recognized an impairment of $3,464 for the year ended December 31, 2014 to adjust this asset to fair value, which was determined to be de minimis.

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

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

Balance at December 31, 2013 and 2014	$254,073
Goodwill resulting from the Synageva acquisition	4,793,812
Balance at December 31, 2015	$5,047,885

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

5. Marketable Securities

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and estimated fair value of available-for-sale investments by type of security at December 31, 2015 and December 31, 2014 were as follows:

	December 31, 2015			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Commercial paper	$254,396	$—	$—	$254,396
Corporate bonds	133,062	23	(336)	132,749
Municipal bonds	87,173	1	(63)	87,111
Other government related obligations:				
U.S.	25,244	—	(94)	25,150
Foreign	163,403	—	(504)	162,899
Bank certificates of deposit	27,000	—	—	27,000
	$690,278	$24	$(997)	$689,305

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

The aggregate fair value of available-for-sale securities in an unrealized loss position as of December 31, 2015 and December 31, 2014 was $293,947 and $472,241. Investments that have been in a continuous unrealized loss position for more than 12 months were not material. As of December 31, 2015 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, 2015	December 31, 2014
Cash and cash equivalents	$323,218	$167,892
Marketable securities	366,087	1,013,290
	$689,305	$1,181,182

The fair values of available-for-sale debt securities at December 31, 2015, by contractual maturity, are summarized as follows:

	December 31, 2015
Due in one year or less	$493,043
Due after one year through three years	196,262
Due after three years through five years	—

$689,305

As of December 31, 2015 and December 31, 2014, the fair value of our trading securities was $8,817 and $4,277.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

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, 2015 and 2014.

6. Derivative Instruments and Hedging Activities

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

We enter into foreign exchange forward contracts, with durations of up to 60 months, to hedge exposures resulting from portions of our forecasted revenues, including intercompany revenues, that are denominated in currencies other than the U.S. dollar. The purpose of the hedges of revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. These hedges are designated as cash flow hedges upon contract inception. At December 31, 2015, we had open contracts with notional amounts totaling $1,978,737 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, 2015 and 2014 were as follows:

	Year Ended December 31,	
	2015	2014
Gain recognized in AOCI, net of tax	$110,455	$110,088
Gain reclassified from AOCI to net product sales (effective portion), net of tax	$103,175	$16,514
Gain reclassified from AOCI to other income and expense (ineffective portion), net of tax	$1,918	$2,439

Assuming no change in foreign exchange rates from market rates at December 31, 2015, $82,223 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, 2015, the notional amount of foreign exchange contracts where hedge accounting is not applied was $556,753.

We recognized a gain of $5,226, $26,295 and $8,306, in other income and expense, for the years ended December 31, 2015, 2014 and 2013, respectively, associated with the foreign exchange contracts not designated as hedging instruments. These amounts were largely offset by gains or losses in monetary assets and liabilities.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

The following tables summarize the fair value of outstanding derivatives at December 31, 2015 and 2014:

	December 31, 2015			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	$85,058	Other current liabilities	$1,491
Foreign exchange forward contracts	Other non-current assets	66,309	Other non-current liabilities	4,773
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	6,687	Other current liabilities	4,157
Total fair value of derivative instruments		$158,054		$10,421

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

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

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

December 31, 2015

				Gross Amounts Not Offset in the Consolidated Balance

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	$ 158,054	$—	$ 158,054	$(10,421)	$—	$147,633
Derivative liabilities	(10,421)	—	(10,421)	10,421	—	—

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

December 31, 2014

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		Net Amount
				Derivative Financial Instruments	Cash Collateral Received (Pledged)	
Derivative assets	$ 136,046	$—	$ 136,046	$(880)	$—	$135,166
Derivative liabilities	(880)	—	(880)	880	—	—

7. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2015	December 31, 2014
Royalties	$29,803	$25,863
Payroll and employee benefits	115,193	88,467
Taxes payable	12,087	94,823
Rebates payable	55,603	36,827
Clinical	56,933	30,123
Manufacturing	19,268	42,631
Other	114,461	76,498
	$403,348	$395,232

8. Debt

On June 22, 2015, Alexion entered into a credit agreement (Credit Agreement) with a syndicate of banks, which provides for a $3,500,000 term loan facility and a $500,000 revolving credit facility maturing in five years. Borrowings under the term loan facility are payable in quarterly installments equal to 1.25% of the original loan amount, beginning December 31, 2015. Final repayment of the term loan and any draw down of revolving credit loans are due on June 22, 2020. In addition to borrowings in which prior notice is required, the revolving credit facility includes a sublimit of $100,000 in the form of letters of credit and borrowings on same-day notice, referred to as swingline loans, of up to $25,000. 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 in an amount that does not cause our consolidated net leverage ratio to exceed the maximum allowable amount.

Under the Credit Agreement we may elect that the loans under the Credit Agreement bear interest at a rate per annum equal to either a base rate or a Eurodollar rate plus, in each case, an applicable margin. The applicable margins on base rate loans range from 0.25% to 1.00% and the applicable margins on Eurodollar loans range from 1.25% to 2.00%, in each case depending upon our consolidated net leverage ratio (as calculated in accordance with the Credit Agreement). At December 31, 2015 the interest rate on our outstanding loans under the Credit Agreement was

1.98%.Our obligations under the credit facilities are guaranteed by certain of Alexion's foreign and domestic subsidiaries and secured by liens on certain of Alexion's and its subsidiaries' equity interests, subject to certain exceptions.

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, and engage in certain investment, acquisition and disposition transactions. 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 $45,492 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 year ended December 31, 2015 was $6,376. Amortization expense associated with deferred financing costs for years ended December 31, 2014 and 2013 was not material.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

In connection with the acquisition of Synageva in June 2015, we borrowed $3,500,000 under the term loan facility and $200,000 under the revolving facility, and we used our available cash for the remaining cash consideration. At December 31, 2015, we had $3,456,250 outstanding on the term loan and zero outstanding on the revolving facility. At December 31, 2015, we had open letters of credit of $13,784, and our borrowing availability under the revolving facility was $486,216.

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

On June 22, 2015, in connection with, and simultaneously with, the execution of the Credit Agreement described above, the 2012 Credit Agreement (Prior Credit Agreement) dated February 7, 2012 was terminated, and outstanding borrowings of $33,500 were repaid.

The contractual maturities of our long-term debt obligations due subsequent to December 31, 2015 are as follows:

Year	
2016	$175,000
2017	175,000
2018	175,000
2019	175,000
2020	2,756,250

9. Facility Lease Obligations

New Haven Facility Lease Obligation

In November 2012, we entered into a new lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. The term of the new lease commenced in 2015 and will expire in 2030, with a renewal option of 10 years. 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 because of the substantial amount of tenant improvements we directly funded during the construction period. Due to the substantial tenant improvements directly funded during construction, we will continue to be deemed the owner of the building once construction is complete. Accordingly, the landlord's costs of constructing the facility during construction are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our consolidated balance sheet.

Construction of the new facility began in June 2013 and was completed in January 2016. Monthly lease payments began in 2015. The imputed interest rate on this facility lease obligation is approximately 9%. For the year ended December 31, 2015, we recognized $4,862 of interest expense. As of December 31, 2015 and 2014, our facility lease obligation was $132,866 and $107,099, respectively.

Aggregate future minimum non-cancellable commitments under the New Haven facility lease obligation, as of December 31, 2015 are as follows:

Year	
2016	$14,391
2017	14,907
2018	15,131
2019	15,581
2020	15,581
Thereafter	163,529

Lonza Facility Lease Obligation

During the third quarter 2015, we entered into a new agreement with Lonza Group AG and its affiliates (Lonza) whereby Lonza will construct a new manufacturing facility dedicated to Alexion at its existing Portsmouth, New Hampshire facility. The agreement requires us to make certain payments during the construction of the new manufacturing facility and annual payments for ten years thereafter. As a result of our contractual right to full capacity of the new manufacturing facility, a portion of the payments under the agreement are considered to be lease payments and a portion as payment for the supply of inventory. Although we will not legally own the premises, we are deemed to be the owner of the manufacturing facility during the construction period based on applicable accounting guidance for build-to-suit leases due to our involvement during the

construction period. As of December 31, 2015, we recorded a construction-in-process asset of $19,259 and an offsetting facility lease obligation of $15,229 associated with the manufacturing facility.

Payments made to Lonza under the agreement are allocated to the purchases of inventory and the repayment of the facility lease obligation on a relative fair value basis. In 2015, we made $31,000 of payments to Lonza under this agreement, of which $4,030 was applied against the outstanding facility lease obligation and $26,970 was recognized as a prepayment of inventory. See Note 10 for minimum fixed payments due under Lonza agreements.

10. Commitments and Contingencies

Commitments

License Agreements

We have entered into a number of license agreements since our inception 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 milestone and royalty payments if certain conditions are met. Certain agreements call for future payments upon the attainment of agreed upon development and/or commercial milestones. These agreements may also require minimum royalty payments based on sales of products developed from the applicable technologies, if any.

In March 2015, we entered into an agreement with a third party that allowed us to exercise an option with another third party for exclusive, worldwide, perpetual license rights to a specialized technology and other intellectual property, and we simultaneously exercised the option. Due to the early stage of these assets, we recorded expense for the payments of $47,000 during the first quarter 2015.

In March 2015, we entered into a collaboration agreement with a third party that allows us to identify and optimize drug candidates. Alexion will have the exclusive worldwide rights to develop and commercialize products arising from the collaboration. Due to the early stage of the assets we are licensing in connection with the collaboration, we recorded expense for the upfront payment of $15,000 during the first quarter 2015. In addition, we could be required to pay up to an additional $250,750 if certain development, regulatory, and commercial milestones are met over time, as well as royalties on commercial sales.

In January 2015, we entered into a license agreement with a third party to obtain an exclusive research, development and commercial license for specific therapeutic molecules. Due to the early stage of these assets, we recorded expense for the upfront payment of $50,000 during the first quarter 2015. In addition, we could be required to pay up to an additional $822,000 if certain development, regulatory, and commercial milestones are met over time, as well as royalties on commercial sales.

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

In January 2014, we entered into an agreement with Moderna Therapeutics, Inc. (Moderna) that allows us to purchase ten product options to develop and commercialize treatments for rare diseases with Moderna's messenger RNA (mRNA) therapeutics platform. Alexion will lead the discovery, development and commercialization of the treatments produced through this broad, long-term strategic agreement, while Moderna will retain responsibility for the design and manufacture of the messenger RNA against selected targets. Due to the early stage of these assets, we recorded expense for an upfront payment of $100,000. We will also be responsible for funding research activities under the

program. In addition, for each drug target, up to a maximum of ten targets, we could be required to make an option exercise payment of $15,000 and to pay up to an additional $120,000 with respect to a rare disease product and $400,000 with respect to a non-rare disease product in development and sales milestones if the specific milestones are met over time as well as royalties on commercial sales.

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

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

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.

Manufacturing Agreements

Manufacturing development agreements provide for us to fund manufacturing development to support our clinical and commercial product needs.

We rely on Lonza, a third party manufacturer, to produce a portion of commercial and clinical quantities of Soliris and Strensiq. We have various agreements with Lonza with remaining total non-cancellable future commitments of approximately $1,156,980. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at Alexion Rhode Island Manufacturing Facility (ARIMF) and a payment with respect to sales of Soliris manufactured at Lonza facilities.

In addition to Lonza, we have non-cancellable commitments of $36,400 with other third party manufacturers.

Contingent Liabilities

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

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

In May 2015, we received a subpoena in connection with an investigation by the Enforcement Division of the U.S. Securities and Exchange Commission (SEC) requesting information related to our grant-making activities and compliance with the Foreign Corrupt Practices Act (FCPA) in various countries. The SEC also seeks information related to Alexion’s recalls of specific lots of Soliris and related securities disclosures. In addition, in October 2015, Alexion received a request from the U.S. Department of Justice for the voluntary production of documents and other information pertaining to Alexion's compliance with the FCPA. Alexion is cooperating with these investigations. At this time, Alexion is unable to predict the duration, scope or outcome of these investigations. Given the ongoing nature of these investigations, management does not currently believe a loss related to these matters is probable or that the potential magnitude of such loss or range of loss, if any, can be reasonably estimated.

In March 2013, we received a Warning Letter (Warning Letter) from the U.S. Food and Drug Administration (FDA) regarding compliance with current Good Manufacturing Practices (cGMP) at ARIMF. The Warning Letter followed receipt of a Form 483 Inspectional Observations by the FDA in connection with an FDA inspection that concluded in

August 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. As previously announced, the FDA issued Form 483s in August 2014 and August 2015 relating to observations at ARIMF. The inspectional observations from the August 2015 letter have since been closed out by the FDA. The observations are inspectional and do not represent a final FDA determination of compliance. We continue to manufacture products, including Soliris, in this facility. While the resolution of the issues raised in the Warning Letter is difficult to predict, we do not currently believe a loss related to this matter is probable or that the potential magnitude of such loss or range of loss, if any, can be reasonably estimated.

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

(amounts in thousands except per share amounts)

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

Operating Leases

As of December 31, 2015, we have operating leases for office and laboratory space in Cheshire, Connecticut, regional executive and sales offices in Zurich, Switzerland, as well as offices in other U.S.and foreign locations to support our operations as a global organization.

Aggregate lease expense was $27,839, $22,738 and $19,094 for the years ended December 31, 2015, 2014 and 2013, respectively. Lease expense is being recorded on a straight-line basis over the applicable lease terms.

Aggregate future minimum annual rental payments, for the next five years and thereafter under non-cancellable operating leases (including facilities and equipment) as of December 31, 2015 are:

Year	
2016	$25,223
2017	18,024
2018	13,962
2019	9,834
2020	5,168
Thereafter	17,424

11. Income Taxes

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

	Year Ended December 31,		
	2015	2014	2013
U.S.	$(125,435)	$222,088	$376,067
Non-U.S.	623,577	650,019	150,202
	$498,142	$872,107	$526,269

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. The partnership income, which is derived in foreign jurisdictions, is classified as “non-U.S. income” for purposes of financial reporting. Substantially all non-U.S. income for the years ended December 31, 2015 and 2014 relates to income from our captive foreign partnership.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

The components of the income tax provision are as follows:

	Year Ended December 31,		
	2015	2014	2013
Domestic			
Current	$(87,605)	$285,624	$141,051
Deferred	388,878	(111,890)	92,040
	301,273	173,734	233,091
Foreign			
Current	49,087	81,810	34,975
Deferred	3,397	(40,349)	5,308
	52,484	41,461	40,283
Total			
Current	(38,518)	367,434	176,026
Deferred	392,275	(152,239)	97,348
	$353,757	$215,195	$273,374

We continue to maintain a valuation allowance against certain deferred tax assets where realization is not certain. We continue to pay cash taxes in U.S. Federal, various U.S. state, and foreign jurisdictions where we have operations and have utilized all of our net operating losses.

At December 31, 2015, we have federal and state net operating loss carryforwards of $423,665 and $13,571, respectively. Our NOL's expire between 2018 and 2035. We also have federal and state income tax credit carryforwards of $463,796 and $13,380, respectively. These income tax credits expire between 2016 and 2035. Of these U.S. federal and state income tax credit carryforwards, $262,216 and $3,501, respectively, are attributable to excess tax benefits from the exercise of non-qualified stock options and vestings of restricted stock.

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

We were granted an incentive tax holiday in the Canton of Vaud in Switzerland effective January 1, 2010. This tax holiday had exempted us from most local corporate income taxes in Switzerland through the end of 2014 and was renewable for an additional 5 years with final expiration in 2019. During 2013, we undertook a restructuring which significantly changed our business model in Switzerland and we converted from a principal company to a distribution and service company. As a result of the significant change to our business activities in Switzerland, the Canton of Vaud in Switzerland provided final notification to us in December 2014 that our structure no longer complied with the conditions of the incentive tax holiday. In the fourth quarter of 2014, we made a payment of $22,817 in satisfaction of the clawback of previously exempted cantonal income taxes for tax years 2010 through 2013. This amount was fully accrued on our balance sheet as of December 31, 2013. Prospectively, our federal and cantonal tax will be based on the current enacted tax rates in Switzerland.

The Tax Reform Act of 1986 contains certain provisions that can limit a taxpayer's ability to utilize net operating loss and tax credit carryforwards in any given year resulting from cumulative changes in ownership interests in excess of

50% over a three-year period. We have determined that these limiting provisions were triggered during a prior year. In connection with our acquisition of Synageva, the change in ownership triggered a new limitation. We are currently in the process of determining the impact of this limitation to Synageva tax attributes, including net operating losses. We do not expect any reduction to the amounts recorded for these attributes as of the date of acquisition. It is reasonably possible, however, based on our ongoing assessment, that the amounts recorded for these attributes will increase in the foreseeable future.

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:

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

	Year Ended December 31,		
	2015	2014	2013
U.S. federal statutory tax rate	35.0 %	35.0 %	35.0 %
State and local income taxes	(0.8)%	0.9 %	3.3 %
Foreign income tax rate differential	(34.8)%	(19.7)%	(14.1)%
Tax credits, net of nondeductible expenses	(7.6)%	(2.5)%	(2.7)%
Foreign income tax credits	(7.6)%	(4.8)%	(20.5)%
Foreign income subject to U.S. taxation	24.3 %	15.8 %	10.2 %
U.S. deferred taxes on foreign earnings	60.1 %	— %	27.2 %
Other permanent differences	2.4 %	— %	13.5 %
Effective income tax rate	71.0 %	24.7 %	51.9 %

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. Starting in 2014, a significant portion of the non-U.S. income flows through the partnership and the portion of the partnership income that is attributable to our U.S. parent company's ownership percentage is taxed in the U.S. The remainder of the non-U.S. income is taxed based on the tax rate enacted in the local foreign jurisdictions in which the income is earned.

We have operations in many foreign tax jurisdictions, which impose income taxes at different rates than the United States. The impact of these rate differences is included in the foreign income tax rate differential that we disclose in our reconciliation of the U.S. statutory income tax rate to our effective tax rate. Additionally, included in the foreign income tax rate differential line item is the impact of ASC 740-10-25-3(e) attributable to intercompany transactions in the amount of approximately $24,000 and $23,000 of tax expense for 2015 and 2014, respectively and $45,000 tax benefit for 2013.

As a U.S.-based multinational corporation, we benefit from U.S. income tax credits for taxes assessed in foreign jurisdictions. Our foreign income tax credit for 2013 included approximately $157,000 of credits generated from the repatriation of the majority of earnings and profits of our non-U.S. subsidiaries via a one-time dividend.

Our 2013 other non-deductible and permanent differences includes expense relating to an intercompany transaction of approximately $46,500. The 2014 rate reconciliation does not include a similar transaction.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

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, 2015	December 31, 2014
Deferred tax assets:		
Net operating losses	$168,097	$3,401
Income tax credits	209,015	1,706
Stock compensation	73,915	49,090
Accruals and allowances	85,575	29,072
Research and development expenses	19,077	129,995
Accrued royalties	15,911	41,201
	571,590	254,465
Valuation allowance	(4,946)	(1,117)
Total deferred tax assets	566,644	253,348
Deferred tax liabilities:		
Depreciable assets	(82,889)	(40,648)
Unrealized gains	(47,246)	(45,191)
Investment in foreign partnership	(409,336)	(116,359)
Intangible assets	(542,631)	—
Total deferred tax liabilities	(1,082,102)	(202,198)
Net deferred tax (liability) asset	$(515,458)	$51,150

The decrease in our research and development deferred tax assets is primarily attributable to our election to deduct, rather than capitalize research and development expenses pursuant to Internal Revenue Code section 59(e) on our 2014 federal income tax return. The increase in our investment in foreign partnership deferred tax liability is due to the contribution of certain assets acquired in the Synageva acquisition into our captive foreign partnership. The increase in our depreciable assets deferred tax liability is primarily attributable to the construction of our corporate headquarters in New Haven, Connecticut. This increase is substantially offset by the increase in our accruals and allowances deferred tax asset, which is primarily attributable to the lease liability for our corporate headquarters in New Haven, Connecticut. The increase in our net operating losses and income tax credit deferred tax assets is primarily attributed to the acquisition of Synageva. The decrease in our accrued royalties deferred tax asset is primarily attributable to realization of tax deductions by our technical operations center in Ireland for previously accrued but unpaid royalties. The increase to our intangible assets deferred tax liability is attributable to intellectual property acquired in the Synageva acquisition.

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.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

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

	2015	2014	2013
Beginning of period balance	$28,675	$46,389	$12,393
Increases for tax positions taken during a prior period	1,937	899	2,571
Decreases for tax positions taken during a prior period	(91)	(2,468)	(812)
Increases for tax positions taken during the current period	85,256	9,063	33,056
Decreases for tax positions related to settlements	(980)	(24,812)	(419)
Decreases for tax positions related to lapse of statute	(852)	(396)	(400)
	$113,945	$28,675	$46,389

The total amount of accrued interest and penalties was not significant as of December 31, 2015. The total amount of tax benefit recorded during 2015 which related to unrecognized tax benefits was $82,717. Expense recognized during 2014 and 2013 was $17,012 and $7,897, respectively. Unless related to excess tax benefits from stock options, all of our unrecognized tax benefits, if recognized, would have a favorable impact on the effective tax rate.

We expect none of our total unrecognized tax benefits to reverse within the next twelve months. We file federal and state income tax returns in the U.S. and in numerous foreign jurisdictions. The U.S. and foreign jurisdictions have statute of limitations ranging from 3 to 5 years. However, the limitation period 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 limitation period has previously expired and can subsequently adjust the NOL carryforward or tax credit amounts. Accordingly, we do not expect to reverse any significant portion of the unrecognized tax benefits.

The Internal Revenue Service (IRS) commenced an examination of our U.S. income tax return for 2013 during the third quarter of 2015 that is anticipated to be completed within the next twelve months. As a result of this audit, it is possible that the amount of the liability for unrecognized tax benefits could change over the next twelve months. The impact to our unrecognized benefits is difficult to determine based on the preliminary stage of the audit. As of December 31, 2015, we have not been notified of any significant proposed adjustments by the IRS.

We do not record U.S. tax expense on the undistributed earnings of our controlled foreign corporation (CFC) subsidiaries. We intend to reinvest these earnings permanently outside the U.S. or repatriate the earnings only when it is tax efficient to do so. Accordingly, we believe that U.S. tax on any earnings that might be repatriated would be substantially offset by other tax attributes. At December 31, 2015, the cumulative amount of these earnings was approximately $1,012,000.

During the fourth quarter of 2013, in connection with the centralization of our global supply chain and technical operations in Ireland, our U.S. parent company became a direct partner in a captive foreign partnership. To the extent that our U.S. parent company receives its allocation of partnership income, the amounts will be taxable in the U.S. each year and therefore the permanent reinvestment assertion will no longer apply to such earnings. The recognition of deferred tax liabilities associated with the aforementioned partnership resulted in tax expense of approximately $95,800 during the fourth quarter of 2013. We also distributed the majority of earnings and profits of our non U.S. subsidiaries via a dividend in the amount of $152,000 during the fourth quarter of 2013. This dividend did not give rise to any U.S. cash tax liability. This resulted in repatriation of a significant portion of our remitted earnings at December 31, 2013.

We do not have any present or anticipated future need for cash held by our CFCs, as cash generated in the U.S., as well as borrowings, are expected to be sufficient to meet U.S. liquidity needs for the foreseeable future.

It is not practicable to estimate the amount of additional taxes which might be payable on our CFCs' undistributed earnings due to a variety of factors, including the timing, extent and nature of any repatriation. While our expectation is that all foreign undistributed earnings, other than our U.S. parent company's share of the foreign partnership profits, are permanently invested, there could be certain unforeseen future events that could impact our permanent reinvestment assertion. Such events include acquisitions, corporate restructuring or tax law changes not currently contemplated.

12. Share-based Compensation

Amended and Restated 2004 Incentive Plan

The 2004 Plan was approved by our stockholders in May 2013 and is a broad based plan that provides for the grant of equity awards including restricted stock and restricted stock units (collectively referred to as Restricted Stock), incentive and non-qualified stock options, and other stock-related awards to our directors, officers, key employees and consultants, for up to a

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

maximum of 47,874 shares. Stock options granted under the 2004 Plan have a maximum contractual term of ten years from the date of grant, have an exercise price not less than the fair value of the stock on the grant date and generally vest over four years. Restricted stock awards also generally vest over four years, with performance-based restricted stock units having a three-year vesting period.

Stock Options

A summary of the status of our stock option plans at December 31, 2015, 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, 2014	6,420	$85.65		
Granted	1,461	177.54		
Exercised	(1,328)	57.59		
Forfeited and canceled	(332)	143.22		
Outstanding at December 31, 2015	6,221	$110.15	6.96	$501,630
Vested and unvested expected to vest at December 31, 2015	6,129	$109.30	6.93	$499,399
Exercisable at December 31, 2015	3,570	$74.89	5.79	$413,637

Total intrinsic value of stock options exercised during the years ended December 31, 2015, 2014 and 2013 was $168,287, $459,940 and $204,470, 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, 2015, 2014 and 2013 was $50,964, $35,859 and $32,249, 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, 2015	December 31, 2014	December 31, 2013
Expected life in years	3.57 - 9.00	3.64 - 5.30	3.30 - 5.37
Interest rate	0.84% - 2.17%	0.97% - 1.74%	0.30% - 1.21%
Volatility	33.35% - 38.13%	32.15% - 34.87%	29.81% - 36.93%
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, 2015, 2014 and 2013 was $53.03, $51.22 and $23.99 per option, respectively.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

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, 2014	1,808	$127.08
Shares granted	1,540	184.09
Shares forfeited	(245)	150.80
Shares vested	(1,063)	127.23
Nonvested Restricted Stock at December 31, 2015	2,040	$167.21

Restricted stock awards granted in 2015 include 460 restricted stock units granted to senior management, which have both non-market performance-based and service-based vesting conditions. The weighted average grant date fair value of these awards granted in 2015 was $191.01. The number of non-market performance-based restricted stock units granted represents the number of shares earned during the performance period, which ended on December 31, 2015, 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, 2015, 2014 and 2013, including restricted stock units with non-market performance conditions, was $184.09, $174.22 and $95.06 per share, respectively. The total weighted average grant date fair value of restricted stock vested during the years ended December 31, 2015, 2014 and 2013 was $135,337, $41,304 and $26,679, respectively.

During 2015 and 2014, we granted market-based performance awards to senior management which provides the recipient the right to receive restricted stock at the end of a three year performance period, based on pre-established market-based performance goals. We used payout simulation models to estimate the grant date fair value of the awards and recognized expense of $526 and $301 during the years ended December 31, 2015 and 2014, respectively.

Employee Stock Purchase Plan

During 2015, the Company adopted the ESPP under which employees can purchase shares of our common stock based on a percentage of their compensation subject to certain limits. The purchase price per share is equal to the lower of 85% of the fair market value of our common stock on the offering date or the purchase date with a six month look-back feature. Under the ESPP, up to 1,000 shares of common stock may be issued to eligible employees who elect to participate in the purchase plan. Shares issued and compensation expense under the ESPP for the year ended December 31, 2015 were not material.

Share-Based Compensation Expense

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

	Year Ended December 31,		
	2015	2014	2013
Cost of sales	$6,630	$4,174	$3,214
Research and development	64,235	36,203	23,905
Selling, general and administrative	156,268	74,084	49,084

Total share-based compensation expense	227,133	114,461	76,203
Income tax effect	(83,721)	(42,082)	(28,652)
Total share-based compensation expense, net of tax	$143,412	$72,379	$47,551

Share-based compensation expense capitalized to inventory during the years ended December 31, 2015, 2014 and 2013 was $7,809, $10,211, and $3,978, respectively.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

As of December 31, 2015, there was $343,301 of total unrecognized share-based compensation expense related to non-vested share-based compensation arrangements granted under the 2004 Plan. The expense is expected to be recognized over a weighted-average period of 2.45 years.

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 could be exercised to purchase one hundredth of a share of a new series of preferred stock , subject to adjustment.The rights, which did not have voting rights, expired on March 23, 2015.

Common Stock

In June 2015, in connection with our acquisition of Synageva, we issued 26,125 shares of common stock to former Synageva stockholders and employees. The fair value of the stock was $4,913,754, and we incurred $4,053 of issuance costs.

Share Repurchases

In November 2012, our Board of Directors authorized a share repurchase program. The repurchase program does not have an expiration date, and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at the Company's discretion. In May 2015, our Board of Directors increased the authorization of shares up to $1,000,000 for future purchases under the repurchase program, which superseded all prior repurchase programs. Under the program, we repurchased 1,963 and 1,903 shares of our common stock at a cost of $327,699 and $302,599 during the years ended December 31, 2015 and 2014, respectively. The Company did not repurchase any shares during the pendency of the Synageva acquisition in the second quarter of 2015 and the Company began repurchasing shares again in the third quarter 2015. Subsequent to December 31, 2015, we repurchased 648 shares of our common stock under our repurchase program at a cost of $98,206. As of February 8, 2016, there is a total of $657,658 remaining for repurchases under the repurchase program.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

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, 2015, 2014 and 2013:

	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, 2012	$(5,712)	$—	$15,156	$(2,809)	$6,635
Other comprehensive income before reclassifications	(6,175)	(197)	(1,000)	(4,573)	(11,945)
Amounts reclassified from other comprehensive income	385	51	(17,983)	—	(17,547)
Net other comprehensive income (loss)	(5,790)	(146)	(18,983)	(4,573)	(29,492)
Balances, December 31, 2013	$(11,502)	$(146)	$(3,827)	$(7,382)	$(22,857)
Other comprehensive income before reclassifications	(5,732)	(63)	110,088	(6,337)	97,956
Amounts reclassified from other comprehensive income	664	(25)	(18,953)	—	(18,314)
Net other comprehensive income (loss)	(5,068)	(88)	91,135	(6,337)	79,642
Balances, December 31, 2014	$(16,570)	$(234)	$87,308	$(13,719)	$56,785
Other comprehensive income before reclassifications	(1,610)	(516)	110,455	(6,276)	102,053
Amounts reclassified from other comprehensive income	8,591	(35)	(105,093)	—	(96,537)
Net other comprehensive income (loss)	6,981	(551)	5,362	(6,276)	5,516
Balances, December 31, 2015	$(9,589)	$(785)	$92,670	$(19,995)	$62,301

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

The table below provides details regarding significant reclassifications from AOCI during the years ended December 31, 2015, 2014 and 2013:

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
	2015	2014	2013	
Unrealized Gains (Losses) on Hedging Activity				
Effective portion of foreign exchange contracts	$117,915	$18,874	$20,569	Net product sales
Ineffective portion of foreign exchange contracts	2,191	2,787	(915)	Foreign currency loss
	120,106	21,661	19,654	
	(15,013)	(2,708)	(1,671)	Income tax provision
	$105,093	$18,953	$17,983	
Unrealized Gains (Losses) from Marketable Securities				
Realized gains (losses) on sale of securities	$55	$40	$(81)	Investment income
	55	40	(81)	
	(20)	(15)	30	Income tax provision
	$35	$25	$(51)	
Defined Benefit Pension Items				
Amortization of prior service costs and actuarial losses	$(1,263)	$(865)	$(421)	(a)
Curtailment	(10,108)	—	—	(a)
	(11,371)	(865)	(421)	
	2,780	201	36	Income tax provision
	$(8,591)	$(664)	$(385)	

(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.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2015 and 2014, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

		Fair Value Measurement at December 31, 2015			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$179,898	$—	$179,898	$—
Cash equivalents	Commercial paper	$192,418	$—	$192,418	$—
Cash equivalents	Corporate bonds	$12,250	$—	$12,250	$—
Cash equivalents	Municipal bonds	$60,001	$—	$60,001	$—
Cash equivalents	Other government-related obligations	$31,549	$—	$31,549	$—
Cash equivalents	Bank certificates of deposit	$27,000	$—	$27,000	$—
Marketable securities	Mutual funds	$8,817	$8,817	$—	$—
Marketable securities	Commercial paper	$61,978	$—	$61,978	$—
Marketable securities	Corporate bonds	$120,499	$—	$120,499	$—
Marketable securities	Municipal bonds	$27,110	$—	$27,110	$—
Marketable securities	Other government-related obligations	$156,500	$—	$156,500	$—
Other current assets	Foreign exchange forward contracts	$91,745	$—	$91,745	$—
Other assets	Foreign exchange forward contracts	$66,309	$—	$66,309	$—
Other current liabilities	Foreign exchange forward contracts	$5,648	$—	$5,648	$—
Other liabilities	Foreign exchange forward contracts	$4,773	$—	$4,773	$—
Other current liabilities	Acquisition-related contingent consideration	$55,804	$—	$—	$55,804
Contingent consideration	Acquisition-related contingent consideration	$121,424	$—	$—	$121,424

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

		Fair Value Measurement at December 31, 2014			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$176,331	$—	$176,331	$—
Cash equivalents	Commercial paper	$117,529	$—	$117,529	$—
Cash equivalents	Corporate bonds	$9,315	$—	$9,315	$—
Cash equivalents	Municipal bonds	$12,050	$—	$12,050	$—
Cash equivalents	Bank certificates of deposit	$5,000	$—	$5,000	$—
Cash equivalents	Other government-related obligations	$23,998	$—	$23,998	$—
Marketable securities	Mutual funds	$4,277	$4,277	$—	$—
Marketable securities	Commercial paper	$24,966	$—	$24,966	$—
Marketable securities	Corporate bonds	$484,551	$—	$484,551	$—
Marketable securities	Municipal bonds	$162,795	$—	$162,795	$—
Marketable securities	Other government-related obligations	$268,978	$—	$268,978	$—
Marketable securities	Bank certificates of deposit	$72,000	$—	$72,000	$—
Other current assets	Foreign exchange forward contracts	$77,348	$—	$77,348	$—
Other assets	Foreign exchange forward contracts	$58,698	$—	$58,698	$—
Other current liabilities	Foreign exchange forward contracts	$794	$—	$794	$—
Other liabilities	Foreign exchange forward contracts	$86	$—	$86	$—
Other current liabilities	Acquisition-related contingent consideration	$46,546	$—	$—	$46,546
Contingent consideration	Acquisition-related contingent consideration	$116,425	$—	$—	$116,425

There were no securities transferred between Level 1, 2 and 3 for the year ended December 31, 2015.

Valuation Techniques
We classify mutual fund investments, which are valued based on quoted market prices in active markets with no valuation adjustment, as Level 1 assets within the fair value hierarchy.
Cash equivalents and marketable securities classified as Level 2 within the valuation hierarchy consist of institutional money market funds, commercial paper, municipal bonds, U.S. and foreign government-related debt, corporate debt securities and certificates of deposit. We estimate the fair values of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable,

either directly or indirectly, to estimate fair value. These inputs include market pricing based on real-time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs. We validate the prices provided by our third-party pricing sources by

(amounts in thousands except per share amounts)

understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances.

Our derivative assets and liabilities include foreign exchange derivatives that are measured at fair value using observable market inputs such as forward rates, interest rates, our own credit risk as well as an evaluation of our counterparties' credit risks. Based on these inputs, the derivative assets and liabilities are classified within Level 2 of the valuation hierarchy.

Contingent consideration liabilities related to acquisitions are classified as Level 3 within the valuation hierarchy and are valued based on various estimates, including probability of success, discount rates and amount of time until the conditions of the milestone payments are met.

As of December 31, 2015, 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 4.8%to 5.5% for developmental milestones and a weighted average cost of capital ranging from 10% to 21% for sales-based milestones.

Each reporting period, we adjust the contingent consideration to fair value with changes in fair value recognized in operating earnings. Changes in fair values reflect new information about the probability and timing of meeting the conditions of the milestone payments. In the absence of new information, changes in fair value will only reflect the interest component of contingent consideration related to the passage of time as development work progresses towards the achievement of the milestones.

Estimated future contingent milestone payments related to prior business combinations range from zero if no milestone events are achieved, to a maximum of $826,000 if all development, regulatory and sales-based milestones are reached. As of December 31, 2015, the fair value of acquisition-related contingent consideration was $177,228.

The following table represents a roll-forward of our acquisition-related contingent consideration:

	December 31, 2015
Balance at beginning of period	$(162,971)
Milestone payments	50,000
Change in fair value	(64,257)
Balance at end of period	$(177,228)

16. Employee Benefit Plans

Deferred Compensation Plan

We have 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. Deferred compensation amounts under this

plan as of December 31, 2015 and 2014 were $8,817 and $4,277, respectively, and are included in other liabilities within the consolidated balance sheets. Employer matching contributions under the plan for the years ended December 31, 2015, 2014 and 2013 were not material.

Defined Contribution Plan

We have one qualified 401(k) plan covering all eligible employees. Under the plan, employees may contribute up to the statutory allowable amount for any calendar year. We make matching contributions equal to $1.00 for each dollar contributed up to the first 6% of an individual's base salary and incentive cash bonus up to the annual IRS maximum. For the years ended December 31, 2015, 2014 and 2013, we recorded matching contributions of approximately $11,478, $8,782, and $6,360 respectively.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

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.

In 2015 we recorded the impacts of a curtailment related to our Swiss plan as a result of a reduction of employees due to the relocation of our European headquarters as discussed in Note 17, "Restructuring".

The following table sets forth the funded status and the amounts recognized for defined benefit plans, including the impacts of the 2015 curtailment:

	December 31, 2015	2014
Change in benefit obligation:		
Projected benefit obligation, beginning of year	$50,701	$38,166
Prior service cost	—	—
Service cost	9,675	8,136
Interest cost	753	780
Change in assumptions	2,475	5,571
Recognized actuarial net loss	3,886	1,350
Curtailment	(24,938)	—
Foreign currency exchange rate changes	562	(3,055)
Net transfers to (from) plan	1,929	(247)
Projected benefit obligation, end of year	$45,043	$50,701
Accumulated benefit obligation, end of year	$42,044	$43,141

	December 31, 2015	2014
Change in plan assets:		
Fair value of plan assets, beginning of year	$26,776	$23,327
Return on plan assets	439	393
Employer contributions	3,747	4,417
Plan participants' contributions	1,701	1,741
Curtailment	(12,836)	—
Foreign currency exchange rate changes	(186)	(2,855)
Net transfers to (from) plan	1,929	(247)
Fair value of plan assets, end of year	$21,570	$26,776
Funded status at end of year	$(23,473)	$(23,925)

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, 2015 and the classification of each investment category within the fair value hierarchy with respect to the inputs used to measure fair value:

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

	December 31, 2015		December 31, 2014	
	Fair Value (Level 2)	as % of total plan assets	Fair Value (Level 2)	as % of total plan assets
Cash and cash equivalents	$244	1 %	$1,794	7 %
Equity security funds	1,905	9 %	10,791	40 %
Debt security funds	16,888	78 %	11,246	42 %
Real estate funds	2,533	12 %	2,945	11 %
	$21,570	100 %	$26,776	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. Plan assets are managed by an independent investment fiduciary and are primarily invested in debt and equity securities and real estate funds in order to maximize the overall return from investment income considering asset allocation limits as determined by pension law.

At December 31, 2015, we have recorded a liability of $23,473 in other non-current liabilities and a charge to accumulated other comprehensive income, net of tax, of $9,589 related to an additional minimum liability.

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

	December 31,	
	2015	2014
Weighted average assumptions - Net Periodic Benefit Cost:		
Discount rate	1.4 %	2.0 %
Long term rate of return on assets	3.5 %	4.0 %
Rate of compensation increase	1.5 %	1.6 %
Weighted average assumptions - Projected Benefit Obligation:		
Discount Rate	0.6 %	1.4 %
Rate of compensation increase	1.4 %	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,		
	2015	2014	2013
Service cost	$9,675	$8,136	$5,413
Interest cost	753	780	504
Expected return on plan assets	(1,014)	(900)	(633)
Employee contributions	(1,701)	(1,741)	(1,523)
Amortization of prior service costs	9	9	9
Curtailment	(1,994)	—	—
Amortization and deferral of actuarial gain	1,254	846	410

Total net periodic benefit cost	$6,982	$7,130	$4,180

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

Other changes in plan assets and benefit obligations recognized in AOCI are as follows:	
Amount included in AOCI - December 31, 2013	$(11,502)
Prior service cost	9
Net loss arising during the period	(1,354)
Change in assumptions	(5,640)
Amortization of net gain	856
Plan assets losses	(513)
Taxes	1,574
Amount included in AOCI - December 31, 2014	$(16,570)
Prior service cost	9
Net loss arising during the period	(3,886)
Change in assumptions	(2,437)
Amortization of net gain	1,254
Plan assets losses	(575)
Curtailment	10,108
Foreign currency exchange rate changes	19
Taxes	2,489
Amount included in AOCI - December 31, 2015	$(9,589)

The amount in accumulated other comprehensive income as of December 31, 2015 that is expected to be recognized as a component of the net periodic pension costs in 2016 is $853.

We estimate that we will pay employer contributions of approximately $3,102 in 2016. The expected future cash flows to be paid in respect of the pension plans as of December 31, 2015 were as follows:

Year	
2016	1,521
2017	1,692
2018	1,522
2019	1,579
2020	1,449
2021 to 2025	6,876

17. Restructuring

In connection with the completion of our new corporate headquarters located in New Haven, Connecticut, we entered into a lease termination agreement for the previous corporate headquarters located in Cheshire, Connecticut during December 2015. As a result of this action, we recorded restructuring expense of $11,236 for contract termination costs in the fourth quarter of 2015.

In conjunction with the acquisition and integration of Synageva in 2015, we recorded restructuring expense of $13,335 primarily related to employee costs during 2015. We expect to pay all remaining accrued amounts related to this restructuring activity by the end of 2016.

In the fourth quarter 2014, we announced plans to move the European headquarters from Lausanne to Zurich, Switzerland. The relocation of the European headquarters supports our operational needs based on growth in the European region. As a result of this action, we recorded restructuring expenses of $15,365 related to employee costs in

the fourth quarter of 2014. During the year ended December 31, 2015, we incurred additional restructuring costs of $17,598. We expect to pay all remaining accrued amounts related to this restructuring activity by the end of 2016.

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

The following table presents a reconciliation of the restructuring reserve recorded within accrued expenses on the Company's condensed consolidated balance sheet for the year ended December 31, 2015 and December 31, 2014, respectively:

	December 31, 2015				December 31, 2014			
	Employee Separation Costs	Contract Termination Costs	Other Costs	Total	Employee Separation Costs	Contract Termination Costs	Other Costs	Total
Liability, beginning of period	$15,365	$ —	$—	$15,365	$—	$ —	$—	$—
Restructuring expenses	21,524	12,419	3,847	37,790	15,365	—	—	15,365
Cash settlements	(34,843)	(11,772)	(3,678)	(50,293)	—	—	—	—
Adjustments to previous estimates	4,344	35	—	4,379	—	—	—	—
Liability, end of period	$6,390	$ 682	$169	$7,241	$15,365	$ —	$—	$15,365

18. Segment Information

We operate as one business segment, which is the innovation, development and commercialization of life-transforming therapeutic products. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with our management reporting. Disclosures about net product sales and long-lived assets by geographic area are presented below.

Net product sales

Net product sales by product are as follows:

	Year Ended December 31,		
	2015	2014	2013
Net product sales:			
Soliris (1)	$2,590,197	$2,233,733	$1,551,346
Strensiq	11,969	—	—
Kanuma	366	—	—
	$2,602,532	$2,233,733	$1,551,346

Geographical information

	Year Ended December 31,		
Net product sales:	2015	2014	2013
United States	$951,307	$730,089	$561,405
Europe (1)	840,465	836,134	514,987
Asia Pacific	276,350	244,059	203,538
Other	534,410	423,451	271,416
	$2,602,532	$2,233,733	$1,551,346

(1) As described in Note 19, "Quarterly Financial Information (unaudited)", included within the Soliris and Europe revenues for 2014 is a reimbursement of $87,830 for shipments made in years prior to January 1, 2014 as a result of an agreement with the French government.

December 31,

Long-lived assets (2):	2015	2014
United States	$444,282	$298,122
Europe	247,474	88,543
Other	5,269	5,583
	$697,025	$392,248

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

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2015, 2014 and 2013
(amounts in thousands except per share amounts)

19. Quarterly Financial Information (unaudited)

The following condensed quarterly financial information is for the years ended December 31, 2015 and 2014:

	March 31		June 30		September 30		December 31	
2015:								
Revenues	$600,333		$636,210		$666,637		$700,867	
Cost of sales	69,399	(1)	52,007		54,057		57,626	
Operating expenses	427,227		403,121	(2)	458,012	(3)	545,927	(3)
Operating income	103,707		181,082		154,568		97,314	
Net income (loss)	$91,323		$170,215		$(183,757)	(4)	$66,604	
Earnings (loss) per common share								
Basic	$0.46		$0.84		$(0.81)		$0.30	
Diluted	$0.45		$0.83		$(0.81)		$0.29	

	March 31		June 30		September 30		December 31	
2014:								
Revenues	$566,616	(5)	$512,495		$555,146		$599,476	
Cost of sales	32,939	(5)	39,626		51,858		49,439	
Operating expenses	324,174		254,020		266,629		346,342	(6)
Operating income	209,503		218,849		236,659		203,695	
Net income	$159,354		$166,495		$177,731		$153,332	
Earnings per common share								
Basic	$0.81		$0.84		$0.90		$0.77	
Diluted	$0.79		$0.83		$0.88		$0.76	

(1) Included within cost of sales for the first quarter 2015 are costs $24,352 associated with the write off a portion of a single manufacturing campaign at a third party manufacturer for Strensiq.

(2) Included within operating expenses for the second quarter 2015 are acquisition costs of $29,777 associated with the acquisition of Synageva.

(3) Included within operating expenses for the third and fourth quarter 2015 is $36,608 and $79,976, respectively,of amortization of purchased intangible assets associated with the approval of Strensiq and Kanuma.

(4) Included within net income for the third quarter of 2015 is a one-time tax expense of $315,569 resulting from our integration of the Synageva business with and into the Alexion business. This tax expense is attributable to the change in our deferred tax liability for the outside basis difference resulting from the movement of assets into our captive foreign partnership.

(5) Included within revenues for the first quarter of 2014 is a reimbursement for shipments made in years prior to January 1, 2014 as a result of an agreement with the French government which positively impacted reimbursement for Soliris. As a result of the agreement, in the first quarter of 2014, we recognized $87,830 of net product sales from

Soliris in France relating to years prior to January 1, 2014. Also, included within cost of sales for the first quarter of 2014 is the incremental impact in cost of sales of $2,055 for additional royalties related to the $87,830 of net product sales from prior year shipments.

(6) Included within operating expenses for the fourth quarter of 2014 is $15,365 for restructuring expenses recognized in connection with the relocation of the European headquarters.