ALEXION PHARMACEUTICALS INC
Form 10-K
February 16, 2017

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, 2016
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)
475-230-2596
(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 ¨ No x
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, 2016, was $25,314,108,813.(1)

The number of shares of Common Stock outstanding as of February 13, 2017 was 224,613,750.

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 10, 2017, are incorporated by reference into Part III of this report.

(1) Excludes 7,417,897 shares of common stock held by directors and executive officers at June 30, 2016. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

Alexion Pharmaceuticals, Inc.
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PART I

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

Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management’s beliefs, and certain assumptions made by our management, and may include, but are not limited to, statements regarding the potential benefits and commercial potential of Soliris®, 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 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 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 eculizumab, asfotase alfa, sebelipase alfa and our other product candidates, commencement dates for new clinical trials, clinical trial results, evaluation of our clinical trial results by regulatory agencies, the adequacy of our pharmacovigilance and drug safety reporting processes, prospects for regulatory approval of our products and 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 legal proceedings, company investigations and government investigations, including our Securities and Exchange Commission (SEC) and U.S. Department of Justice (DOJ) investigations, the securities fraud class action litigation filed in December 2016, the investigation by our Audit and Finance Committee announced November 2016 (the Audit Committee Investigation), and the inquiry by the U.S. Attorney’s Office for the District of Massachusetts requesting documents relating generally to our support of patient assistance programs, risks related to potential disruptions to our business as a result of the leadership changes and transition announced in December 2016, the risk that hiring a new CEO may take longer than anticipated, the short and long-term effects of other government healthcare measures, and the effect of shifting foreign exchange rates. Words such as “anticipates,” “expects,” “intends,” “plans,” “believes,” “seeks,” “estimates,” variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this report under the section entitled “Risk Factors”. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers should

carefully review the risk factors set forth in this and other reports or documents we file from time to time with the SEC.

Item 1. BUSINESS.
(dollars and shares in millions)

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 result from chronic uncontrolled activation of the complement component of the immune system.

In our metabolic franchise, we commercialize 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 an ultra-rare genetic 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 devastating and ultra-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 patients with devastating and ultra-rare diseases.

Products and Development Programs

We focus our product development programs on life-transforming therapeutics for devastating 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
Soliris (eculizumab)	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)
	Hematology/Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)
Strensiq (asfotase alfa)	Metabolic Disorders	Hypophosphatasia (HPP)
Kanuma (sebelipase alfa)	Metabolic Disorders	Lysosomal Acid Lipase Deficiency (LAL-D)

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, neurology and transplant rejection. 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 (U.S.), 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 addition, Soliris has been granted orphan drug designation for the treatment of PNH in the U.S., Europe, Japan and several other territories.

Atypical Hemolytic Uremic Syndrome (aHUS)

aHUS is a severe and life-threatening, ultra-rare genetic 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

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organs. Soliris is approved for the treatment of pediatric and adult patients with aHUS in the U.S., Europe and Japan. We are sponsoring a multinational registry to gather information regarding the natural history of patients with aHUS and the longer term outcomes during Soliris treatment. In addition, the FDA and European Commission (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 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 Ministry of Health Labour and Welfare (MHLW) approved Strensiq for the treatment of patients with HPP. We are sponsoring a multinational registry to gather information regarding the natural history of patients with HPP and the longer-term outcomes during Strensiq treatment.

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. In 2015, the FDA approved Kanuma for the treatment of patients with LAL-D and the EC granted marketing authorization of Kanuma for long-term enzyme replacement therapy in patients of all ages with LAL-D. On March 28, 2016, we announced that the MHLW approved Kanuma for the treatment of patients of all ages in Japan with LAL-D. We are sponsoring a multinational registry to gather information regarding the natural history of patients with LAL-D and the longer term outcomes during Kanuma treatment.

Clinical Development Programs

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

Product	Development Area	Indication	Development Stage
Soliris (eculizumab)	Neurology	Refractory Generalized Myasthenia Gravis (gMG)	Phase III
		Relapsing Neuromyelitis Optica Spectrum Disorder (NMOSD)	Phase III
	Transplant	Antibody Mediated Rejection (AMR) Presensitized Renal Transplant - Deceased Donor	Phase II
cPMP (ALXN1101)	Metabolic Disorders	Molybdenum Cofactor Deficiency (MoCD)Type A	Phase II / III
SBC-103	Metabolic Disorders	Mucopolysaccharidoses IIIB (MPS IIIB)	Phase I / II
ALXN1210 (IV)	Next Generation Complement Inhibitor	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Phase III
		Atypical Hemolytic Uremic Syndrome (aHUS)	Phase III
ALXN1210 (Subcutaneous)	Next Generation Complement Inhibitor		Phase I

Soliris (eculizumab)

Neurology

Refractory Generalized Myasthenia Gravis (gMG)

Refractory gMG is an ultra-rare segment of Myasthenia Gravis, a debilitating, complement-mediated neuromuscular disease in which patients suffer profound muscle weakness throughout the body, resulting in slurred speech, impaired swallowing and choking, double vision, upper and lower extremity weakness, disabling fatigue, shortness of breath due to respiratory muscle weakness and episodes of respiratory failure. The FDA, EC and MHLW have granted orphan drug designation for eculizumab as a treatment for patients with refractory gMG.

In June 2016, we announced topline results of the Phase III REGAIN trial of eculizumab for the treatment of refractory gMG. The primary efficacy endpoint of change from baseline in Myasthenia Gravis-Activities of Daily Living Profile (MG-ADL) total score, a patient-reported assessment, at week 26, did not reach statistical significance (p=0.0698) as measured by a worst-rank analysis. The totality of data reviewed to date, including the first three secondary endpoints and a series of prospectively defined sensitivity analyses, shows early and sustained substantial improvements over 26 weeks for patients treated with eculizumab compared to placebo. The safety of eculizumab in this study was consistent with the Soliris labels. Additional data from the Phase III study was presented in July 2016. The data showed that 18 of 22 pre-defined endpoints and pre-specified analyses in the study, based on the primary and five secondary endpoints, achieved p-values below 0.05.

In January 2017, we announced that we filed for regulatory approval for eculizumab in refractory gMG in both the U.S. and Europe. These marketing applications were based on the comprehensive data from the Phase III REGAIN trial.

Relapsing Neuromyelitis Optica Spectrum Disorder (NMOSD)

Relapsing NMOSD is a severe and ultra-rare autoimmune disease of the central nervous system (CNS) that primarily affects the optic nerves and spinal cord. The disease leads to severe weakness, paralysis, respiratory failure, loss of bowel and bladder function, blindness and premature death. Enrollment and dosing are ongoing in a global, randomized, double-blind, placebo-controlled trial 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 relapsing NMOSD.

Transplant

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.

cPMP (ALXN1101)

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. 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. Enrollment is ongoing in the Phase II/III pivotal open-label, single-arm trial of ALXN1101 for treatment-naïve neonates with MoCD Type A.

SBC-103

Mucopolysaccharidosis IIIB (MPS IIIB)

MPS IIIB is an ultra-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 and by the EC. It received Fast Track designation by the FDA. The first-in-human trial of patients with MPS IIIB is ongoing. In March 2016, researchers presented 24-week results from this study that showed a 26.2 percent mean reduction in heparan sulfate in cerebrospinal fluid at the highest dose studied (3mg/kg every other week) in a Phase I/II study at six months. In July 2016, researchers presented preliminary results on brain MRI and neurocognitive assessments performed after 24 weeks of dosing suggesting preliminary evidence of potential for dose-dependent disease stabilization in patients treated with 0.3, 1, or 3mg/kg every other week of doses of SBC-103. Planned dose escalation of SBC-103 is now ongoing in this trial. In February 2017, the Board of Directors of Alexion made the decision to reduce our investment in SBC-103. The current Phase I/II clinical trial will not be expanded and no new patients will be added to the trial. Patients currently enrolled in the trial will continue to receive therapy.

ALXN1210

ALXN1210 is a highly innovative, longer-acting anti-C5 antibody discovered and developed by Alexion that inhibits terminal complement. In early studies, ALXN1210 demonstrated rapid, complete, and sustained reduction of free C5 levels. Alexion has completed enrollment in two ongoing clinical studies of ALXN1210 in patients with PNH-a Phase 1/2 dose-escalating study and an open-label, multi-dose Phase II study that is also evaluating longer dosing intervals beyond 8 weeks.

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Paroxysmal Nocturnal Hemoglobinuria (PNH)

In June 2016, we announced interim data from a Phase I/II study in patients with PNH showing that once-monthly dosing of ALXN1210 achieved rapid and sustained reductions in hemolysis, as measured by mean levels of lactate dehydrogenase (LDH), in 100 percent of treated patients. 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). Researchers also reported that, at the time of analysis, 80 percent of patients who required at least 1 blood transfusion in the 12 months prior to treatment with ALXN1210 did not require transfusions while on treatment with ALXN1210. Furthermore, in December 2016, we reported new data from this same ongoing study that showed rapid and sustained reductions LDH in patients with PNH treated with once-monthly dosing. Patients also had improvements in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score from baseline, with patients in the higher-dose cohort achieving a two-fold greater improvement compared with the lower-dose cohort. In addition, we have completed enrollment and treatment is ongoing in an open-label, multi-dose Phase II study of ALXN1210 in patients with PNH designed to measure reductions in hemolysis and safety in several dosing cohorts and intervals evaluating monthly and longer dosing intervals. We have initiated a Phase III open-label, multinational, active-controlled study of ALXN1210 compared to eculizumab (Soliris) in adult patients with PNH who have never been treated with a complement inhibitor. The study is evaluating ALXN1210 administered intravenously every eight weeks. Patient enrollment is ongoing in this trial.

In June 2016 and January 2017, the EC and the FDA, respectively, granted orphan drug designation to ALXN1210, for the treatment of patients with PNH.

Atypical Hemolytic Uremic Syndrome (aHUS)

We initiated a Phase III open-label, single arm, multicenter study of ALXN1210 in adolescent and adult patients with aHUS who have never been treated with a complement inhibitor. In patients with aHUS, complement-mediated TMA leads to life-threatening damage to the kidney, brain, heart and other vital organs. The study will evaluate ALXN1210 administered intravenously every eight weeks. Patient recruitment will initiate in 2017 on this trial.

Subcutaneous (SC) Delivery

We have completed enrollment in a Phase I study in healthy volunteers to evaluate ALXN1210 delivered subcutaneously.

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 Ireland manufacturing facilities, 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 $1,148. 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 one of its existing facilities.

In addition, we have non-cancellable commitments of approximately $27 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 disclosed, the FDA issued Form 483s in August 2014 and August 2015 relating to observations at ARIMF and the inspectional observations from the August 2014 and 2015 Form 483s have since been closed out by the FDA. During July 2016, the FDA completed a routine inspection at ARIMF and have

since confirmed receipt of our responses to the inspectional observations included in the Form 483 received during that inspection. We continue to manufacture products, including Soliris, at ARIMF, and we anticipate that the supply of Soliris to patients will not be interrupted as a result of the inspectional observations. 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. After regulatory approvals, the facility will become our first company-owned fill/finish facility for our commercial and clinical products. In July 2016, we announced plans to construct a new biologics manufacturing facility at this site, which is expected to be completed by 2018.

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 U.S., 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 healthcare providers. In some cases, we may also sell our products to governments and government agencies. During 2016 and 2015, sales to our largest customer accounted for 16% and 18% respectively, 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, financial strength of distributors and our ability to estimate returns. 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. We also 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 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 other patents and pending patent applications that are directed to various aspects of 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 have applied 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 have applied 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 and 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 also applied 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

From time to time, we enter into arrangements with third parties, including collaboration and licensing arrangements, for the development, manufacture and commercialization of products and product candidates. These strategic alliances are intended to strengthen and advance our R&D capabilities and diversify our product pipeline to support the growth of our marketed product base. The arrangements, which generally provide Alexion with rights to specialized technology and intellectual property for the development of potential product candidates, often require non-refundable, upfront license fees, development, regulatory and commercial milestones, as well as royalty payments on commercial sales.

Government Regulation

Drug Development and Approval in the United States

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 US, the European Union (EU) and other territories. In the U.S., pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 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 sixty 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 (BPCIA) 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 BPCIA 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 BPCIA, 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 U.S. 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 BPCIA 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 BPCIA 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 numerous guidance documents interpreting the BPCIA in recent 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 and interchangeability.

The FDA approved the first biosimilar product under the BPCIA 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 BPCIA 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 “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 such uses. Broadly speaking, a manufacturer may not promote a drug or biologic for unapproved use, but may engage in non-promotional, balanced communication regarding such uses 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 U.S., the EU 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 two hundred thousand individuals in the U.S. 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 ten thousand people in the EU; 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 EU. 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 EU member states, the EMA, or the EC 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 U.S., the EU, and in several other territories; (b) the prevention of delayed graft function in renal transplant patients in the U.S.; (c) the treatment of patients with myasthenia gravis in the U.S., Japan, and the EU; and (d) the prevention of graft rejection and delayed graft rejection following solid organ transplantation in the EU. In 2008, Strensiq received orphan drug designation for the treatment of patients with HPP in the U.S. and the EU, and in Japan in November 2014. Furthermore, in 2010, Kanuma received orphan drug designation for the treatment of LAL-D in the U.S. and the EU. 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 U.S.

Congress has created the Breakthrough Therapy designation program under which 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.

21st Century Cures Act (the Cures Act)

In December 2016, Congress passed the Cures Act which included a number of provisions designed to speed development of innovative therapies, provide funding authorization to the NIH, and provide funding for certain oncology-directed research. Because the Cures Act has only recently been enacted, its potential affect on our business remains unclear with the exception of a provision requiring that we post our policies on the availability of expanded access programs for individuals. In addition, the Cures Act includes requiring the FDA to assess and publish guidance on the use of novel clinical trial designs, the use of real world evidence in applications, the availability of summary level review for supplemental applications for certain indications, and the qualification of drug development tools. Because these provisions allow FDA to spend several years developing these policies, the effect on us could be delayed.

The Cures Act also authorizes $1,800 in funding for “cancer moonshot” initiative (the Initiative) to be run by the NIH. The Cancer Moonshot Initiative’s strategic goals encourage inter-agency cooperation and fund research and innovation to catalyze new scientific breakthroughs, bring new therapies to patients, and strengthen prevention and diagnosis. The Initiative aims to stimulate drug development through the creation of a public-private partnership with 20 to 30 pharmaceutical and biotechnology companies to expedite cancer researchers’ access to investigational agents and approved drugs. This partnership is designed to permit researchers to obtain drugs and other technologies from a preapproved “formulary” list without having to negotiate with each company for individual research projects. We will monitor these developments but cannot currently assess how the Initiative may impact our business

Foreign Regulation of Drug Development and Approval

In addition to regulations in the U.S., 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 EU 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 EC on the basis of a positive opinion by the EMA. A centralized marketing authorization is valid for all EU member states and three of the four EFTA States (Iceland, Liechtenstein and Norway). The decentralized procedure and the mutual recognition procedure apply between EU member states. The decentralized marketing authorization procedure involves the submission of an application for marketing authorization to the competent authority of all EU 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 EU 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 EU member states by the competent authorities of other EU member states. The holder of a national marketing authorization may submit an application to

the competent authority of a EU member state requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU 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 EU member states both before and after grant of the manufacturing and marketing authorizations. This includes control of compliance by the entities with EU 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 EU laws and the related national laws of individual EU 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 EU has had an established regulatory pathway for biosimilars since 2005 and has approved several biosimilar products. In addition, in February 2017 the EMA will launch a pilot project with the aim of providing scientific advice to companies for the development of new biosimilar products.

The approval of a biosimilar of one of our products marketed in the EU 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 U.S., 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 and grantees, 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 innovator “covered drugs” 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 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 and Medicare Part B programs 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 one hundred seventy eight thousand dollars 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 EU the sole legal instrument at the EU 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 EU member states are transparent and objective, do not hinder the free movement and trade of medicinal products in the EU 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 EU member states. Neither does it have any direct consequence for pricing or levels of reimbursement in individual EU member states. The national authorities of the individual EU 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 EU member states adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other EU 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 EU 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 EU member states. These countries include the United Kingdom, France, Germany and Sweden. The HTA process in the EU 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 EU member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of

a specific medicinal product vary between the EU member states.

In 2011, Directive 2011/24/EU was adopted at the EU 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 EU. Pursuant to Directive 2011/24/EU, a voluntary network of national authorities or bodies responsible for HTA in the individual EU Member States was established. 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 EU member states in pricing and reimbursement decisions and negatively impact price in at least some EU 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. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of five thousand to eleven thousand dollars per false claim or statement (and ten thousand to twenty thousand dollars per false claim or statement for penalties assessed after August 1, 2016 for violations occurring after November 2, 2015). 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 healthcare programs to provide items or services reimbursable by a federal healthcare 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 healthcare 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, relationships with specialty pharmacies, and grants to independent charitable foundations. In December 2016, we received a subpoena from the U.S. Attorney's Office (USAO) for the District of Massachusetts relating generally to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients, Alexion's provision of free drug to Medicare patients and Alexion's related compliance policies and training materials. Some of these investigations have resulted in significant civil and criminal settlements. 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 U.S. 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. In early 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate Program under PPACA, which became effective on April 1, 2016. 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 $4,000 in 2017 (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). Legislative changes to PPACA also remain possible and appear likely in the 115th U.S. Congress and under the Trump Administration.

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 healthcare 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 U.S. 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 healthcare 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 EU 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 EU 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 Organizations and related codes developed at national level in individual EU 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, 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, 2016, we had 3,121 full-time, world-wide employees, of which 1,247 were engaged in research, product development, manufacturing, and clinical development, 1,240 in sales and marketing, and 634 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.

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EXECUTIVE OFFICERS OF THE COMPANY

The executive officers of the Company and their respective ages and positions as of February 13, 2017 are as follows:

Name	Age	Position with Alexion
David R. Brennan	62	Interim Chief Executive Officer
David J. Anderson, M.B.A.	67	Executive Vice President and Chief Financial Officer
Clare Carmichael	57	Executive Vice President and Chief Human Resources Officer
Martin Mackay, Ph.D.	60	Executive Vice President and Global Head of Research and Development
John B. Moriarty, J.D.	49	Executive Vice President and General Counsel
Julie O'Neill, M.B.A.	50	Executive Vice President of Global Operations
Carsten Thiel, Ph.D.	53	Executive Vice President and Chief Commercial Officer
Edward Miller, J.D.	52	Senior Vice President and Global Chief Compliance Officer
Heidi L. Wagner, J.D.	52	Senior Vice President, Global Governmental Affairs

David R. Brennan has been a member of the Board of Directors since July 2014 and as Interim Chief Executive Officer since December 2016. Prior to joining Alexion, Mr. Brennan held various positions of increasing responsibility at AstraZeneca PLC, from 1999-2012, including Chief Executive Officer and Executive Director, Executive Vice President of North America, and Senior Vice President of Commercialization and Portfolio Management. Mr. Brennan began his career in 1975 at Merck and Co. Inc., where he held various sales and general manager positions. Mr. Brennan currently serves on the Board of Directors of Innocoll, Inc. and Insmed Incorporated, and previously served on the Board of Directors of AstraZeneca PLC, Reed Elsevier PLC and the Pharmaceutical Research & Manufacturers of America (PhRMA). Mr. Brennan received a Bachelor of Arts in Business Administration from Gettysburg College, where he is a member of the Board of Trustees.

David J. Anderson, M.B.A. has been with Alexion since December 2016, serving as Executive Vice President and Chief Financial Officer. Prior to joining Alexion, Mr. Anderson served as Senior Vice President and Chief Financial Officer of Honeywell International from 2003-2014, where he was responsible for all corporate finance activities including accounting, treasury, tax, audit, investments, financial planning and acquisitions, and was integral to the reshaping of the company's business portfolio. Prior to joining Honeywell, Mr. Anderson was Senior Vice President and Chief Financial Officer of ITT Industries, as well as Newport News Shipbuilding. Previously, he also held senior financial positions with RJR Nabisco and the Quaker Oats Company. Mr. Anderson serves on the Boards of several public companies, including Cardinal Health, a Fortune 20 leader in healthcare products and services. Mr. Anderson received a Bachelor of Science in Economics from Indiana University and a Masters of Business Administration from the University of Chicago (Booth School of Business).

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. Prior to joining Alexion, Ms. Carmichael served as Senior Vice President, Global Human Resources at Watson Pharmaceuticals, Inc., from August 2008 to March 2011, 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 Bachelor of Arts in Psychology from Rider University.

Martin Mackay, Ph.D. 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 Bachelor's of Arts, with distinction, from the University of Virginia and his J.D., cum laude, from the University of Georgia School of Law.

Julie O'Neill, M.B.A. 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 of Science in Pharmacy from University of Dublin, Trinity College and a Masters of Business Administration from University College Dublin (Smurfit School of Business).

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 Senior 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 Master Degree in Biochemistry from the University of Marburg, Germany, and a Ph.D. in Molecular Biology and Biochemistry from the Max Planck Institute, Germany.

Edward Miller, J.D. 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 DOJ in Washington, D.C. Mr. Miller received a Bachelor of Arts 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 healthcare-related companies. Ms. Wagner received a Bachelor of Science in Journalism and Mass Communication from the University of Colorado in Boulder, and her J.D. 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 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 millions, 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 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 healthcare payers view Soliris as therapeutically effective and safe relative to cost. Since we launched Soliris in the U.S. in 2007, substantially all of our revenue has been attributed to sales of Soliris. In 2015, we received marketing approval in the U.S., the EU 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 EU 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 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 maintain 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.

Because the target patient populations of Kanuma and Stensiq are small and have not been definitively determined, we must be able to successfully identify patients in order to maintain growth.

Kanuma and Stensiq are currently approved to treat ultra-rare diseases with small patient populations that have not been definitively determined. There can be no guarantee that any of our programs will be effective at identifying patients and the number of patients in the United States, Japan and Europe and elsewhere may turn out to be lower

than expected, may not be otherwise amenable to treatment with Kanuma and Stensiq, or new patients may become increasingly difficult to identify, all of which would adversely affect our results of operations and our business.

Sales of our products depend on reimbursement by 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 their cost. We depend, to a significant extent, on governmental payers, such as Medicare and Medicaid in the U.S. 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 or funding 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 as well as 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. Therefore, 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 U.S., the EU member states, and elsewhere, there have been, and we expect there will continue to be, efforts to control and reduce healthcare 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 healthcare 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 or limit 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 first 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, healthcare 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 healthcare providers, government agencies or private insurers will determine or continue to accept that our products are safe and therapeutically effective relative to their 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 our products 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 or 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 U.S., the EU, Japan and certain other territories. However, manufacturing Soliris for commercial

sale in certain other territories may only be performed at a single facility in some cases until such time as we have received the required regulatory approval for an additional facility, if ever, however in certain territories only a single manufacturing facility may be registered and we will continue to rely on a single manufacturing facility in such instances. 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 of the EU member states, 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 have completed the build-out of a fill-finish facility in Ireland to support global drug product manufacture or vial fill finish of Soliris and Alexion's other clinical and commercial products. We cannot guarantee that this facility will receive the necessary global regulatory approvals in a timely manner and we will continue to rely on appropriate third parties to supplement our fill finish operations until that time. 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 lysosomal 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 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 U.S. 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 EU 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 U.S. 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 prescribing 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 healthcare 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 U.S., 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 U.S. 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 U.S., 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 U.S., 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 years 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 U.S., 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 EU 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, which 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 U.S., 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. 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 healthcare “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 healthcare item or service reimbursable under Medicare, Medicaid, or other federal healthcare 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 healthcare 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 the 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 U.S. 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 U.S., we market our products for their approved uses. Although we believe our marketing materials and training programs for physicians do not constitute improper 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 improper 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 the 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 DOJ for the voluntary production of documents and other information pertaining to Alexion’s compliance with the FCPA and in December 2016, we received a subpoena from the USAO for the District of Massachusetts requesting documents relating generally to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients, Alexion’s provision of free drug to Medicare patients and Alexion’s related compliance policies and training materials. 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 U.S. 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 III Soliris trial for gMG that we announced in June 2016, 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 U.S. 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 U.S. 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 and other non-U.S. patent offices. 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 have identified a material weakness in our internal control over financial reporting. If we are unable to remediate this material weaknesses, or if we experience additional material weaknesses or deficiencies in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

Current management concluded and the Audit Committee concurred that there was a material weakness in the Company's internal controls over financial reporting because we did not maintain an effective control environment as senior management failed to set an appropriate "Tone at the Top." A "material weakness" is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As further described in Item 9A "Controls and Procedures", the aforementioned material weakness arose from actions identified during the Audit Committee Investigation which found that senior management applied pressure on personnel to use pull-in sales to meet targets, and such pressure was particularly significant during the fourth quarter 2015. The Audit Committee Investigation also found that certain Company personnel engaged in inappropriate

business conduct to realize pull-in sales, as a result of pressure from senior management.

As further described in Item 9A “Controls and Procedures-Remediation Plan and Activities”, we have undertaken steps to improve our internal controls over financial reporting. However, there can be no assurance that we will be successful in making the improvements necessary to remediate the material weakness identified by management, that we will do so in a timely manner, or that we will not identify additional control deficiencies or material weaknesses in the future. If we are unable to

successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities laws and NASDAQ listing requirements regarding the timely filing of periodic reports, investors may lose confidence in our financial reporting and our stock price may decline.

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. 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. Our revenues could be negatively affected if patients or potential patients enroll in our clinical trials or clinical trials of other companies with respect to diseases that we also target with approved therapies.

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. In December 2016, our Board appointed an interim CEO, and a search for a new CEO is ongoing. 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, or if our recruitment efforts take longer than anticipated, 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 Credit Agreement. 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, but 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, 2016, the net carrying value of our goodwill and other intangible assets totaled $9,340. 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. For example, in the fourth quarter 2016, we recorded an impairment charge of $85 related to

SBC-103 as discussed below in our “Results of Operations.” Any charges relating to such impairments could adversely affect our results of operations in the periods in which 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 U.S. 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 and in December 2016, we received a subpoena from the USAO for the District of Massachusetts requesting documents relating generally to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients, Alexion's provision of free drug to Medicare patients and Alexion's related compliance policies and training materials . Further, securities fraud class action litigation has been filed against the Company and individual executive officers, and we could also become subject to legal proceedings and government investigations relating to matters addressed in the Audit Committee Investigation. 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 U.S. and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities. Although we believe our estimates are reasonable, the ultimate outcome with respect to the taxes we owe may differ from the amounts recorded in our financial statements. If the Internal Revenue Service, or other taxing authority, disagrees with the positions we take, we could have additional tax liability, and this could have a material impact on our results of operations and financial position. Our effective tax rate could be adversely affected by changes in the mix of earnings in countries with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in tax laws and regulations, changes in interpretations of tax laws, including pending tax law changes, changes in our manufacturing activities and changes in our future levels of research and development spending.

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

In addition, the U.S. Federal government and other U.S. State and foreign 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 corporations, 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 U.S. 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 currencies decrease. When the U.S. dollar weakens against these currencies, the relative value of such sales increase. 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 implementing regulations, as well as changes in healthcare 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 healthcare. The Patient Protection and Affordable Care Act (PPACA) was enacted in the U.S. 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. In early 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate Program under PPACA. These regulations became effective on April 1, 2016. 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. Legislative changes to the PPACA also remain possible and appear likely in the 115th U.S. Congress under the Trump Administration. 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 healthcare. 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 one hundred seventy-eight thousand dollars 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 thirteen thousand dollars 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 eighteen thousand dollars 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. A final regulation that has been published but is not yet effective would impose a civil monetary penalty of up to five thousand dollars for each

instance of knowingly and intentionally charging a 340B covered entity more than the 340B ceiling price.

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. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EC 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 EU member states could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

In May 2016, the EU formally adopted the General Data Protection Regulation, which will apply to all EU member states from May 25, 2018 and will replace the current EU Data Protection Directive on that date. The regulation introduces new data protection requirements in the EU and substantial fines for breaches of the data protection rules. It 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 and under Delaware law 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 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	160,000	Owned
Athlone, Ireland	Commercial, research and development manufacturing	80,000	Owned
Lexington, Massachusetts	Research and development offices	81,000	2019
Bogart, Georgia	Commercial, research and development manufacturing	70,000	Owned
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 facilities, 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.

In May 2015, we announced plans to construct a new bulk biologics manufacturing facility on our existing property in Dublin Ireland, which is expected to be completed by 2020.
In July 2016, we announced plans to construct a new biologics manufacturing facility at our existing property in Athlone, Ireland, which is expected to be completed by 2018.

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. In addition, in October 2015, we received a request from the DOJ for the voluntary production of documents and other information pertaining to Alexion's compliance with FCPA. The SEC and DOJ also seek information related to Alexion's recalls of specific lots of Soliris and related securities disclosures. Alexion is cooperating with these investigations. At this time, Alexion is unable to predict the duration, scope or outcome of these investigations. While it is possible that a loss related to these matters may be incurred, given the ongoing nature of these investigations, management cannot reasonably estimate the potential magnitude of such loss or range of loss, if any.
Several securities class action lawsuits have been filed against the Company and former officers in federal district court alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Rule 10b-5, promulgated thereunder, alleging that defendants made misstatements and/or omissions concerning the Company's sales of Soliris.
On November 17, 2016, a shareholder filed a putative class action in the U.S. District Court for the Southern District of New York. While the litigation was in the early stages, and before defendants had responded to the complaint, on December 30, 2016 plaintiffs filed a notice of voluntary dismissal and dismissed all claims without prejudice. This case is now closed.
On December 29, 2016, a second shareholder filed a putative class action against the Company and certain former employees in the U.S. District Court for the District of Connecticut, alleging that defendants made misrepresentations and omissions about Soliris between February 10, 2014 and December 9, 2016. On January 17, 2017, three parties filed motions to be named lead plaintiff in this action. Briefing on these motions is ongoing. The litigation is in the early stages, and defendants have not yet responded to the complaint. Given the early stages of this litigation, management does not currently believe that 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 December 2016, we received a subpoena from the USAO for the District of Massachusetts requesting documents relating generally to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients taking drugs sold by Alexion, Alexion's provision of free drug to Medicare patients, and Alexion compliance policies and training materials concerning the anti-kickback statute or payments to any 501(c)(3) organization that provides financial assistance to Medicare patients. Other companies have disclosed similar inquiries. We are cooperating with this inquiry.

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, 2015.

Fiscal 2015	High	Low
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
Fiscal 2016		
First Quarter (January 1, 2016 to March 31, 2016)	$187.59	$124.16
Second Quarter (April 1, 2016 to June 30, 2016)	$162.00	$110.56
Third Quarter (July 1, 2016 to September 30, 2016)	$138.40	$115.84
Fourth Quarter (October 1, 2016 to December 31, 2016)	$145.42	$109.12

As of February 8, 2017, we had approximately 111 stockholders of record of our common stock and an estimated 185,102 beneficial owners. The closing sale price of our common stock on February 8, 2017 was $126.37 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 millions except per share amounts)

The following table summarizes our common stock repurchase activity during the fourth quarter of 2016:

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, 2016	0.25	$122.74	0.25	325
November 1-30, 2016	—	—	—	325
December 1-31, 2016	—	—	—	325
Total	0.25	$122.74	0.25	

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 for future purchases under the repurchase program. In February 2017, our Board of Directors increased the authorization of shares up to $1,000 for future purchases under the repurchase program, which superseded all prior repurchase programs. As of February 16, 2017, there is a total of $1,000 remaining for repurchases under the repurchase program.

EQUITY COMPENSATION PLAN INFORMATION (amounts in millions 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 (years)	Number of shares of common stock remaining available for future issuance under equity compensation plans (2)
Equity compensation plans approved by stockholders	6	$ 116.65	6.02	7
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 3 restricted shares outstanding that were issued under the Amended and Restated 2004 Incentive Plan.

(2) Of these shares, 6 remain available for future issuance under the Amended and Restated 2004 Incentive Plan and 1 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, 2011 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

	12/11	12/12	12/13	12/14	12/15	12/16
Alexion Pharmaceuticals, Inc.	100.00	131.10	185.85	258.78	266.78	171.12
NASDAQ Composite	100.00	116.41	165.47	188.69	200.32	216.54
NASDAQ Biotechnology	100.00	134.68	232.37	307.67	328.76	262.08

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 millions, except per share amounts)

Consolidated Statements of Operations Data:

	Year Ended December 31,				
	2016	2015	2014	2013	2012
Net product sales [1]	$3,082	$2,603	$2,234	$1,551	$1,134
Other revenue	2	1	—	—	—
Total revenues	3,084	2,604	2,234	1,551	1,134
Cost of sales:					
Cost of sales	258	233	174	168	126
Change in contingent liability from intellectual property settlements	—	—	—	9	(53)
Total cost of sales	258	233	174	177	73
Operating expenses:					
Research and development	757	709	514	317	223
Selling, general and administrative	954	863	630	490	385
Amortization of purchased intangible assets [2]	322	117	—	—	—
Change in fair value of contingent consideration	36	64	20	4	7
Acquisition-related costs	2	39	—	1	16
Restructuring expenses	3	42	15	—	—
Impairment of intangible assets	85	—	12	34	26
Total operating expenses	2,159	1,834	1,191	846	657
Operating income	667	537	869	528	404
Other income (expense)	(91)	(39)	3	(2)	(6)
Income before income taxes	576	498	872	526	398
Income tax expense [3] [4]	177	354	215	273	143
Net income	$399	$144	$657	$253	$255
Earnings per common share					
Basic	$1.78	$0.68	$3.32	$1.29	$1.34
Diluted	$1.76	$0.67	$3.26	$1.27	$1.28
Shares used in computing earnings per common share					
Basic	224	213	198	196	190
Diluted	227	216	202	200	199

Consolidated Balance Sheet Data:

	As of December 31,				
	2016	2015	2014	2013	2012
Cash, cash equivalents and marketable securities	$1,293	$1,385	$1,962	$1,515	$990
Total assets [5]	13,253	13,097	4,202	3,318	2,614
Long-term debt (current and noncurrent) [6]	3,055	3,420	58	113	149
Contingent consideration (current and noncurrent)	153	177	163	143	142
Facility lease obligation (current and noncurrent)	243	151	107	32	—
Total stockholders' equity[7]	8,694	8,259	3,303	2,383	1,971

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 $88 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 $316 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 $96 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 of intangible assets and $4,783 of goodwill.
[6] In connection with the acquisition of Synageva, we borrowed $3,500 under our term loan under a new credit facility.
[7] In connection with the acquisition of Synageva, we issued $4,918 of common stock to former Synageva stockholders.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS. (amounts in millions, 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, or aHUS, a life-threatening and ultra-rare genetic disease. PNH and aHUS result from chronic uncontrolled activation of the complement component of the immune system.

In our metabolic franchise, we commercialize Strensiq for the treatment of patients with HPP and Kanuma for the treatment of patients with LAL-D. HPP is an ultra-rare genetic 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 devastating and ultra-rare disorders.

Recent Developments

As previously reported, the Audit and Finance Committee of the Company's Board of Directors (Audit Committee) commenced an investigation of allegations made by a former employee concerning the Company's Soliris sales practices. The former employee alleged that certain of such practices resulted in certain customers placing orders for shipments of Soliris in an earlier fiscal quarter than the fiscal quarter they otherwise would have (referred to here as pull-in or advanced sales, and more fully described below). The former employee alleged that such practices were used by the Company in order to meet certain financial targets and at times involved inappropriate business conduct. The Audit Committee conducted its investigation (Audit Committee Investigation) with the assistance of outside counsel, forensic accountants and other accounting firm advisors. The Audit Committee Investigation is substantially complete, and no further investigative procedures are currently planned except as necessary to respond to regulatory inquiries, if any, or because of matters that arise in the ordinary course of the Company's future business activities. The Audit Committee concluded, based on the facts of the investigation that the Company's previously issued financial results do not require restatement. In addition, the Audit Committee Investigation did not identify any instances of improper revenue recognition associated with pull-in sales, instances where Soliris orders were not placed by customers for patients in order to fulfill an actual need, or instances where Soliris was sold to build stock of unwanted product. However, management concluded and the Audit Committee concurred that there was a material weakness in the Company's internal control over financial reporting because we did not maintain an effective control environment as senior management failed to set an appropriate "Tone at the Top." Specifically, senior management failed to reinforce the need for compliance with the Company's policies and procedures, which resulted in inappropriate business conduct. The Audit Committee Investigation found that senior management applied pressure on personnel to use pull-in sales to meet targets, and such pressure was particularly significant during the fourth quarter of 2015. The Audit Committee Investigation also found that certain Company personnel engaged in inappropriate business conduct to realize pull-in sales, as a result of pressure from senior management.

For purposes of this Annual Report on Form 10-K, "pull-in" or "advanced" sales are certain Soliris sales transactions, coordinated by Company personnel (primarily personnel in the customer operations department in their capacity as coordinators for the shipment of orders for customers) that increase revenue recognized in an earlier fiscal quarter than the one in which a sale otherwise would have occurred and result in a corresponding decrease in the revenue that will be recognized in the subsequent fiscal quarter. The Company is able to forecast the estimated date of certain shipments of Soliris due to customer order history, known infusion dates, or other similar data to support the operations of our business and patient needs. Pull-in sales may occur, for example, when a customer, as a result of encouragement by a Company employee, places an order for a patient earlier than the customer might otherwise place the order. Pull-in sales are not inherently problematic or impermissible, when in accordance with U.S. GAAP. The Audit Committee Investigation included a review of sales transactions for evidence of pull-in sales, the reasons for pull-in sales, whether such transactions were conducted in accordance with the Company's policies and procedures, and whether revenue from pull-in sales was properly recognized in accordance with U.S. GAAP.

The Audit Committee Investigation concluded that revenue from the pull-in sales under review was appropriately recognized in the quarter in which such sales actually occurred and that there were no financial statement errors related to the pull-in sales. However, the Audit Committee Investigation found that certain revenue pulled into the fourth quarter of 2015 from the first quarter of 2016 was realized as the result of employee actions that involved inappropriate business conduct, including conduct that was inconsistent with, and in violation of Company policies and procedures. Pull-in sales during the fourth quarter of 2015 were estimated to be between approximately $10 to $17 and were significantly higher than for other quarters. Some portion of these estimated sales did not involve inappropriate business conduct. These estimated pull-in sales represented less than 1% of total revenue for 2015.

During the past two completed fiscal years and through the fourth quarter of 2016, but excluding the fourth quarter of 2015, pull-in sales were estimated to be between $1 to $7 in the aggregate, representing 0% - 1% of total revenue. Although pull-in sales are not inherently problematic or impermissible, they must not be realized through violations of the Company's policies and procedures and must be in accordance with U.S. GAAP. The conclusions concerning the material weakness in the Company's internal controls over financial reporting are discussed further under Item 9A "Controls and Procedures" in this Form 10-K.

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 U.S., 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 healthcare 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 healthcare 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 demand, contractual terms, financial strength of distributors and our ability to estimate returns. 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 U.S. and other programs outside the U.S., 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, 2016, 2015 and 2014 as follows:

	Rebates Payable
Balance at December 31, 2013	$ 124
Current provisions relating to sales in current year	63
Adjustments relating to prior years	(87)
Payments/credits relating to sales in current year	(34)
Payments/credits relating to sales in prior years	(29)
Balance at December 31, 2014	$ 37
Current provisions relating to sales in current year	90
Adjustments relating to prior years	(2)
Payments/credits relating to sales in current year	(43)
Payments/credits relating to sales in prior years	(26)
Balance at December 31, 2015	$ 56
Current provisions relating to sales in current year	115
Adjustments relating to prior years	(2)
Payments/credits relating to sales in current year	(50)
Payments/credits relating to sales in prior years	(49)
Balance at December 31, 2016	$ 70

In 2016 compared to 2015, current provisions relating to sales in the current year increased by $25 primarily due to increased unit volumes in the U.S. and Europe which were subject to rebates.

In 2015 compared to 2014, current provisions relating to sales in the current year increased by $27 primarily due to increased unit volumes in the U.S. 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 $88 of net product sales from Soliris in France relating to years prior to January 1, 2014.

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 on a standard cost basis, which approximates average 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.

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. If our estimate of the tax effect of reversing temporary differences is not reflective of actual outcomes, is modified to reflect new developments or interpretations of the tax law, revised to incorporate new accounting principles, or changes in the expected timing or manner of the reversal our results of operations could be materially impacted. 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 currently anticipate adopting the standard using the modified retrospective method. We do not expect the implementation of this new standard to have a material impact 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. We adopted the provisions of this standard in the first quarter 2016 and reclassified $9 of deferred financing costs from prepaid expenses and other current assets to the current portion of long-term debt and $27 from other assets to long-term debt, less current portion in our consolidated balance sheets as of December 31, 2015.

In April 2015, the FASB issued a new standard clarifying the accounting for a customer’s fees paid in a cloud computing arrangement. Under this standard, if a cloud computing arrangement includes a software license, the customer would account for the software license consistent with other software licenses. If a cloud computing arrangement does not include a software license, the customer would account for the arrangement as a service contract. We adopted the provisions of this standard in the first quarter 2016. The adoption did not have a material effect on our financial condition or results of operations.

In February 2016, the FASB issued a new standard requiring that the rights and obligations arising from leases be recognized on the balance sheet by recording a right-of-use asset and corresponding lease liability. The new standard also requires qualitative and quantitative disclosures to understand the amount, timing, and uncertainty of cash flows arising from leases, as well as significant management estimates utilized. The standard is effective for interim and annual periods beginning after December 15, 2018 and requires a modified retrospective adoption. We are currently assessing the impact of this standard on our financial condition and results of operations.

In March 2016, the FASB issued a new standard intended to simplify certain aspects of the accounting for employee share-based payments. We elected to early adopt this standard during the third quarter of 2016. One aspect of the standard requires an entity to recognize all excess tax benefits and deficiencies associated with stock-based compensation as a reduction or increase to tax expense in the income statement. Previously, such amounts were recognized in additional paid-in capital. This aspect of the new standard was adopted prospectively, and accordingly we recorded tax benefits of $10 within income tax expense for the year ended December 31, 2016. The amendments require recognition of excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. As a result, $238 associated with previously unrecognized excess tax benefits was recorded as a deferred tax asset and an increase in retained earnings as of the beginning of 2016. Furthermore, the amendment requires that excess tax benefits be classified as an operating activity in the statement of cash flows instead of a financing activity. We elected to adopt this provision of the standard prospectively and thus, prior periods have not been adjusted. We have also elected to continue to estimate the impact of forfeitures when determining the amount of compensation cost to be recognized each period rather than account for forfeitures as they occur.

In October 2016 the FASB issued a new standard that eliminates the prohibition of immediate recognition of current and deferred income tax impacts for an intra-entity asset transfer other than inventory. Under the new standard, entities should recognize the income tax consequences on an intra-entity transfer of an asset other than inventory when the transfer occurs. This new standard will be effective for interim periods beginning after December 15, 2017 and requires a modified retrospective adoption through a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. We are currently assessing the impact of this standard on our financial condition and results of operations.

Results of Operations

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

	Year Ended December 31,		
	2016	2015	2014
Net product sales	$3,082	$2,603	$2,234
Other revenue	2	1	—
Total revenues	3,084	2,604	2,234
Cost of sales	258	233	174
Operating expenses:			
Research and development	757	709	514
Selling, general and administrative	954	863	630
Amortization of purchased intangible assets	322	117	—
Change in fair value of contingent consideration	36	64	20
Acquisition-related costs	2	39	—
Restructuring expenses	3	42	15
Impairment of intangible assets	85	—	12
Total operating expenses	2,159	1,834	1,191
Operating income	667	537	869
Other (expense) income	(91)	(39)	3
Income before income taxes	576	498	872
Income tax expense	177	354	215
Net income	$399	$144	$657
Earnings per common share:			
Basic	$1.78	$0.68	$3.32
Diluted	$1.76	$0.67	$3.26

Comparison of the Year Ended December 31, 2016 to the Year Ended December 31, 2015

Net Product Sales

Net product sales by significant geographic region are as follows:

	Year Ended December 31,			
	2016	2015	% Change	
Net product sales:				
United States	$1,257	$951	32	%
Europe	961	841	14	%
Asia Pacific	318	276	15	%
Rest of World	546	535	2	%
	$3,082	$2,603	18	%

Net product sales by product are as follows:

	Year Ended December 31,			
	2016	2015	% Change	
Net product sales:				
Soliris	2,843	2,591	10	%
Strensiq	210	12	-	
Kanuma	29	—	-	
	$3,082	$2,603	18	%

The components of the increase in net product sales for the year ended December 31, 2016 are as follows:

	Year Ended December 31, 2016
Components of change:	
Price	(1)%
Volume	22 %
Foreign exchange	(3)%
Total change in net product sales	18 %

The increase in net product sales for fiscal year 2016 as compared to the same period in 2015 was primarily due to an increase in unit volumes of 22% due to increased demand globally for Soliris therapy for patients with PNH or aHUS and sales of Strensiq and Kanuma during 2016.

The positive impact of volume on net product sales was partially offset by the negative impact on foreign exchange of 3%, for the year ended December 31, 2016, as compared to the same period in 2015. The negative impact on foreign exchange of $(74), or 3%, was due to changes in foreign currency exchange rates (inclusive of hedging activity) versus the U.S. dollar for the year ended December 31, 2015. The negative impact was primarily due to the weakening of the Euro, Japanese Yen, Russian Ruble, and the British Pound. We recorded a gain in revenue of $73 and $118 related to our foreign currency cash flow hedging program, for the years ended December 31, 2016 and 2015, respectively. We expect the strong dollar compared to other currencies to continue to have a negative impact on revenue into 2017.

Cost of Sales

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

The following table summarizes cost of sales for the year ended December 31, 2016 and 2015:

	Year Ended December 31,		
	2016	2015	Change
Cost of sales	$258	$233	$25
Cost of sales as a percentage of net product sales	8 %	9 %	(1)%

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, including ALX1210. 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, 2016	Year Ended December 31, 2015	$ Change	% Change
Clinical development	$ 208	$ 155	$ 53	34 %
Product development	168	120	48	40 %
Licensing agreements	10	130	(120)	(92)%
Discovery research	54	44	10	23 %
Total external direct expenses	440	449	(9)	(2)%
Payroll and benefits	274	219	55	25 %
Facilities and other costs	43	41	2	5 %
Total other R&D expenses	317	260	57	22 %
Research and development expense	$ 757	$ 709	$ 48	7 %

During the year ended December 31, 2016, we incurred research and development expenses of $757, an increase of $48, or 7%, versus the $709 incurred during the year ended December 31, 2015. The increase was primarily related to the following:

- Increase of $53 in external clinical development expenses related primarily to an expansion of studies for ALXN1210, sebelipase alfa, and eculizumab (see table below).
- Increase of $48 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.

- Decrease of $120 in licensing agreement expenses primarily related to upfront payments made in the first quarter 2015.
- Increase of $10 in discovery research expenses primarily related to increases in external research expenses associated with our collaboration agreements.

- Increase of $55 in payroll and benefits expense primarily related to the additional headcount acquired as part of the Synageva acquisition on June 22, 2015 and the continued global expansion of staff supporting our increasing number of clinical and development programs.

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

	Year Ended December 31, 2016	Year Ended December 31, 2015	Accumulated Expenditures
External direct expenses			
Eculizumab	$ 88	$ 78	(a)
Asfotase alfa	18	22	$ 85
cPMP	7	8	32
ALXN1007	7	14	28
Sebelipase alfa	24	5	29
ALXN1210	37	8	46
SBC-103	9	3	12
Other programs	7	10	31
Shared expenses	11	7	(b)
	$ 208	$ 155	$ 263

(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 2017 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 our products; 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, 2016	Year Ended December 31, 2015	$ Change	% Change
Salary, benefits and other labor expense	$ 556	$ 550	$ 6	1 %
External selling, general and administrative expense	398	313	85	27 %

Total selling, general and administrative expense	$ 954	$ 863	$ 91	11 %

During the year ended December 31, 2016, we incurred selling, general and administrative expenses of $954, an increase of $91, or 11%, versus the $863 incurred during the year ended December 31, 2015. The increase was primarily related to the following:

- Increase in external selling, general and administrative expenses of $85. The increase was primarily due to an increase in legal expenses from investigations overseen by the Audit and Finance Committee relating to the SEC and DOJ

investigations as well as the Audit Committee Investigation that occurred in the fourth quarter 2016. The increase was also attributable to additional facilities costs as a result of continuing growth of operations worldwide.

We expect our selling, general and administrative expenses to increase in 2017, 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, 2016 and 2015, we recorded amortization expense of $322 and $117, respectively, primarily associated with intangible assets related to Strensiq and Kanuma.

Change in Fair Value of Contingent Consideration

For the years ended December 31, 2016 and 2015, the change in fair value of contingent consideration expense associated with our prior business combinations was $36 and $64, respectively. The change in the fair value of contingent consideration for the years ended December 31, 2016 and 2015 was primarily due to increases in the likelihood of payments for contingent consideration.

Acquisition-related Costs

For the years ended December 31, 2016 and 2015, acquisition-related costs associated with our business combinations included the following:

	Year Ended December 31, 2016	Year Ended December 31, 2015
Transaction costs [1]	$ —	$ 27
Integration costs	2	12
	$ 2	$ 39

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

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 in restructuring expense in the fourth quarter of 2015.

In conjunction with the acquisition and integration of Synageva we recorded restructuring expense of $13 primarily related to employee costs during 2015. Synageva restructuring charges were not material for the year ended December 31, 2016.

In the fourth quarter 2014, we announced plans to relocate our European headquarters from Lausanne to Zurich, Switzerland. The relocation of our 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 related to employee costs in the fourth quarter of 2014. During the years ended December 31, 2016 and 2015, we incurred additional restructuring costs of $4 and $18, respectively.

Impairment of Intangible Asset

During the fourth quarter 2016, we reviewed SBC-103, an early stage clinical indefinite-lived intangible asset related to the Synageva acquisition as part of our annual impairment testing. The estimated fair value that can be obtained for this asset from a market participant in an arm's length transaction is $31, which was lower than the carrying amount of the asset. As a result, in the fourth quarter 2016, we recognized an impairment charge of $85 to write-down this asset to fair value.

Other Income and Expense

The following table provides information regarding other income and expense:

	Year Ended December 31, 2016	Year Ended December 31, 2015	$ Change
Investment income	$ 11	$ 8	$ 3
Interest expense	(97)	(48)	(49)
Foreign currency gain (loss)	(5)	1	(6)
Total other income (expense)	$ (91)	$ (39)	$ (52)

The increase in interest expense for the year ended December 31, 2016 as compared to the prior year was due to us borrowing $3,500 under a term loan facility in conjunction with the acquisition of Synageva on June 22, 2015. The increase was also attributable to increases in interest expense associated with our facility lease obligations.

Income Taxes

During the year ended December 31, 2016, we recorded an income tax expense of $177 and an effective tax rate of 30.7%, compared to an income tax expense of $354 and an effective tax rate of 71.0% for the year ended December 31, 2015. The decrease in the effective tax rate is primarily attributable to the tax charge we recorded in 2015 related 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%. This decrease was partially offset by deferred tax expense we recognized in 2016 attributable to first quarter distributions from our foreign captive partnership. This distribution increased our 2016 effective tax rate by 20.7%. Exclusive of these charges, we expect to continue to benefit from a reduced tax rate compared 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 expense for 2016 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. Additionally, included for the year ended December 31, 2016, is the impact to deferred tax attributable to first quarter distributions from our captive foreign partnership of $119.

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 $316. There was no cash tax payment associated with this deferred expense.

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, 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	$730	30 %
Europe (1)	841	836	1 %
Asia Pacific	276	244	13 %
Rest of World	535	424	26 %

$2,603 $2,234 17 %

Net product sales by product are as follows:

	Year Ended December 31,		
	2015	2014	% Change
Net product sales:			
Soliris (1)	$2,591	$2,234	16 %
Strensiq	12	—	N/A
Kanuma	—	—	N/A
	$2,603	$2,234	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 $88 of net product sales from Soliris in France relating to years prior to January 1, 2014. Exclusive of the $88, 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 $88 recognized 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, 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 $118 and $19 related to our foreign currency cash flow hedging program, for the years ended December 31, 2015 and 2014, respectively.

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	174	59
Cost of sales as a percentage of net product sales	9 %	8 %	1 %

We recorded an expense of $24 in the first quarter of 2015 associated with a portion of a single manufacturing campaign at a third party manufacturer for Strensiq. The cost was comprised of raw materials, internal overhead and external production costs. This expense did not impact the clinical supply of inventory or the commercial launch of Strensiq.

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	$ 116	$ 39	34 %
Product development	120	58	62	107 %
Licensing agreements	130	110	20	18 %
Discovery research	44	14	30	214 %
Total external direct expenses	449	298	151	51 %
Payroll and benefits	219	191	28	15 %
Facilities and other costs	41	25	16	64 %
Total other R&D expenses	260	216	44	20 %
Research and development expense	$ 709	$ 514	$ 195	38 %

During the year ended December 31, 2015, we incurred research and development expenses of $709, an increase of $195, or 38%, versus the $514 incurred during the year ended December 31, 2014. The increase was primarily related to the following:

- Increase of $39 in external clinical development expenses related primarily to an expansion of studies for eculizumab, ALXN1007, ALXN1210, and other programs (see table below).
- Increase of $62 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 $20 in licensing agreement expenses related to the achievement of additional license milestones.
- Increase of $30 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 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 $16 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.

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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
External direct expenses		
Eculizumab	$ 78	$ 68
Asfotase alfa	22	27
cPMP	8	8
ALXN1007	14	3
Sebelipase alfa	5	—
ALXN1210	8	1
Other programs	13	3
Unallocated	7	6
	$ 155	$ 116

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.

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	$ 550	$ 389	$ 161
External selling, general and administrative expense	313	241	72
Total selling, general and administrative expense	$ 863	$ 630	$ 233

During the year ended December 31, 2015, we incurred selling, general and administrative expenses of $863, an increase of $233, or 37%, versus the $630 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. 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 $30 related to the acceleration of Alexion stock awards for former Synageva employees.
- Increase in external selling, general and administrative expenses of $72. 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.

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 $117 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]	$ 27	$ —
Integration costs	12	—
	$ 39	$ —

(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 and $20 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 in restructuring expense in the fourth quarter of 2015.

In conjunction with the acquisition and integration of Synageva we recorded restructuring expense of $13 primarily related to employee costs during 2015.

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. 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 $18.

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 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	$ 8	$ —
Interest expense	(48)	(3)	(45)
Foreign currency loss	1	(2)	3
Total other income (expense)	$ (39)	$ 3	$ (42)

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 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 expense of $354 and an effective tax rate of 71.0%, compared to an income tax expense of $215 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 rate compared 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 expense 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 $316. There was no cash tax payment associated with this deferred expense.

The income tax expense 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 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.

Financial Condition, Liquidity and Capital Resources

The following table summarizes the components of our financial condition as of December 31, 2016 and 2015:

	December 31, 2016	December 31, 2015	$ Change
Cash and cash equivalents	$ 966	$ 1,010	$ (44)
Marketable securities	327	375	(48)
Long-term debt (includes current portion)	3,081	3,456	(375)
Current assets	$ 2,578	$ 2,416	$ 162
Current liabilities	823	709	114
Working capital	$ 1,755	$ 1,707	$ 48

The aggregate decrease in cash and cash equivalents and marketable securities was primarily attributable to cash utilized to repurchase shares, principal payments on our term loan, payments of contingent consideration, and purchases of property, plant and equipment. Partially offsetting these decreases was cash generated through operations.

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 derivative contracts. At December 31, 2016, three customers accounted for 47% of the accounts receivable balance, with these individual customers accounting for 14% to 19% of the accounts

receivable balance. At December 31, 2015, three customers accounted for 51% of the accounts receivable balance, with individual customers accounting for 14% to 22% of the accounts receivable balance. For the year ended December 31, 2016, three customers accounted for 37% of our product sales, with these individual customers ranging from 10% to 16% of product sales. 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 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 and interest rate 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, 2016, we have foreign exchange forward contracts with notional amounts totaling $2,389. These outstanding foreign exchange forward contracts had a net fair value of $140, of which $156 is included in other current assets and noncurrent assets and $16 is included in other current liabilities and noncurrent liabilities. As of December 31, 2016, we have interest rate swap contracts with notional amounts totaling $656. These outstanding interest rate swap contracts had a net fair value of $10, which is included in other noncurrent assets. The counterparties to these contracts are large domestic and multinational commercial banks, and we believe the risk of nonperformance is not material.

At December 31, 2016, 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 and equity securities. 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 derivative contracts. Our Level 2 liabilities consist also of derivative 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 $766 that will become payable if and when certain development and commercial milestones are achieved. Of these milestone amounts, $451 and $315 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 $25 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. In the fourth quarter 2016, the criteria were met for the achievement of a milestone payment associated with our acquisition of Enobia Pharma Corp. In connection with this, $60 was paid in December 2016.

Financing Lease Obligations

In November 2012, we entered into a lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. The term of the lease commenced in 2015 and will expire in 2030, with a renewal option of ten years. Although we do not legally own the premises, we are deemed to be the owner of the building due to the substantial improvements directly funded during the construction period based on applicable accounting guidance for build-to-suit leases. Accordingly, the landlord’s costs of constructing the facility during the construction period 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 was completed and the building was placed into service in the first quarter 2016. As of December 31, 2016 and 2015, our total facility lease obligation was $136 and $133, respectively, recorded within other current liabilities and facility lease obligation on our consolidated balance sheets.

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 one of its existing facilities. 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, 2016 and 2015, we recorded a construction-in-process asset of $118 and $19, respectively, and an offsetting facility lease obligation of $107 and $15, respectively, within other current liabilities and facility lease obligation on our consolidated balance sheets.

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 during the first quarter 2015. In addition, as of December 31, 2016 we could be required to pay up to

an additional $249 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 during the first quarter 2015. In addition, as of December 31, 2016 we could be required to pay up to an additional $822 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. 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, 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. 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 and to pay up to an additional $120 with respect to a rare disease product and $400 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 $415 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 $51.

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 term loan facility and a $500 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 in the form of letters of credit and borrowings on same-day notice, referred to as swingline loans, of up to $25. Borrowings can be used for working capital requirements, acquisitions and other general corporate purposes.

Under the Credit Agreement, we are required to deliver to the administrative agent, not later than 50 days after each fiscal quarter, our quarterly financial statements, and within 5 days thereafter, a compliance certificate. In November 2016, we obtained a waiver from the necessary lenders for this requirement and the due date for delivery of the third quarter 2016 financial statements and compliance certificate was extended to January 18, 2017. The posting of the Third Quarter report on Form 10-Q on our website on January 4, 2017 satisfied the financial statement covenant, and we simultaneously delivered the required compliance certificate, as required by the lenders.

In connection with the acquisition of Synageva in June 2015, we borrowed $3,500 under the term loan facility and $200 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, 2016, we had $3,081 outstanding on the term loan. As of December 31, 2016, we had open letters of credit of $15, and our borrowing availability under the revolving facility was $485.

Manufacturing Obligations

We have supply agreements with Lonza through 2028 relating to the manufacture of Soliris and Strensiq, 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 $1,148 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 $27 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 $1,462 at December 31, 2016. 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, 2016, approximately $445 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 U.S. 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 to acquire shares with an aggregate value of up to $1,000 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 3 and 2 shares of our common stock at a cost of $430 and $328 during the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, there is a total of $325 remaining for repurchases under the program. 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.

In February 2017, our Board of Directors increased the authorization to acquire shares with an aggregate value of up to $1,000 for future purchases under the repurchase program, which superseded all prior repurchase programs. . As of February 16, 2017, there is a total of $1,000 remaining for repurchases under the repurchase program.

Cash Flows

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

	Year Ended December 31,		
	2016	2015	$ Change
Net cash provided by operating activities	$ 1,086	$ 675	$411
Net cash used in investing activities	(287)	(3,585)	3,298
Net cash provided by financing activities	(836)	2,985	(3,821)
Effect of exchange rate changes on cash	(7)	(9)	2
Net change in cash and cash equivalents	$ (44)	$ 66	$(110)

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Operating Activities

Cash flows provided by operations in 2016 were $1,086 compared to $675 in 2015. The increase was primarily due to an increase in gross margin on product sales of $454 resulting primarily from an increase in global demand for Soliris and the launch of Strensiq and Kanuma, as well as a decrease in cash outflows relates to our licensing arrangements of $120. The increase in gross margin was offset by an increase in clinical development costs, interest expense and selling, general and administrative expenses during 2016.

In 2017, 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 $51 related to milestone payments on our license agreements.

Investing Activities

Cash used for investing activities in 2016 was $287 compared to $3,585 in 2015. The decrease in cash used was primarily due to the payment of $3,939 in 2015 related to the Synageva acquisition and net cash flows related to the purchase and maturities of available-for-sale securities of $51 in 2016 compared to $640 in 2015.

We expect to continue to have significant spending on property, plant and equipment in 2017 related to the construction of our new biologics manufacturing facilities in Ireland.

Financing Activities

Cash flows (used in) provided by financing activities in 2016 were $(836) compared to $2,985 in 2015. The decrease was primarily due to the following:

- Borrowing of $3,655, net of issuance costs, under our credit facility, in connection with the acquisition of Synageva in June 2015.
- Principal payments against the credit facility of $375 in 2016, compared to $301 in 2015.
- Repurchased of common stock of $430 in 2016, compared to $328 in 2015.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2016 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	$3,081	$ —	$ 325	$ 2,756	$ —
Interest expense [1]	265	79	151	35	—
Facility lease obligation [2]	225	16	31	32	146
Operating leases	90	21	32	13	24
Total contractual obligations	$3,661	$ 116	$ 539	$ 2,836	$ 170
Commercial commitments:					
Clinical and manufacturing development [3]	$1,175	$ 227	$ 356	$ 200	$ 392
Total commercial commitments	$1,175	$ 227	$ 356	$ 200	$ 392

[1] Interest on variable rate debt calculated based on interest rates at December 31, 2016. Interest that is fixed, associated to our interest rate swaps, is calculated based on the fixed interest swap rate at December 31, 2016

[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 do not legally own the premises, we were 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, 2016.

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 liability for unrecognized tax benefits related to various federal, state and foreign income tax matters of $139 at December 31, 2016 was not included within the table above. The timing of the settlement of these amounts was not reasonably estimable at December 31, 2016. We do not expect payment of amounts related to the unrecognized tax benefits within the next twelve months.

Contingent payments related to business acquisitions completed in prior years or license agreements are not included within the table above, as the timing of payment for these amounts was not reasonably estimable at December 31, 2016. Contingent payments associated with these business combinations total up to $766 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 $25 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 $51.

Future obligations related to our defined benefit plans are not included within the table above, as the timing and amounts of these payments was not reasonably estimable as of December 31, 2016. The total unfunded obligation on our defined benefit plans as of December 31, 2016 was $20. Our unfunded obligation can be impacted by changes in the laws and regulations, interest rates, investment returns, and other variables.

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 term loan facility and a $500 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 in the form of letters of credit and borrowings on same-day notice, referred to as swingline loans, of up to $25. 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 space in the U.S. 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 millions, except percentages)

Interest Rate Risk

As of December 31, 2016, 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) and $4, 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.

To achieve a desired mix of floating and fixed interest rates on our term loan, we entered into two interest rate swap agreements in June 2016 that qualified for and are designated as cash flow hedges. The first agreement had a notional amount of $3,281 and was effective from June 30, 2016 through December 30, 2016. This agreement hedged the contractual floating interest rate of our term loan. As a result of this agreement, the interest rate for our term loan was fixed at 0.535%, plus the borrowing spread, until December 30, 2016. The second agreement has a notional amount of $656 and is effective December 31, 2016 through December 31, 2019. The second agreement converts the floating rate on a portion of our term loan to a fixed rate of 0.98%, plus a borrowing spread, from December 31, 2016 through December 2019. The impact of a hypothetical increase or decrease in interest rates on the fair value of our interest rate swap contract would be offset by a change in the value of the underlying liability. If interest rates were to increase or decrease by 1%, annual interest expense, beginning in 2017, would increase or decrease by $24, based on the unhedged portion of our outstanding term loan.

Foreign Exchange Market Risk

Our operations include activities in many countries outside the U.S., 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 51% of our product sales were denominated in foreign currencies during 2016, 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 approximately 90 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, 2016 and 2015, we held foreign exchange forward contracts with notional amounts totaling $2,389 and $2,536, respectively. The decrease 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, 2016 and 2015, our outstanding foreign exchange forward contracts had a net fair value of $140 and $148, respectively.

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, 2016, 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 $162 at December 31, 2016. 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. The majority of our receivables are due from wholesale distributors, public hospitals and other government entities. We monitor the financial performance and creditworthiness of our large customers so that we can properly assess and respond to changes in their credit profile. We continue to monitor these conditions, including the volatility associated with international economies and the relevant financial markets, and assess their possible impact on our business. Although collection of our accounts receivables from certain countries may extend beyond our standard credit terms, we do not expect any such delays to have a material impact on our financial condition or results of operations

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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

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

None.

Item 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures.

We have established disclosure controls and procedures to provide reasonable assurance that information is accumulated and communicated to our management, including our principal executive officer and principal 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 Securities Exchange Act of 1934, as amended (Exchange Act) is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms.

Our management, with the participation of our Interim 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 Exchange Act, as of December 31, 2016. Based on this evaluation, our Interim Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2016, due to the material weakness in internal control over financial reporting that was previously disclosed in our Form 10-Q filed on January 4, 2017 and described below, which was not remediated as of December 31, 2016.

Management’s Report on Internal Control over Financial Reporting

Management of the Company 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, 2016 based on the framework in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

We did not maintain an effective control environment as our senior management failed to set an appropriate Tone at the Top. Specifically, senior management failed to reinforce the need for compliance with the Company's policies and procedures, which resulted in inappropriate business conduct. This control deficiency did not result in a misstatement to the Company's consolidated financial statements. However, this control deficiency could result in a misstatement to disclosures that would result in a material misstatement to our annual or interim consolidated financial statements that would not be prevented or detected. Accordingly, our management has determined that this control deficiency constitutes a material weakness.

The effectiveness of our internal control over financial reporting as of December 31, 2016 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, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Remediation Plan and Activities

Management is engaged in remedial activities to address the material weakness described above. The remedial activities include the following:

•The Board of Directors has and will reinforce to key leadership the importance of setting appropriate Tone at the Top and of appropriate behavior with respect to the Company's commitment to ethics and compliance programs in the performance of the Company's mission, as well as adherence to the Company's internal control over financial reporting framework;

•Members of senior management, with the participation and input of the Audit and Finance Committee and the Board of Directors, have and will increase communication with, and training of employees regarding:

Our commitment to ethical standards and the integrity of our business practices;

Requirements for compliance with applicable laws, our Code of Ethics and Business Conduct and other Company policies; and

Availability of and processes for reporting suspected violations of law or our Code of Ethics and Business Conduct.

•Revised financial reporting processes to ensure that all employees annually confirm compliance with the Company's Code of Ethics and Business Conduct and that deviations are identified and timely remediated; and

•The Board of Directors, together with management, is evaluating certain Company practices and procedures, including those related to compensation, planning and forecasting, as well as the Company's organizational structure, to determine which practices and procedures should be modified or terminated, and management is assessing roles and responsibilities to enhance controls and compliance.

In addition, on December 11, 2016, our Board of Directors oversaw a change in the Company's senior leadership when it appointed a new Interim Chief Executive Officer and a new Chief Financial Officer following the departures of our former Chief Executive Officer and Chief Financial Officer, as well as other personnel changes.

The Company is committed to maintaining a strong internal control environment. Management believes the foregoing efforts will effectively remediate the material weakness. We will provide further updates to the Company's Board on an ongoing basis with measurable milestones and responsibilities regarding the progress of our remediation efforts.

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/corporate-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	Amendment to the April 1, 2015,Consulting Agreement by and between Alexion Pharmaceuticals, Inc. and Dr. Leonard Bell, dated September 21, 2016.(26)
10.3	Letter Agreement, by and between Alexion Pharmaceuticals, Inc. and Dr. Leonard Bell, dated April 1, 2015.(9)
10.4	Confidential Separation Agreement and Release by and between Vikas Sinha and Alexion Pharmaceuticals, Inc. dated December 11, 2016.
10.5	

	Confidential Release and Separation Agreement by and between David Hallal and Alexion Pharmaceuticals, Inc. dated December 11, 2016.
10.6	Employment Agreement, dated as of December 11, 2016, by and between David Brennan and Alexion Pharmaceuticals, Inc.
10.7	Employment Agreement, dated as of December 12, 2016, by and between David J. Anderson and Alexion Pharmaceuticals, Inc.
10.8	Employment Agreement, dated February 26, 2016, by and between Alexion Pharmaceuticals, Inc. and Clare Carmichael.(27)**
10.9	Employment Agreement, dated February 26, 2016, by and between Alexion Pharmaceuticals, Inc. and Martin Mackay.(27)**
10.10	Employment Agreement, dated February 26, 2016, by and between Alexion Pharmaceuticals, Inc. and John Moriarty.(27)**
10.11	Form of Employment Agreement (Senior Vice Presidents).(10)**
10.12	Form of Amendment No. 1 to Employment Agreements (Senior Vice Presidents). (11)**

10.13 Form of Indemnification Agreement for Officers and Directors. (12)

10.14 Lease, dated November 15, 2012, between Alexion and WE Route 34, LLC.(14)

10.15 Alexion's 2000 Stock Option Plan, as amended.(15)**

10.16 Alexion's 1992 Outside Directors Stock Option Plan, as amended.(16)**

10.17 Alexion's Amended and Restated 2004 Incentive Plan.(17)**

10.18 License Agreement dated March 27, 1996 between Alexion and Medical Research Council.(18)+

10.19 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)*

10.20 Form of Stock Option Agreement for Directors.(20)**

10.21 Form of Stock Option Agreement for Executive Officers (Form A).(21)**

10.22 Form of Stock Option Agreement for Executive Officers (Form B).(21)**

10.23 Form of Restricted Stock Award Agreement for Executive Officers (Form A).(22)**

10.24 Form of Stock Option Agreement (Incentive Stock Options).(19)

10.25 Form of Stock Option Agreement (Nonqualified Stock Options).(19)

10.26 Form of Restricted Stock Award Agreement.(19)

10.27 Form of Restricted Stock Unit Award Agreement.(23)

10.28 Form of Stock Option Agreement for Participants in France.(19)**

10.29 Form of Restricted Stock Unit Agreement for Participants in France.(19)**

10.30 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, 2016 formatted in eXtensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Operations, (ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Changes in Stockholders' Equity, (v) the Consolidated Statements of Cash Flows and (vi) related notes, tagged as blocks of text.

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(1) Incorporated by reference to our Report on Form 8-K, filed on February 3, 2011.
(2) Incorporated by reference to our Report on Form 8-K, filed on January 4, 2012.
(3) Incorporated by reference to our Report on Form 8-K, filed on February 7, 2012.
(4) Incorporated by reference to our 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.
(26) Incorporated by reference to our report on Form 8-K, filed on September 22, 2016.
(27) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016.

+ 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.

Item 16 Form 10-K Summary
Not applicable.

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 R. Brennan
David R. Brennan
Interim Chief Executive Officer (principal executive officer)

Dated: February 16, 2017

By: /s/ David J. Anderson
David J. Anderson, Executive Vice President and Chief Financial Officer
(principal financial officer)
Dated: February 16, 2017

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 R. Brennan David R. Brennan	Interim Chief Executive Officer and Director (principal executive officer)	February 16, 2017
/s/ David J. Anderson David J. Anderson	Executive Vice President and Chief Financial Officer (principal financial officer)	February 16, 2017
/s/ Daniel A. Bazarko Daniel A. Bazarko, C.P.A.	Senior Vice President and Chief Accounting Officer (principal accounting officer)	February 16, 2017
/s/ Leonard Bell Leonard Bell, M.D.	Chairman	February 16, 2017
/s/ Felix J. Baker Felix J. Baker, Ph.D.	Director	February 16, 2017
/s/ M. Michele Burns M. Michele Burns	Director	February 16, 2017
/s/ Christopher J. Coughlin Christopher J. Coughlin	Director	February 16, 2017
/s/ John T. Mollen	Director	February 16, 2017

John T. Mollen		
/s/ R. Douglas Norby R. Douglas Norby	Director	February 16, 2017
/s/ Alvin S. Parven Alvin S. Parven	Director	February 16, 2017
/s/ Andreas Rummelt Andreas Rummelt, Ph.D.	Director	February 16, 2017
/s/ Ann M. Veneman Ann M. Veneman	Director	February 16, 2017

Alexion Pharmaceuticals, Inc.
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For the Years Ended December 31, 2016, 2015 and 2014

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Alexion Pharmaceuticals, Inc.

In our opinion, the 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 as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) because a material weakness in internal control over financial reporting existed as of that date related to not maintaining an effective control environment as senior management failed to set an appropriate tone at the top. Specifically, senior management failed to reinforce the need for compliance with the Company's policies and procedures, which resulted in inappropriate business conduct. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness referred to above is described in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. We considered this material weakness in determining the nature, timing, and extent of audit tests applied in our audit of the 2016 consolidated financial statements, and our opinion regarding the effectiveness of the Company's internal control over financial reporting does not affect our opinion on those consolidated financial statements. 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 referred to above. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it accounts for the classification of debt issuance costs and the manner in which it accounts for certain elements of its employee share-based payments in 2016.

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

a material effect on the financial statements.

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

/s/ PricewaterhouseCoopers LLP

Hartford, Connecticut
February 16, 2017

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

	December 31,	
	2016	2015
Assets		
Current Assets:		
Cash and cash equivalents	$966	$1,010
Marketable securities	327	375
Trade accounts receivable, net	650	533
Inventories	375	290
Prepaid expenses and other current assets	260	208
Total current assets	2,578	2,416
Property, plant and equipment, net	1,036	697
Intangible assets, net	4,303	4,708
Goodwill	5,037	5,048
Other assets	299	228
Total assets	$13,253	$13,097
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$64	$57
Accrued expenses	508	403
Deferred revenue	37	21
Current portion of long-term debt	167	166
Current portion of contingent consideration	24	56
Other current liabilities	23	6
Total current liabilities	823	709
Long-term debt, less current portion	2,888	3,254
Contingent consideration	129	121
Facility lease obligation	233	151
Deferred tax liabilities	396	529
Other liabilities	90	74
Total liabilities	4,559	4,838
Commitments and contingencies (Note 10)		
Stockholders' Equity:		
Common stock, $.0001 par value; 290 shares authorized; 232 and 230 shares issued at December 31, 2016 and 2015, respectively	—	—
Additional paid-in capital	7,957	7,727
Treasury stock, at cost, 8 and 5 shares at December 31, 2016 and 2015, respectively	(1,141)	(711)
Accumulated other comprehensive income	60	62
Retained earnings	1,818	1,181
Total stockholders' equity	8,694	8,259
Total liabilities and stockholders' equity	$13,253	$13,097

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

Alexion Pharmaceuticals, Inc.
Consolidated Statements of Operations
(amounts in millions, except per share amounts)

	Year Ended December 31,		
	2016	2015	2014
Net product sales	$3,082	$2,603	$2,234
Other revenue	2	1	—
Total revenues	3,084	2,604	2,234
Cost of sales	258	233	174
Operating expenses:			
Research and development	757	709	514
Selling, general and administrative	954	863	630
Amortization of purchased intangible assets	322	117	—
Change in fair value of contingent consideration	36	64	20
Acquisition-related costs	2	39	—
Restructuring expenses	3	42	15
Impairment of intangible assets	85	—	12
Total operating expenses	2,159	1,834	1,191
Operating income	667	537	869
Other income and expense:			
Investment income	11	8	8
Interest expense	(97)	(48)	(3)
Foreign currency gain (loss)	(5)	1	(2)
Income before income taxes	576	498	872
Income tax expense	177	354	215
Net income	$399	$144	$657
Earnings per common share			
Basic	$1.78	$0.68	$3.32
Diluted	$1.76	$0.67	$3.26
Shares used in computing earnings per common share			
Basic	224	213	198
Diluted	227	216	202

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

Alexion Pharmaceuticals, Inc.
Consolidated Statements of Comprehensive Income
(amounts in millions)

	Year Ended December 31,		
	2016	2015	2014
Net income	$ 399	$ 144	$ 657
Other comprehensive (loss) income, net of tax:			
Foreign currency translation	(4)	(6)	(6)
Unrealized losses on marketable securities	—	(1)	—
Unrealized gains (losses) on pension obligation	3	7	(5)
Unrealized (losses) gains on hedging activities, net of tax of $0, $6 and $45, respectively	(1)	6	91
Other comprehensive (loss) income, net of tax	(2)	6	80
Comprehensive income	$ 397	$ 150	$ 737

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

Alexion Pharmaceuticals, Inc.
Consolidated Statements of Changes in Stockholders' Equity
(amounts in millions)

	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, 2013	198	$ —	$ 2,107	1	$ (80)	$ (24)	$ 380	$ 2,383
Repurchase of common stock	—	—	—	2	(303)	—	—	(303)
Issuance of common stock from exercise of options	3	—	114	—	—	—	—	114
Issuance of restricted common stock	1	—	—	—	—	—	—	—
Excess tax benefit from stock options	—	—	251	—	—	—	—	251
Share-based compensation expense	—	—	121	—	—	—	—	121
Net income	—	—	—	—	—	—	657	657
Other comprehensive income	—	—	—	—	—	80	—	80
Balances, December 31, 2014	202	$ —	$ 2,593	3	$ (383)	$ 56	$ 1,037	$ 3,303
Repurchase of common stock	—	—	—	2	(328)	—	—	(328)
Issuance of common stock, net of issuance costs of $4	26	—	4,914	—	—	—	—	4,914
Issuance of common stock under stock option and stock purchase plans	1	—	82	—	—	—	—	82
Issuance of restricted common stock	1	—	—	—	—	—	—	—
Excess tax benefit from stock options	—	—	(90)	—	—	—	—	(90)
Share-based compensation expense	—	—	228	—	—	—	—	228
Net income	—	—	—	—	—	—	144	144
Other comprehensive income	—	—	—	—	—	6	—	6
Balances, December 31, 2015	230	$ —	$ 7,727	5	$ (711)	$ 62	$ 1,181	$ 8,259
Repurchase of common stock	—	—	—	3	(430)	—	—	(430)
Issuance of common stock under stock option and stock purchase plans	1	—	37	—	—	—	—	37
Issuance of restricted common stock	1	—	—	—	—	—	—	—
Excess tax benefit from stock options	—	—	—	—	—	—	—	—
Share-based compensation expense	—	—	193	—	—	—	—	193
Net income	—	—	—	—	—	—	399	399
Other comprehensive loss	—	—	—	—	—	(2)	—	(2)
Adoption of new share-based compensation guidance	—	—	—	—	—	—	238	238
Balances, December 31, 2016	$ 232	$ —	$ 7,957	$ 8	$ (1,141)	$ 60	$ 1,818	$ 8,694

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

Alexion Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(amounts in millions)

	Year Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net income	$399	$144	$657
Adjustments to reconcile net income to net cash flows from operating activities:			
Depreciation and amortization	396	167	47
Impairment of intangible assets	85	—	12
Change in fair value of contingent consideration	36	64	20
Share-based compensation expense	192	227	114
Deferred taxes	104	395	(154)
Change in excess tax benefit from stock options	—	90	(251)
Other	10	3	37
Changes in operating assets and liabilities, excluding the effect of acquisitions:			
Accounts receivable	(122)	(116)	(28)
Inventories	(84)	(88)	(67)
Prepaid expenses and other assets	(97)	(57)	(18)
Accounts payable, accrued expenses and other liabilities	150	(116)	265
Deferred revenue	17	(38)	6
Net cash provided by operating activities	1,086	675	640
Cash flows from investing activities:			
Purchases of available-for-sale securities	(667)	(520)	(664)
Proceeds from maturity or sale of available-for-sale securities	718	1,160	620
Purchases of trading securities	(8)	(15)	(3)
Proceeds from sale of trading securities	4	10	—
Purchases of property, plant and equipment	(333)	(286)	(137)
Purchases of other investments	—	—	(38)
Payments for acquisitions of businesses, net of cash acquired	—	(3,939)	—
Other	(1)	5	(1)
Net cash used in investing activities	(287)	(3,585)	(223)
Cash flows from financing activities:			
Debt issuance costs	—	(45)	—
Proceeds from revolving credit facility	—	200	—
Payments on revolving credit facility	—	(200)	—
Proceeds from term loan	—	3,500	—
Payments on term loan	(375)	(101)	(55)
Equity issuance costs for shares issued in connection with acquisition of business	—	(4)	—
Change in excess tax benefit from stock options	—	(90)	251
Repurchase of common stock	(430)	(328)	(303)
Net proceeds from issuance of stock under share-based compensation arrangements	37	82	114
Payment of contingent consideration	(60)	(50)	—
Proceeds from development-related grants	—	26	—
Other	(8)	(5)	—
Net cash (used in) provided by financing activities	(836)	2,985	7
Effect of exchange rate changes on cash	(7)	(9)	(10)
Net change in cash and cash equivalents	(44)	66	414
Cash and cash equivalents at beginning of period	1,010	944	530

Cash and cash equivalents at end of period	$966	$1,010	$944

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

Alexion Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(amounts in millions)

	Year Ended December 31,		
	2016	2015	2014
Supplemental cash flow disclosures:			
Cash paid for interest (net of amounts capitalized)	$80	$41	$ 2
Cash paid for income taxes	$38	$123	$ 91
Supplemental cash flow disclosures from investing and financing activities:			
Common stock issued in acquisition of business	$—	$4,918	$ —
Capitalization of construction costs related to facility lease obligations	$103	$41	$ 75
Accrued expenses for purchases of property, plant and equipment	$23	$30	$ 17

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, 2016, 2015 and 2014
(amounts in millions 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 disorders resulting from chronic uncontrolled activation of the complement component of the immune system.

In our metabolic franchise, we commercialize 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 an ultra-rare genetic 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 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 devastating and ultra-rare disorders.

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 patients with devastating and ultra-rare diseases.

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 U.S., 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;

Alexion Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
For the Years ended December 31, 2016, 2015 and 2014
(amounts in millions except per share amounts)

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

Foreign Currency Translation

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

Cash and Cash Equivalents

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

Fair Value of Financial Instruments

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

Marketable Securities

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

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

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

Accounts Receivable

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

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customers extend beyond normal payment terms, we seek to collect interest. We record interest on customer receivables as interest income when collected. For non-interest bearing receivables with an estimated payment beyond one year, we discount the accounts receivable to present value at the date of sale, with a corresponding adjustment to revenue. Subsequent adjustments for further declines in credit rating are recorded as bad debt expense as a component of selling, general and administrative expense. We also use judgments as to our ability to collect outstanding receivables and provide allowances for the portion of receivables if and when collection becomes doubtful, and we also assess on an ongoing basis whether collectibility is reasonably assured at the time of sale.

Concentration of Credit Risk

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

At December 31, 2016, three customers accounted for 47% of the accounts receivable balance, with these individual customers ranging from 14% to 19% of the accounts receivable balance. 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. For the year ended December 31, 2016, three customers accounted for 37% of our product sales, with these individual customers ranging from 10% to 16% of our product sales. 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. No other customers accounted for more than 10% of accounts receivable or net product sales. David Anderson, Alexion’s Executive Vice President and Chief Financial Officer since December 2016, has been a member of the Board of Directors of Cardinal Health, Inc. since April 2014. Cardinal Health, Inc. and its affiliates provide product distribution and other services to Alexion in the United States.

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 on a standard cost basis, which approximates average costs.

The components of inventory are as follows:

	December 31,	
	2016	2015
Raw materials	$ 17	$ 18
Work-in-process	143	180
Finished goods	215	92
	$ 375	$ 290

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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. We had no inventory capitalized for products awaiting regulatory approval as of December 31, 2016 and 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 or interest

expense, based on the nature of the derivative instrument. 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.

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.

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 healthcare 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.

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Our customers are primarily comprised of distributors, pharmacies, hospitals, hospital buying groups, and other healthcare 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, financial strength of distributors and our ability to estimate returns. 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 U.S. and other programs outside the U.S., 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.

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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 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) is 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 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, 2016, 2015 and 2014:

	Year Ended December 31,		
	2016	2015	2014
Net income used for basic and diluted calculation	$399	$144	$657
Shares used in computing earnings per common share—basic	224	213	198
Weighted-average effect of dilutive securities:			
Stock awards	3	3	4
Shares used in computing earnings per common share—diluted	227	216	202
Earnings per common share:			
Basic	$1.78	$0.68	$3.32
Diluted	$1.76	$0.67	$3.26

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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, 2016, 2015 and 2014 were 4, 2, and 1 shares of common stock, respectively, because their effect is anti-dilutive.

Income Taxes

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

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

Comprehensive Income

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

Other Investments

We invest in companies with securities that are not publicly traded and where fair value is not readily available. Other investments include an investment in the preferred stock of the non-public entity Moderna Therapeutics, Inc. During 2014, we purchased $38 of preferred equity of Moderna. 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, 2016.

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 currently anticipate adopting the standard using the modified retrospective method. We do not expect the implementation of this new standard to have a material impact 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. We adopted the provisions of this standard in the first quarter

2016 and reclassified $9 of deferred financing costs from prepaid expenses and other current assets to the current portion of long-term debt and $27 from other assets to long-term debt, less current portion in our consolidated balance sheets as of December 31, 2015.

In April 2015, the FASB issued a new standard clarifying the accounting for a customer's fees paid in a cloud computing arrangement. Under this standard, if a cloud computing arrangement includes a software license, the customer would account for the software license consistent with other software licenses. If a cloud computing arrangement does not include a software license, the customer would account for the arrangement as a service contract. We adopted the provisions of this standard in the first quarter 2016. The adoption did not have a material effect on our financial condition or results of operations.

In February 2016, the FASB issued a new standard requiring that the rights and obligations arising from leases be recognized on the balance sheet by recording a right-of-use asset and corresponding lease liability. The new standard also requires qualitative and quantitative disclosures to understand the amount, timing, and uncertainty of cash flows arising from leases, as well as significant management estimates utilized. The standard is effective for interim and annual periods beginning after December 15, 2018 and requires a modified retrospective adoption. We are currently assessing the impact of this standard on our financial condition and results of operations.

In March 2016, the FASB issued a new standard intended to simplify certain aspects of the accounting for employee share-based payments. We elected to early adopt this standard during the third quarter of 2016. One aspect of the standard requires an entity to recognize all excess tax benefits and deficiencies associated with stock-based compensation as a reduction or increase to tax expense in the income statement. Previously, such amounts were recognized in additional paid-in capital. This aspect of the new standard was adopted prospectively, and accordingly we recorded tax benefits of $10, within income tax expense for the year ended December 31, 2016. The amendments require recognition of excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. As a result, $238 associated with previously unrecognized excess tax benefits was recorded as a deferred tax asset and an increase in retained earnings as of the beginning of 2016. Furthermore, the amendment requires that excess tax benefits be classified as an operating activity in the statement of cash flows instead of a financing activity. We elected to adopt this provision of the standard prospectively and thus, prior periods have not been adjusted. We have also elected to continue to estimate the impact of forfeitures when determining the amount of compensation cost to be recognized each period rather than account for forfeitures as they occur.

In October 2016 the FASB issued a new standard that eliminates the prohibition of immediate recognition of current and deferred income tax impacts for an intra-entity asset transfer other than inventory. Under the new standard, entities should recognize the income tax consequences on an intra-entity transfer of an asset other than inventory when the transfer occurs. This new standard will be effective for interim periods beginning after December 15, 2017 and requires a modified retrospective adoption through a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. We are currently assessing the impact of this standard on our financial condition and results of operations.

2. Acquisitions

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 furthered our objective to develop and commercialize life-transforming therapies to an increasing number of patients

with devastating and rare diseases. Synageva's lead product candidate was Kanuma, an enzyme replacement therapy for patients suffering with LAL-D, a life-threatening, ultra-rare disease for which there were no approved treatments at the closing of the business combination.

We acquired all of the outstanding shares of common stock of Synageva for $4,565 in cash and 26 shares of common stock. 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	$4,918
Cash consideration	4,565
Total purchase price	$9,483

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

Cash	$	626
Inventory	24	
In-process research and development (IPR&D)	4,236	
Deferred tax liabilities, net	(160)	
Other assets and liabilities	(26)	
Net assets acquired	4,700	
Goodwill	4,783	
Total purchase price	$	9,483

The fair value of the assets acquired and liabilities assumed were initially based upon preliminary calculations, and our estimates and assumptions were subject to change as we obtained additional information for our estimates during the measurement period (up to one year from the acquisition date). During the year ended December 31, 2016, we recorded fair value adjustments of $11 primarily due to tax related items.

We acquired $24 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 Kanuma. The estimated fair value of IPR&D assets of $4,236 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%, 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 $160. This amount was primarily comprised of $603 of deferred tax liabilities related to the IPR&D and inventory acquired, offset by $443 of deferred tax assets related to net operating loss carryforwards (NOLs), tax credits, and other temporary differences, which we expect to utilize.

For the year ended December 31, 2015, we recorded $96 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. 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 would have had we completed the transaction on January 1, 2014.

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	Year Ended December 31, 2015	Year Ended December 31, 2014
Pro forma revenues	$ 2,606	$ 2,240
Pro forma net income	21	261
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 and $127, 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 $53 and $62, 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, 2016, 2015 and 2014 include the following:

	Year Ended December 31,		
	2016	2015	2014
Transaction costs [1]	$—	$ 27	$ —
Integration costs	2	12	—
	$ 2	$ 39	$ —

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

The acquisition of Synageva resulted in $13 of restructuring related charges for the year ended December 31, 2015. Synageva restructuring related charges were not material for the year ended December 31, 2016. See Note 17 for additional details.

3. Property, Plant and Equipment, Net

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

	December 31, 2016	December 31, 2015
Land	$ 10	$ 9
Buildings and improvements	450	252
Machinery and laboratory equipment	126	92
Computer hardware and software	123	84

Furniture and office equipment	25	16
Construction-in-progress	495	420
	1,229	873
Less: Accumulated depreciation and amortization	(193)	(176)
	$ 1,036	$ 697

Included in construction-in-progress at December 31, 2015 was $227 of costs associated with the construction of our facility in New Haven, Connecticut. This facility was placed into service in 2016. Additionally, there were costs of $118 and $19 as of December 31, 2016 and 2015, included within construction-in-process 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

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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 the facility 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 and tax credits of up to $25. 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 ten years; (ii) satisfying minimum employment obligations; and (iii) minimum capital spending requirements. In the third quarter 2015, we received $26 for the forgivable loan and grants. In 2016, we satisfied the second and third criteria. The proceeds reduce the costs of our assets associated with the project. As of December 31, 2016, 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 $64, $44 and $35 for the years ended December 31, 2016, 2015 and 2014, respectively.

At December 31, 2016 and 2015, computer software costs included in property, plant and equipment were $37 and $20, respectively. Depreciation and amortization expense for capitalized computer software costs was $12, $10 and $7 for the years ended December 31, 2016, 2015 and 2014, respectively.

4. Intangible Assets and Goodwill

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

		December 31, 2016			December 31, 2015		
	Estimated Life (years)	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Licenses	6-8	$29	$ (29)	$—	$29	$ (29)	$—
Patents	7	11	(11)	—	11	(11)	—
Purchased technology	6-16	4,711	(439)	4,272	4,709	(117)	4,592
Acquired IPR&D	Indefinite	31	—	31	116	—	116
Total		$4,782	$ (479)	$4,303	$4,865	$ (157)	$4,708
Goodwill	Indefinite	$5,040	$ (3)	$5,037	$5,051	$ (3)	$5,048

Amortization expense was $322, $117 and $11 for the years ended December 31, 2016, 2015 and 2014, respectively. Assuming no changes in the gross cost basis of intangible assets, the total estimated amortization expense for finite-lived intangible assets is $320 for each of the years ending December 31, 2017 through December 31, 2021.

During the fourth quarter 2016, we reviewed SBC-103, an early stage clinical indefinite-lived intangible asset related to the Synageva acquisition as part of our annual impairment testing. The fair value of this IPR&D asset was determined using the income approach and included significant unobservable (Level 3) inputs. These unobservable inputs included, among other things, expected development, regulatory and commercial time lines, risk-adjusted forecasted 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 cost of capital of 12% to be applied in calculating the present value of future cash flows. Based on our strategic portfolio evaluation, increases in development, regulatory and commercial time lines and updated cash flows, the estimated value that can be obtained for this asset from a market participant in an arm’s length transaction is $31, which was lower than the carrying amount of the asset. As a result, in the fourth quarter 2016, we recognized an impairment charge of $85 to write-down this asset to fair value. The impairment was recorded in operating expenses in our consolidated statement of operations for

the year ended December 31, 2016. In February 2017, the Board of Directors of Alexion made the decision to reduce our investment in SBC-103. The current Phase I/II clinical trial will not be expanded and no new patients will be added to the trial. Patients currently enrolled in the trial will continue to receive therapy. We will reassess the value of this asset on a go forward basis for indicators of impairment.

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

Balance at December 31, 2014	$254
Goodwill resulting from the Synageva acquisition	4,794
Balance at December 31, 2015	$5,048
Change in goodwill associated with prior acquisition	$(11)
Balance at December 31, 2016	$5,037

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, 2016 and December 31, 2015 were as follows:

	December 31, 2016			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Commercial paper	$114	$ —	$ —	$ 114
Corporate bonds	124	—	(1)	123
Municipal bonds	91	—	—	91
Other government related obligations:				
U.S.	28	—	—	28
Foreign	73	—	(1)	72
Bank certificates of deposit	5	—	—	5
Total available-for-sale debt securities	$435	$ —	$ (2)	$ 433
Equity securities	—	1	—	1
Total available-for-sale securities	$435	$ 1	$ (2)	$ 434

	December 31, 2015			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Commercial paper	$254	$ —	$ —	$ 254
Corporate bonds	133	—	—	133
Municipal bonds	87	—	—	87
Other government related obligations:				
U.S.	25	—	—	25
Foreign	164	—	(1)	163
Bank certificates of deposit	27	—	—	27
Total available-for-sale securities	$690	$ —	$ (1)	$ 689

The aggregate fair value of available-for-sale securities in an unrealized loss position as of December 31, 2016 and December 31, 2015 was $265 and $294. Investments that have been in a continuous unrealized loss position for more than 12 months were not material. As of December 31, 2016 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, 2016	December 31, 2015
Cash and cash equivalents	$ 120	$ 323
Marketable securities	314	366
	$ 434	$ 689

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The fair values of available-for-sale debt securities at December 31, 2016, by contractual maturity, are summarized as follows:

	December 31, 2016
Due in one year or less	$ 236
Due after one year through three years	197
Due after three years through five years	—
	$ 433

As of December 31, 2016 and December 31, 2015, the fair value of our trading securities was $13 and $9.
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, 2016 and 2015.

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 are also exposed to fluctuations in interest rates on our outstanding term loan debt. We manage these exposures 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 these hedges 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, 2016, we had open foreign exchange forward contracts with notional amounts totaling $1,742 that qualified for hedge accounting.
To achieve a desired mix of floating and fixed interest rates on our term loan, we entered into two interest rate swap agreements in June 2016 that qualified for and are designated as cash flow hedges. The first agreement had a notional amount of $3,281 and was effective from June 30, 2016 through December 30, 2016. This agreement hedged the contractual floating interest rate of our term loan. As a result of this agreement, the interest rate for our term loan was fixed at 0.535%, plus the borrowing spread, until December 30, 2016. The second agreement has a notional amount of $656 and is effective December 31, 2016 through December 31, 2019. The second agreement converts the floating rate on a portion of our term loan to a fixed rate of 0.98%, plus a borrowing spread, from December 31, 2016 through December 2019. In the first quarter of 2017, we entered into an additional interest rate swap agreement with a notional amount of $300 that is effective from January 31, 2017 through December 31, 2018 that converts the floating rate on a portion of our term loan to a fixed rate of 1.29%, plus a borrowing spread, from January 2017 through December 2018.
The impact on accumulated other comprehensive income (AOCI) and earnings from derivative instruments that qualified as cash flow hedges, for the years ended December 31, 2016 and 2015 were as follows:

	Year Ended December 31,

Foreign Exchange Contracts:	2016	2015
Gain recognized in AOCI, net of tax	$40	$111
Gain reclassified from AOCI to net product sales (effective portion), net of tax	$47	$103
Gain reclassified from AOCI to other income and expense (ineffective portion), net of tax	$—	$2
Interest Rate Contracts:		
Gain recognized in AOCI, net of tax	$6	$—
Gain reclassified from AOCI to interest expense, net of tax	$—	$—

Assuming no change in foreign exchange rates or LIBOR-based interest rates from market rates at December 31, 2016, $78 of gains recognized in AOCI will be reclassified to revenue over the next 12 months. The amount of gains recognized in AOCI that will be reclassified to interest expense over the next 12 months is immaterial.

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We enter into foreign exchange forward contracts, with durations of approximately 90 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, 2016, the notional amount of foreign exchange contracts where hedge accounting is not applied was $647.

We recognized a (loss) gain of $(5), $5 and $26, in other income and expense, for the years ended December 31, 2016, 2015 and 2014, respectively, associated with the foreign exchange contracts not designated as hedging instruments. These amounts were largely offset by gains or losses in monetary assets and liabilities.

The following tables summarize the fair value of outstanding derivatives at December 31, 2016 and 2015:

	December 31, 2016			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	$ 80	Other current liabilities	$ 2
Foreign exchange forward contracts	Other assets	59	Other liabilities	4
Interest rate contracts	Prepaid expenses and other current assets	—	Other current liabilities	—
Interest rate contracts	Other assets	10	Other liabilities	—
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	17	Other current liabilities	10
Total fair value of derivative instruments		$ 166		$ 16

	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	Prepaid expenses and other current assets	$ 85	Other current liabilities	$ 1
Foreign exchange forward contracts	Other assets	66	Other liabilities	5
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	7	Other current liabilities	4

Total fair value of derivative instruments	$ 158	$ 10

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Although we do not offset derivative assets and liabilities within our condensed consolidated balance sheets, our International Swap and Derivatives Association 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 and interest rate contracts subject to such provisions:

December 31, 2016

Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/Liabilities Presented in the Consolidated Balance Sheet	Gross Amounts Not Offset in the Consolidated Balance Sheet		
				Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 166	$ —	$ 166	$ (16)	$ —	$ 150
Derivative liabilities	(16)	—	(16)	16	—	—

December 31, 2015

Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/Liabilities Presented in the Consolidated Balance Sheet	Gross Amounts Not Offset in the Consolidated Balance Sheet		
				Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 158	$ —	$ 158	$ (10)	$ —	$ 148
Derivative liabilities	(10)	—	(10)	10	—	—

7. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2016	December 31, 2015
Royalties	$ 20	$ 30
Payroll and employee benefits	121	115
Taxes payable	39	12
Rebates payable	70	56
Clinical	64	57

Manufacturing	52	19
Other	142	114
	$ 508	$ 403

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 term loan facility and a $500 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 in the form of letters of credit and borrowings on same-day notice, referred to as swingline loans, of up to $25. 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, 2016, the interest rate on our outstanding loans under the Credit Agreement was 2.52%. 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. Under these financial covenants, we are required to deliver to the administrative agent, not later than 50 days after each fiscal quarter, our quarterly financial statements, and within 5 days thereafter, a compliance certificate. In November 2016, we obtained a waiver from the necessary lenders for this requirement and the due date for delivery of the third quarter 2016 financial statements and compliance certificate was extended to January 18, 2017. The posting of the Third Quarter report on Form 10-Q on our website on January 4, 2017 satisfied the financial statement covenant, and we simultaneously delivered the required compliance certificate, as required by the lenders.

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 in financing costs which are being amortized as interest expense over the life of the debt. Amortization expense associated with deferred financing costs for the years ended December 31, 2016 and 2015 was $10 and $6, respectively. Amortization expense associated with deferred financing costs for the year ended December 31, 2014 was not material.

In connection with the acquisition of Synageva in June 2015, we borrowed $3,500 under the term loan facility and $200 under the revolving facility, and we used our available cash for the remaining cash consideration. We made principal payments of $375 during the year ended December 31, 2016. At December 31, 2016, we had $3,081 outstanding on the term loan and zero outstanding on the revolving facility. At December 31, 2016, we had open letters of credit of $15, and our borrowing availability under the revolving facility was $485.

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

The contractual maturities of our long-term debt obligations due subsequent to December 31, 2016 are as follows:

Year	
2017	$ —
2018	150
2019	175
2020	2,756

Based upon our intent and ability to make payments during 2017, we included $175 within current liabilities on our consolidated balance sheet as of December 31, 2016, net of current deferred financing costs.

9. Facility Lease Obligations

New Haven Facility Lease Obligation

In November 2012, we entered into a lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. The term of the lease commenced in 2015 and will expire in 2030, with a renewal option of 10 years.

Although we do not legally own the premises, we are deemed to be the owner of the building due to the substantial improvements directly funded by us during the construction period based on applicable accounting guidance for build-to-suit leases. Accordingly, the landlord's costs of constructing the facility during the construction period 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 was completed and the building was placed into service in the first quarter 2016. The imputed interest rate on this facility lease obligation as of December 31, 2016 was approximately 11%. For the year ended December 31, 2016 and 2015, we recognized $14 and $5, respectively, of interest expense associated with this arrangement. As of December 31, 2016 and 2015, our total facility lease obligation was $136 and $133, respectively, recorded within other current liabilities and facility lease obligation on our consolidated balance sheets.

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Aggregate future minimum non-cancellable commitments under the New Haven facility lease obligation, as of December 31, 2016 are as follows:

Year	
2017	$16
2018	15
2019	16
2020	16
2021	16
Thereafter	146

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 one of its existing facilities. 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, 2016 and 2015, we recorded a construction-in-process asset of $118 and $19, respectively, and an offsetting facility lease obligation of $107 and $15, respectively, associated with the manufacturing facility.

Payments 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 2016, we incurred $58 of payments to Lonza under this agreement, of which $8 was applied against the outstanding facility lease obligation and $50 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 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 during the first quarter 2015. In addition, as of December 31, 2016, we could be required to pay up to an additional $249 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 during the first quarter 2015. In addition, we could be required to pay up to an additional $822 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. 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, 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. 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 and to pay up to an additional $120 with respect to a rare disease product and $400 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.

Manufacturing Agreements

We have various manufacturing development agreements 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 $1,148. 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 $27 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 our products. 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 our products that we could be required to pay the owners of patents for technology used in the manufacture and sale of our products. 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. In addition, in October 2015, Alexion received a request from the U.S. Department of Justice (DOJ) for the voluntary production of document and other

information pertaining to Alexion's compliance with FCPA. The SEC and DOJ also seek information related to Alexion's recalls of specific lots of Soliris and related securities disclosures. Alexion is cooperating with these investigations. At this time, Alexion is unable to predict the duration, scope or outcome of these investigations. While it is possible that a loss related to these matters may be incurred, given the ongoing nature of these investigations, management cannot reasonably estimate the potential magnitude of such loss or range of loss, if any.

Several securities class action lawsuits have been filed against the Company and former officers in federal district court alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Rule 10b-5, promulgated thereunder, alleging that defendants made misstatements and/or omissions concerning the Company's sales of Soliris.

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On November 17, 2016, a shareholder filed a putative class action in the U.S. District Court for the Southern District of New York. While the litigation was in the early stages, and before defendants had responded to the complaint, on December 30, 2016 plaintiffs filed a notice of voluntary dismissal and dismissed all claims without prejudice. This case is now closed.

On December 29, 2016, a second shareholder filed a putative class action against the Company and certain former employees in the U.S. District Court for the District of Connecticut, alleging that defendants made misrepresentations and omissions about Soliris between February 10, 2014 and December 9, 2016. On January 17, 2017, three parties filed motions to be named lead plaintiff in this action. Briefing on these motions is ongoing. The litigation is in the early stages, and defendants have not yet responded to the complaint. Given the early stages of this litigation, management does not currently believe that 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 December 2016, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents relating generally to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients taking drugs sold by Alexion, Alexion's provision of free drug to Medicare patients, and Alexion compliance policies and training materials concerning the anti-kickback statute or payments to any 501(c)(3) organization that provides financial assistance to Medicare patients. Other companies have disclosed similar inquiries. We are cooperating with this inquiry.

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 disclosed, the FDA issued Form 483s in August 2014 and August 2015 related to observations at ARIMF and the inspectional observations from the August 2014 and 2015 Forms 483s have since been closed out by the FDA. During July 2016, the FDA completed a routine inspection at ARIMF and have since confirmed receipt of our responses to the inspectional observations included in the Form 483 received during that inspection. 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.

Operating Leases

As of December 31, 2016, we have operating leases for office and laboratory space in U.S. and foreign locations to support our operations as a global organization.

Aggregate lease expense was $29, $28 and $23 for the years ended December 31, 2016, 2015 and 2014, 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, 2016 are:

Year	
2017	$21
2018	19
2019	13
2020	7
2021	6

Thereafter	24

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11. Income Taxes

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

	Year Ended December 31,		
	2016	2015	2014
U.S.	$(165)	$(126)	$222
Non-U.S.	741	624	650
	$576	$498	$872

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, 2016 and 2015 relates to income from our captive foreign partnership.

The components of the income tax expense are as follows:

	Year Ended December 31,		
	2016	2015	2014
Domestic			
Current	$4	$(88)	$285
Deferred	107	389	(112)
	111	301	173
Foreign			
Current	69	49	82
Deferred	(3)	4	(40)
	66	53	42
Total			
Current	73	(39)	367
Deferred	104	393	(152)
	$177	$354	$215

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 utilized all of our tax attributes or have met the applicable limitation for attribute utilization.

At December 31, 2016, we have tax effected federal and state net operating loss carryforwards of $57 and $5, respectively. Our NOL’s expire between 2020 and 2036. We also have federal and state income tax credit carryforwards of $536 and $11, respectively. These income tax credits expire between 2019 and 2036.

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:

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	Year Ended December 31,		
	2016	2015	2014
U.S. federal statutory tax rate	35.0 %	35.0 %	35.0 %
State and local income taxes	4.1 %	(0.8)%	0.9 %
Foreign income tax rate differential	(33.8)%	(32.5)%	(16.5)%
Tax credits, net of nondeductible expenses	(6.0)%	(7.6)%	(2.5)%
Foreign income tax credits	(8.4)%	(7.6)%	(4.8)%
Foreign income subject to U.S. taxation	26.6 %	24.3 %	15.8 %
U.S. deferred taxes on foreign earnings	16.5 %	60.1 %	— %
Other permanent differences	(3.3)%	0.1 %	(3.2)%
Effective income tax rate	30.7 %	71.0 %	24.7 %

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 U.S. 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 taxes attributable to intercompany transactions in the amount of approximately $22, $24, and $23 of tax expense for 2016, 2015, and 2014, respectively.

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 are as follows:

	December 31, 2016	December 31, 2015
Deferred tax assets:		
Net operating losses	$ 58	$ 168
Income tax credits	537	209
Stock compensation	89	74
Accruals and allowances	91	86
Research and development expenses	15	19
Accrued royalties	23	16
	813	572
Valuation allowance	(4)	(5)
Total deferred tax assets	809	567
Deferred tax liabilities:		
Depreciable assets	(95)	(83)
Unrealized gains	(44)	(47)

Investment in foreign partnership	(546)	(409)
Intangible assets	(502)	(543)
Total deferred tax liabilities	(1,187)	(1,082)
Net deferred tax (liability) asset	$ (378)	$ (515)

In the second quarter of 2016, we adopted the new share-based compensation guidance. Under the prior guidance, the effect of certain windfall tax benefit deductions were not recognized in deferred tax. The new guidance fully incorporates the deferred tax impact of these deductions. As a result, we recorded an increase to the deferred tax asset for income tax credits for

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the period ended December 31, 2016. Consistent with this new guidance, deferred tax balances for the period ended December 31, 2015 have not been restated.

The decrease in our net operating losses is due to the utilization of historical Synageva net operating loss carryforwards. The increase in income tax credits is primarily attributable to the adoption of new share-based compensation guidance and the corresponding recognition of "windfall" tax benefits. The increase in our investment in foreign partnership deferred tax liability is due to 2016 distributions from our captive foreign partnership.

We follow authoritative guidance regarding accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosures, and transition.

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

	2016	2015	2014
Beginning of period balance	$114	$29	$46
Increases for tax positions taken during a prior period	3	2	1
Decreases for tax positions taken during a prior period	(1)	—	(2)
Increases for tax positions taken during the current period	23	85	9
Decreases for tax positions related to settlements	—	(1)	(25)
Decreases for tax positions related to lapse of statute	—	(1)	—
	$139	$114	$29

The total amount of accrued interest and penalties was not significant as of December 31, 2016. The total amount of tax benefit recorded during 2016, 2015, and 2014 which related to unrecognized tax benefits was $22, $83, and $17, respectively. All of our unrecognized tax benefits, if recognized, would have a favorable impact on the effective tax rate.

It is reasonably possible that a portion of our unrecognized tax benefits could reverse within the next twelve months. Reversal of these amounts is contingent upon the completion of field audits by the taxing authorities in several jurisdictions, whether a tax adjustment is proposed, the nature and amount of any adjustment, and the administrative path to resolving the proposed adjustment. We cannot reasonably estimate the range of the potential change.

We file federal and state income tax returns in the U.S. and in numerous foreign jurisdictions. The U.S. and foreign jurisdictions have statutes of limitations ranging from 3 to 5 years. However, the limitation period could be extended due to our tax attribute 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 tax attribute values.

The Internal Revenue Service (IRS) has commenced an examination of our U.S. income tax returns for 2013 and 2014. We anticipate this audit will conclude within the next twelve months. As of February 16, 2017, 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, such as foreign tax credits or deficits in the foreign earnings and profits account. At December 31, 2016, the cumulative amount of these earnings was approximately $1,462.

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. The permanent reinvestment assertion is inapplicable to such earnings.

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

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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 maximum of 48 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, 2016, 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, 2015	6	$ 110.15		
Granted	2	139.71		
Exercised	(1)	55.36		
Forfeited and canceled	(1)	157.80		
Outstanding at December 31, 2016	6	$ 116.65	6.02	$ 177
Vested and unvested expected to vest at December 31, 2016	6	$ 116.08	5.97	$ 177
Exercisable at December 31, 2016	4	$ 97.02	4.59	$ 175

Total intrinsic value of stock options exercised during the years ended December 31, 2016, 2015 and 2014 was $42, $168 and $460, 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, 2016, 2015 and 2014 was $58, $51 and $36, 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, 2016	December 31, 2015	December 31, 2014
Expected life in years	3.82 - 6.29	3.57 - 9.00	3.64 - 5.30
Interest rate	0.87% - 1.66%	0.84% - 2.17%	0.97% - 1.74%
Volatility	33.45% - 37.61%	33.35% - 38.13%	32.15% - 34.87%
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, 2016, 2015 and 2014 was $41.46, $53.03 and $51.22 per option, respectively.

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Restricted Stock

A summary of the status of our nonvested Restricted Stock and changes during the period then ended is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested Restricted Stock at December 31, 2015	2	$ 167.21
Shares granted	2	133.35
Shares forfeited	—	165.23
Shares vested	(1)	155.03
Nonvested Restricted Stock at December 31, 2016	3	$ 149.48

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, 2016, 2015 and 2014, including restricted stock units with performance conditions, was $133.35, $184.09 and $174.22 per share, respectively. The total weighted average grant date fair value of restricted stock vested during the years ended December 31, 2016, 2015 and 2014 was $124, $135 and $41, respectively.

We also grant market-based performance awards to senior management which provide 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 use payout simulation models to estimate the grant date fair value of the awards. Expense recognized for market-based performance awards was not material for the years ended December 31, 2016, 2015 and 2014.

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 shares of common stock may be issued to eligible employees who elect to participate in the purchase plan. Shares issued and compensation expense recognized under the ESPP for the years ended December 31, 2016 and 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,		
	2016	2015	2014
Cost of sales	$11	$7	$4
Research and development	57	64	36
Selling, general and administrative	124	156	74
Total share-based compensation expense	192	227	114
Income tax effect	(70)	(84)	(42)
Total share-based compensation expense, net of tax	$122	$143	$72

Share-based compensation expense capitalized to inventory during the years ended December 31, 2016, 2015 and 2014 was $12, $8, and $10, respectively.

As of December 31, 2016, there was $356 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 2.71 years.

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13. Stockholders' Equity

Common Stock

In June 2015, in connection with our acquisition of Synageva, we issued 26 shares of common stock to former Synageva stockholders and employees. The fair value of the stock was $4,914, and we incurred $4 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 to acquire shares with an aggregate value of up to $1,000 for future purchases under the repurchase program, which superseded all prior repurchase programs. Under the program, we repurchased 3 and 2 shares of our common stock at a cost of $430 and $328 during the years ended December 31, 2016 and 2015, 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.

In February 2017, our Board of Directors increased the authorization to acquire shares with an aggregate value of up to $1,000 for future purchases under the repurchase program, which superseded all prior repurchase programs. As of February 16, 2017, there is a total of $1,000 remaining for repurchases under the repurchase program.

14. Other Comprehensive Income and Accumulated Other Comprehensive Income

The following table summarizes the changes in AOCI, by component, for the years ended December 31, 2016, 2015 and 2014:

	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, 2013	$ (12)	$ —	$ (4)	$ (8)	$ (24)
Other comprehensive income before reclassifications	(6)	—	110	(6)	98
Amounts reclassified from other comprehensive income	1	—	(19)	—	(18)
Net other comprehensive income (loss)	(5)	—	91	(6)	80
Balances, December 31, 2014	$ (17)	$ —	$ 87	$ (14)	$ 56
Other comprehensive income before reclassifications	(2)	(1)	111	(6)	102
Amounts reclassified from other comprehensive income	9	—	(105)	—	(96)
Net other comprehensive income (loss)	7	(1)	6	(6)	6
Balances, December 31, 2015	$ (10)	$ (1)	$ 93	$ (20)	$ 62
Other comprehensive income before reclassifications	2	—	46	(4)	44
Amounts reclassified from other comprehensive income	1	—	(47)	—	(46)
Net other comprehensive income (loss)	3	—	(1)	(4)	(2)
Balances, December 31, 2016	$ (7)	$ (1)	$ 92	$ (24)	$ 60

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The table below provides details regarding significant reclassifications from AOCI during the years ended December 31, 2016, 2015 and 2014:

Details about Accumulated Other Comprehensive Income Components	Amount Reclassified From Accumulated Other Comprehensive Income during the year ended December 31, 2016	2015	2014	Affected Line Item in the Consolidated Statements of Operations
Unrealized Gains (Losses) on Hedging Activity				
Effective portion of foreign exchange contracts	$73	$118	$19	Net product sales
Ineffective portion of foreign exchange contracts	—	2	3	Foreign currency gain (loss)
	73	120	22	
	(26)	(15)	(3)	Income tax expense
	$47	$105	$19	
Defined Benefit Pension Items				
Amortization of prior service costs and actuarial losses	$(1)	$(1)	$(1)	(a)
Curtailment	—	(10)	—	(a)
	(1)	(11)	(1)	
	—	2	—	Income tax expense
	$(1)	$(9)	$(1)	

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

15. Fair Value Measurement

Authoritative guidance establishes a valuation hierarchy for disclosure of the inputs to the valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value.

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The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2016 and 2015, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

		Fair Value Measurement at December 31, 2016			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Money market funds	$266	$ —	$266	$ —
Cash equivalents	Commercial paper	$70	$ —	$70	$ —
Cash equivalents	Corporate bonds	$10	$ —	$10	$ —
Cash equivalents	Municipal bonds	$40	$ —	$40	$ —
Marketable securities	Mutual funds	$13	$ 13	$—	$ —
Marketable securities	Commercial paper	$44	$ —	$44	$ —
Marketable securities	Corporate bonds	$113	$ —	$113	$ —
Marketable securities	Municipal bonds	$51	$ —	$51	$ —
Marketable securities	Other government-related obligations	$100	$ —	$100	$ —
Marketable securities	Bank certificates of deposit	$5	$ —	$5	$ —
Marketable securities	Equity securities	$1	$ 1	$—	$ —
Prepaid expenses and other current assets	Foreign exchange forward contracts	$97	$ —	$97	$ —
Other assets	Foreign exchange forward contracts	$59	$ —	$59	$ —
Other current liabilities	Foreign exchange forward contracts	$12	$ —	$12	$ —
Other liabilities	Foreign exchange forward contracts	$4	$ —	$4	$ —
Other assets	Interest rate contracts	$10	$ —	10	$ —
Current portion of contingent consideration	Acquisition-related contingent consideration	$24	$ —	$—	$ 24
Contingent consideration	Acquisition-related contingent consideration	$129	$ —	$—	$ 129

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		Fair Value Measurement at December 31, 2015			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Money market funds	$180	$ —	$180	$ —
Cash equivalents	Commercial paper	$192	$ —	$192	$ —
Cash equivalents	Corporate bonds	$13	$ —	$13	$ —
Cash equivalents	Municipal bonds	$60	$ —	$60	$ —
Cash equivalents	Other government-related obligations	$31	$ —	$31	$ —
Cash equivalents	Bank certificates of deposit	$27	$ —	$27	$ —
Marketable securities	Mutual funds	$9	$ 9	$—	$ —
Marketable securities	Commercial paper	$62	$ —	$62	$ —
Marketable securities	Corporate bonds	$120	$ —	$120	$ —
Marketable securities	Municipal bonds	$27	$ —	$27	$ —
Marketable securities	Other government-related obligations	$157	$ —	$157	$ —
Prepaid expenses and other current assets	Foreign exchange forward contracts	$92	$ —	$92	$ —
Other assets	Foreign exchange forward contracts	$66	$ —	$66	$ —
Other current liabilities	Foreign exchange forward contracts	$5	$ —	$5	$ —
Other liabilities	Foreign exchange forward contracts	$5	$ —	$5	$ —
Current portion of contingent consideration	Acquisition-related contingent consideration	$56	$ —	$—	$ 56
Contingent consideration	Acquisition-related contingent consideration	$121	$ —	$—	$ 121

There were no securities transferred between Level 1, 2 and 3 during the year ended December 31, 2016.

Valuation Techniques

We classify mutual fund investments and equity securities, which are valued based on quoted market prices in active markets with no valuation adjustment, as Level 1 assets within the fair value hierarchy.

Cash equivalents and marketable securities classified as Level 2 within the valuation hierarchy consist of institutional money market funds, commercial paper, municipal bonds, U.S. and foreign government-related debt, corporate debt securities and certificates of deposit. We estimate the fair values of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include market pricing based on real-time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs. We validate the prices provided by our third-party pricing sources by understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances.

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Our derivative assets and liabilities include foreign exchange and interest rate 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, 2016, 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 approvals or sales-based milestone events. We determine the fair value of these obligations on the acquisition date using various estimates that are not observable in the market and represent a Level 3 measurement within the fair value hierarchy. The resulting probability-weighted cash flows were discounted using a cost of debt of 4.7% 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.

Estimated future contingent milestone payments related to prior business combinations range from zero if no milestone events are achieved, to a maximum of $766 if all development, regulatory and sales-based milestones are reached. As of December 31, 2016, the fair value of acquisition-related contingent consideration was $153. The following table represents a roll-forward of our acquisition-related contingent consideration:

	December 31, 2016
Balance at beginning of period	$ (177)
Milestone payments	60
Changes in fair value	(36)
Balance at end of period	$ (153)

In the fourth quarter 2016, the criteria was met for the achievement of a milestone payment associated with our acquisition of Enobia Pharma Corp. In connection with this, $60 was paid in December 2016.

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, 2016 and 2015 were $13 and $9, respectively, and are included in other liabilities within the

consolidated balance sheets. Employer matching contributions under the plan for the years ended December 31, 2016, 2015 and 2014 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, 2016, 2015 and 2014, we recorded matching contributions of approximately $17, $11, and $9 respectively.

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Defined Benefit Plans

We maintain defined benefit plans for employees in certain countries outside the U.S., 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,	
	2016	2015
Change in benefit obligation:		
Projected benefit obligation, beginning of year	$ 45	$ 51
Prior service cost	—	—
Service cost	8	10
Interest cost	—	1
Change in assumptions	(1)	2
Recognized actuarial net loss	—	4
Curtailment	—	(25)
Plan amendment	(4)	—
Foreign currency exchange rate changes	(3)	—
Net transfers to (from) plan	—	2
Other	3	—
Projected benefit obligation, end of year	$ 48	$ 45
Accumulated benefit obligation, end of year	$ 41	$ 42

	December 31,	
	2016	2015
Change in plan assets:		
Fair value of plan assets, beginning of year	$ 22	$ 27
Return on plan assets	—	—
Employer contributions	3	4
Plan participants' contributions	2	2
Curtailment	—	(13)
Foreign currency exchange rate changes	(1)	—
Net transfers to (from) plan	—	2
Other	2	—
Fair value of plan assets, end of year	$ 28	$ 22
Funded status at end of year	$ (20)	$ (23)

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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, 2016 and 2015 and the classification of each investment category within the fair value hierarchy with respect to the inputs used to measure fair value:

	December 31, 2016		December 31, 2015	
	Fair Value (Level 2)	as % of total plan assets	Fair Value (Level 2)	as % of total plan assets
Cash and cash equivalents	$ —	— %	$ —	— %
Equity security funds	2	7 %	2	9 %
Debt security funds	22	79 %	17	77 %
Real estate funds	4	14 %	3	14 %
	$ 28	100 %	$ 22	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, 2016, we have recorded a liability of $20 in other noncurrent liabilities and a charge to accumulated other comprehensive income, net of tax, of $7 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,	
	2016	2015
Weighted average assumptions - Net Periodic Benefit Cost:		
Discount rate	0.6 %	1.4 %
Long term rate of return on assets	3.0 %	3.5 %
Rate of compensation increase	1.4 %	1.5 %
Weighted average assumptions - Projected Benefit Obligation:		
Discount Rate	0.7 %	0.6 %
Rate of compensation increase	1.4 %	1.4 %

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,		
	2016	2015	2014

Service cost	$8	$10	$ 8
Interest cost	—	1	1
Expected return on plan assets	—	(1)	(1)
Employee contributions	(2)	(2)	(2)
Amortization of prior service costs	—	—	—
Curtailment	—	(2)	—
Amortization and deferral of actuarial gain	1	1	1
Total net periodic benefit cost	$7	$7	$ 7

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

Amount included in AOCI - December 31, 2014	$(17)
Prior service cost	—
Net loss arising during the period	(4)
Change in assumptions	(2)
Amortization of net gain	1
Plan assets losses	(1)
Curtailment	10
Foreign currency exchange rate changes	—
Taxes	3
Amount included in AOCI - December 31, 2015	$(10)
Prior service cost	—
Net loss arising during the period	—
Plan amendment	4
Change in assumptions	1
Amortization of net gain	1
Plan assets losses	—
Curtailment	—
Foreign currency exchange rate changes	—
Taxes	(1)
Other	(2)
Amount included in AOCI - December 31, 2016	$(7)

We estimate that we will pay employer contributions of approximately $3 in 2017. The expected future benefits to be paid in respect of the pension plans as of December 31, 2016 were as follows:

Year	
2017	$2
2018	1
2019	1
2020	1
2021	1
2022 to 2026	5

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 for contract termination costs in the fourth quarter of 2015.

In connection with the acquisition and integration of Synageva in 2015, we recorded restructuring expense of $13 primarily related to employee costs during 2015. Synageva restructuring charges were not material in 2016.

In the fourth quarter 2014, we announced plans to relocate our European headquarters from Lausanne to Zurich, Switzerland. The relocation of our 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 related to employee costs in the fourth quarter of 2014. During the years ended December 31, 2016 and 2015, we incurred additional restructuring costs of $4 and $18, respectively.

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The following table presents a reconciliation of the restructuring reserve recorded within accrued expenses on the Company's consolidated balance sheets for the years ended December 31, 2016 and 2015, respectively:

	December 31, 2016				December 31, 2015			
	Employee Separation Costs	Contract Termination Costs	Other Costs	Total	Employee Separation Costs	Contract Termination Costs	Other Costs	Total
Liability, beginning of period	$6	$ 1	$ —	$ 7	$15	$ —	$ —	$15
Restructuring expenses	—	2	1	3	22	12	4	38
Cash settlements	(5)	(4)	(1)	(10)	(35)	(11)	(4)	(50)
Adjustments to previous estimates	(1)	1	—	—	4	—	—	4
Liability, end of period	$—	$ —	$ —	$ —	$6	$ 1	$ —	$7

18. Segment Information

We operate in a single segment, focusing on serving patients with devastating and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Consistent with our operational structure, our chief operating decision maker manages and allocates resources at a global, consolidated level. 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,		
	2016	2015	2014
Net product sales:			
Soliris (1)	$2,843	$2,591	$2,234
Strensiq	210	12	—
Kanuma	29	—	—
	$3,082	$2,603	$2,234

Geographical information

	Year Ended December 31,		
Net product sales:	2016	2015	2014
United States	$1,257	$951	$730
Europe (1)	961	841	836
Asia Pacific	318	276	244
Rest of World	546	535	424
	$3,082	$2,603	$2,234

(1) Included within the Soliris and Europe revenues for 2014 is a reimbursement of $88 for shipments made in years prior to January 1, 2014 as a result of an

agreement with the French government.

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	December 31,	
Long-lived assets (2):	2016	2015
United States	$490	$444
Europe	538	248
Other	8	5
	$1,036	$697

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

19. Quarterly Financial Information (unaudited)

The following condensed quarterly financial information is for the years ended December 31, 2016 and 2015:

	March 31	June 30		September 30	December 31	
2016:						
Revenues	$ 701	$ 753		$ 799	$ 831	
Cost of sales	59	60		71	68	
Operating expenses	476	498		549	636	(1)
Operating income	166	195		179	127	
Net income (loss)	$ 92	$ 120	(2)	$ 94	$ 93	
Earnings (loss) per common share						
Basic	$ 0.41	$ 0.54	(2)	$ 0.42	$ 0.41	
Diluted	$ 0.41	$ 0.53	(2)	$ 0.42	$ 0.41	

	March 31	June 30	September 30	December 31
2015:				
Revenues	$ 600	$ 636	$ 667	$ 701
Cost of sales	69	52	54	58
Operating expenses	427	403	458	546
Operating income	104	181	155	97
Net income (loss)	$ 91	$ 170	$ (184) (3)	$ 67
Earnings (loss) per common share				
Basic	$ 0.46	$ 0.84	$ (0.81)	$ 0.30
Diluted	$ 0.45	$ 0.83	$ (0.81)	$ 0.29

(1) Included within operating expenses for the fourth quarter of 2016 is an impairment charge of $85 associated with an early stage clinical indefinite-lived intangible asset .

(2) Included within net income for the second quarter of 2016 are tax benefits of $5 resulting from our adoption of new share-based compensation guidance during the third quarter of 2016. This resulted in an increase in basic EPS and diluted EPS of $0.03 and $0.02, respectively.

(3) Included within net income for the third quarter of 2015 is a one-time tax expense of $316 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.

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