ALEXION PHARMACEUTICALS INC
Form 10-K
February 08, 2018
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, 2017
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 x No ¨
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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 ¨ Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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, 2017, was $26,128,956,666.(1)

The number of shares of Common Stock outstanding as of February 5, 2018 was 221,681,437.

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 8, 2018, are incorporated by reference into Part III of this report.

(1) Excludes 8,789,185 shares of common stock held by directors and executive officers at June 30, 2017. 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. 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.

Forward-looking 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 statements. 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;
- 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, ALXN1210 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;
- periods of patent, regulatory and market exclusivity for our products;
- the scope of our intellectual property and the outcome of any challenges or opposition 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; and
- potential costs resulting from product liability or other third party claims, the sufficiency of our existing capital resources and projected cash needs.

Such risks and uncertainties include, but are not limited to, the possibility that expected tax benefits will not be realized, assessment of impact of recent accounting pronouncements, potential 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 class action litigation filed in December 2016, 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, the investigation of our Brazilian operations by Brazilian authorities, risks related to potential disruptions to our business as a result of the leadership changes and transition announced in December 2016 and March 2017, the anticipated effects of the company-wide restructuring initiated in the first quarter 2017 and operational plan initiated in the third quarter 2017, including relocation of our global headquarters, the short and long-term effects of other government healthcare measures, and the effect of shifting foreign exchange rates, as well as those risks and uncertainties 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

Alexion Pharmaceuticals, Inc. (Alexion, the Company, we, our or us) is a global biopharmaceutical company focused on serving patients and families affected by rare diseases through the innovation, development and commercialization of life-changing therapies.

We are the global leader in complement inhibition and have developed and commercialize the first and only approved complement inhibitor to treat patients with paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), and anti-acetylcholine receptor (AChR) antibody-positive generalized myasthenia gravis (gMG). In addition, Alexion has two highly innovative enzyme replacement therapies for patients with life-threatening and ultra-rare metabolic disorders, hypophosphatasia (HPP) and lysosomal acid lipase deficiency (LAL-D).

As the leader in complement biology for over 20 years, Alexion focuses its research efforts on novel molecules and targets in the complement cascade, and its development efforts on the core therapeutic areas of hematology, nephrology, neurology, and metabolic disorders. We were incorporated in 1992 under the laws of the State of Delaware.

Products and Development Programs

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

Marketed Products

Our marketed products include the following:

Product	Development Area	Indication
	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)
	Hematology/Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)
	Neurology	Generalized Myasthenia Gravis (gMG)
	Metabolic Disorders	Hypophosphatasia (HPP)
	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 and neurology. Soliris is a humanized monoclonal antibody that effectively blocks terminal complement activity at the doses currently prescribed. The initial indication for which we received approval for Soliris is PNH.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

PNH is a debilitating and life-threatening, ultra-rare genetic blood disorder defined by chronic uncontrolled complement activation leading to the destruction of red blood cells (hemolysis). The chronic hemolysis in patients with PNH may be associated with life-threatening thromboses, recurrent pain, kidney disease, disabling fatigue, impaired quality of life, severe anemia, pulmonary hypertension, shortness of breath and intermittent episodes of dark-colored urine (hemoglobinuria). We continue to work with researchers to expand the base of knowledge in PNH and the utility of Soliris to treat patients with PNH. Soliris is approved for the treatment of PNH in the U.S., Europe, Japan and in several other countries. 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 countries.

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 organs. Soliris is approved for the treatment of pediatric and adult patients with aHUS in the U.S., Europe, Japan and in several other countries. 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 U.S. Food and Drug Administration (FDA) and European Commission (EC) have granted Soliris orphan drug designation for the treatment of patients with aHUS.

Generalized Myasthenia Gravis (gMG)

Myasthenia Gravis (MG), is 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. Soliris has received orphan drug designation for the treatment of patients with MG in the U.S. and Europe, and for the treatment of patients with refractory gMG, a subset of MG, in Japan.

In August 2017, we announced that the EC approved the extension of the indication for Soliris to include the treatment of refractory gMG in adults who anti-acetylcholine receptor (AChR) antibody-positive. In October 2017, the FDA approved the Company's supplemental Biologics License Application to extend the indication for Soliris as a potential treatment for adult patients with gMG who are AChR antibody-positive. In December 2017, the Ministry of Health, Labour and Welfare (MHLW) in Japan approved Soliris as a treatment for patients with generalized myasthenia gravis (gMG) who are AChR antibody-positive and whose symptoms are difficult to control with high-dose intravenous immunoglobulin therapy or plasmapheresis (PLEX).

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 the 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. In 2016, 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 clinical development programs include the following:

Product	Development Area	Phase I	Phase II	Phase III	Filed
ALXN1210 (IV)	Next Generation Complement Inhibitor	Paroxysmal Nocturnal Hemoglobinuria (PNH) Atypical Hemolytic Uremic Syndrome (aHUS)			
ALXN1210 (Subcutaneous)	Next Generation Complement Inhibitor	PNH aHUS			
Soliris (eculizumab)	Neurology	Relapsing Neuromyelitis Optica Spectrum Disorder (NMOSD)			

ALXN1210
ALXN1210 is an innovative, long-acting C5 inhibitor discovered and developed by Alexion that works by inhibiting the C5 protein in the terminal complement cascade. In early studies, ALXN1210 demonstrated rapid, complete, and sustained reduction of free C5 levels. Alexion has completed enrollment in four ongoing clinical studies of ALXN1210 in patients with PNH: 1) an open-label Phase I/II dose-escalating study to evaluate the safety, tolerability, efficacy, pharmaco-kinetics (PK) and pharmaco-dynamics (PD) of ALXN1210 administered by intravenous (IV) infusion; 2) a Phase II, open-label, study to evaluate the efficacy, safety, tolerability, immunogenicity, PK and PD of ALXN1210 administered by IV infusion investigating multiple dosing intervals from four to twelve weeks; 3) a Phase III open-label, randomized, active-controlled multicenter study to evaluate the safety and efficacy of ALXN1210 versus eculizumab administered by IV infusion to adult patients with PNH who have never received treatment of a complement inhibitor; and 4) a Phase III open-label, randomized, active-controlled, multicenter study to evaluate the safety and efficacy of ALXN1210 versus eculizumab administered by IV infusion to adult patients with PNH who have been treated with eculizumab for at least the past 6 months.

In addition, two clinical studies in patients with aHUS are ongoing and continuing to enroll: 1) a Phase III, single arm, multicenter study to evaluate the safety and efficacy of ALXN1210 administered by IV infusion to adolescent and adult patients with aHUS who have never been treated with a complement inhibitor; and 2) a Phase III, single arm, multicenter study to evaluate the safety, efficacy, PK, and PD of ALXN1210 administered by IV infusion in pediatric patients with aHUS who have never been treated with a complement inhibitor.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

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). Two open-label studies were designed to provide dose ranging data to optimize the dosing regimen for the Phase III development of ALXN1210 as a treatment for patients with PNH based on exposure-response assessments.

In 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. 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. 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 2017, these studies showed continued treatment of PNH patients with ALXN1210 for up to eight months resulted in rapid and sustained reduction of plasma LDH levels, with reductions in mean LDH levels from Baseline (BL) ranging from 73% to 88%.

We have also initiated a Phase III open-label, randomized, active-controlled multicenter study to evaluate the safety and efficacy of ALXN1210 versus eculizumab administered by IV infusion to adult patients with PNH who have never been treated by a complement inhibitor. The study is evaluating ALXN1210 administered intravenously every eight weeks. Patient enrollment has been completed in this trial and we expect to receive data from this study in the second quarter 2018.

In addition, we have initiated a supportive Phase III open-label, randomized, active-controlled, multicenter study to evaluate the safety and efficacy of ALXN1210 versus eculizumab administered by IV infusion to adult patients with PNH who have been treated with eculizumab for at least the past six months. The study is evaluating ALXN1210 administered intravenously every eight weeks. Patient enrollment has been completed in this trial and we expect to receive data from this study in the second quarter 2018.

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 have initiated a Phase III, single arm, multicenter study to evaluate the safety and efficacy of ALXN1210 administered by intravenous (IV) infusion to 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 enrollment is ongoing in this trial.

In addition, we have initiated a supportive Phase III, single arm, multicenter study to evaluate the safety, efficacy, PK, and PD of ALXN1210 administered by intravenous (IV) infusion in pediatric patients with aHUS 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.

Subcutaneous (SC) Delivery

Initial data from a Phase I study in healthy volunteers to evaluate ALXN1210 delivered subcutaneously supports progressing the development of a subcutaneous formulation of ALXN1210. Based on discussions with regulators, Alexion plans to initiate a single, PK-based Phase III study of ALXN1210 delivered subcutaneously once per week in PNH and aHUS in late 2018.

Soliris (eculizumab)

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. Patient enrollment is complete and we expect to receive data from this study in mid-2018. Dosing is 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.

Other Programs

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 has 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. These trials will not be expanded and no new patients will be added to the trials. Patients currently enrolled in the trials will continue to receive therapy. No additional studies are planned. Out-licensing opportunities are being pursued for cPMP.

Samalizumab (ALXN6000)

Samalizumab is a first-in-class immunomodulatory humanized monoclonal antibody that blocks CD200, a key immune checkpoint protein expressed in both hematologic and solid malignancies. The safety and efficacy of samalizumab were being evaluated in patients with advanced solid tumors and in conjunction with the Leukemia and Lymphoma Society, in patients with acute myeloid leukemia (AML). The solid tumor Phase I trial has been terminated and no new patients will be added to the multi-arm AML study, referred to as the BEAT AML Master Trial. Out-licensing opportunities are being pursued for samalizumab.

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. In September 2017, we announced our intention to close ARIMF to align our manufacturing facilities with our ongoing multi-product network manufacturing strategy, which utilizes manufacturing operations in the U.S. and Ireland, and manufacturing capacity through manufacturing partners. During the fourth quarter 2017, we began to actively market the facility to potential buyers. We do not expect the closing of ARIMF to impact our clinical or commercial supply of inventory.

We have various agreements with Lonza through 2028, with remaining total non-cancellable commitments of approximately $1,098.9. 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 $27.3 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. In October 2017, the FDA notified Alexion that the Warning Letter has been resolved.

In April 2014, we purchased a fill/finish facility in Athlone, Ireland, which has been refurbished to become our first company-owned fill/finish facility. In July 2016, we announced plans to construct a new biologics manufacturing facility at this site, which is expected to be completed and receive regulatory approval in 2019.

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 and receive regulatory approval in 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, Latin America, 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 2017, 2016, and 2015, sales to our largest customer accounted for 15.0%, 16.0%, and 17.5% 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 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 protect investment in discovering, developing and marketing our products, and are therefore important to our business. We own or license rights to many patents in the U.S. and foreign countries that cover our products and investigational compounds. We also file and prosecute many 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.

Two forms of intellectual property generally determine the period of market exclusivity for our products: patent rights and regulatory protections. It is during the period of market exclusivity that our products have their greatest commercial value.

Patents provide a right to exclude others from practicing an invention for a defined period of time. 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. Because a significant portion of a product’s patent protection can elapse during the course of developing and obtaining regulatory approval of the product, certain countries provide compensatory mechanisms to extend patent terms for the biopharmaceutical products.

Regulatory protections are another source of exclusive rights that contribute toward market exclusivity for our products. Many developed countries provide such non-patent incentives to develop medicines. For example, countries 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. Some countries provide additional incentives to develop medicines for rare diseases, or

orphan drugs, and medicines for pediatric patients. Regulatory protections can work in conjunction with patents to strengthen market exclusivity, and in countries where patent protection has expired or does not exist, regulatory protections can extend a product’s market exclusivity period. Different forms of regulatory protection are described in the section of this document titled “Government Regulation”.

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. We also own other issued U.S. patents that cover the composition, use and formulation of eculizumab, that expire in 2027. Soliris is also protected in the U.S. by regulatory data exclusivity until 2019, by orphan drug exclusivity for treating aHUS until 2018 and by orphan drug exclusivity for treating gMG until 2024. 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, until 2023 for aHUS and until 2027 for gMG. In Japan we own issued patents that cover the eculizumab composition of matter and will expire in 2019 and 2027. Soliris is also protected in Japan by orphan drug exclusivity until 2020 for PNH, until 2023 for aHUS and until 2027 for gMG. 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 in the U.S., Europe, Japan and other countries.

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. We maintained the European patent in an opposition proceeding that was favorably resolved

in 2017. 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.

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 U.S., 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 that will prevent the trials from moving forward. 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.

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 $2.0 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 and Mitigation Strategy (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 final guidance on the assignment of nonproprietary, clearly distinguishable product names for both biologic and biosimilar products and draft guidance on interchangeability and evaluation of analytical similarity.

The FDA approved the first biosimilar product under the BPCIA in 2015, and as of December 2017, nine biosimilar products have been approved in total. 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 when the application is made; 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 European Medicines Agency (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 the FDA may grant Breakthrough Therapy status to a drug intended for the treatment of a serious condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint over existing therapies. The

Breakthrough Therapy designation, which may be requested by a sponsor when filing or amending an IND, is intended to facilitate and expedite the development and FDA review of a product candidate. Specifically, the Breakthrough Therapy designation may entitle the sponsor to more frequent meetings with FDA during drug development, intensive guidance on clinical trial design, and expedited FDA review by a cross-disciplinary team comprised of senior managers. The designation does not guarantee a faster development or review time as compared to other drugs, however, nor does it assure that the drug will obtain ultimate marketing approval by the FDA. Once granted, the FDA may withdraw this designation at any time if subsequent data no longer support the breakthrough therapy designation. 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. 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 FDA is still working to implement many aspects of the Cures Act, its potential effect 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 the FDA to spend several years developing these policies, the effect on us could be delayed. At this time, we cannot anticipate what effect these future policies may have on our

business.

The Cures Act also authorizes $1,800.0 in funding for the “Cancer Moonshot” initiative (the Initiative) to be run by the NIH. The 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 an 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 launched 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 + 6.0%, except that the hospital outpatient payment rate for products purchased by certain hospitals under the 340B drug pricing program is at ASP minus 22.5% effective January 1, 2018. 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 2.0% under sequestration (i.e., automatic spending reductions). Subsequent legislation extended the 2.0% reduction, on average, to 2025. This 2.0% 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, in

the case of innovator products, the best price for each drug. 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. Any failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results.

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. 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 our products from the ceiling price requirements for these newly-eligible entities. 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, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Any changes to the definition of average manufacturer price and the Medicaid rebate amount also could affect our 340B ceiling price calculation for our products and could negatively impact our results of operations.

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. 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 pricing program.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, or if we fail to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

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 purchase off 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 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) imposes civil penalties against individuals or entities for, 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 Health Insurance Portability and Accountability Act of 1996 (HIPAA), among other things, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also 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 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, and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Some states and cities require identification or licensing of state representatives. 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 significant criminal, civil, and administrative penalties, including damages, fines, imprisonment, and exclusion of a manufacturer's products from reimbursement under government programs.

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. If we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. 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. Please see the discussion below in the "Risk Factors" section for additional details regarding this investigation. Similar investigations of other pharmaceutical companies 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 100.0% of the average manufacturer price. In addition, PPACA and subsequent legislation changed the definition of average manufacturer price. Finally, PPACA requires pharmaceutical manufacturers of branded prescription drugs 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 $4,100.0 in 2017 ($2,800.0 in each ensuing year), 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 of 1986 (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 (IRS). 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). In early 2016, CMS issued a final regulation to implement the changes to the Medicaid Drug Rebate Program under PPACA, which became effective on April 1, 2016. The issuance of the final regulation, as well as any other regulations and coverage expansion by various governmental agencies

relating to the Medicaid Drug Rebate Program, has increased and will continue to increase our costs and the complexity of compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final rule.

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 50.0% 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.

Moreover, certain legislative changes to and regulatory changes under PPACA have occurred in the 115th U.S. Congress and under the Trump Administration. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017 eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate, beginning in 2019. Additional legislative changes to and regulatory changes under PPACA remain possible.

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 not directly subject to HIPAA other than with respect to providing certain

employee benefits, we could be potentially subject to criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA. Failure to comply with current and future laws and regulations could result in government enforcement actions (including the imposition of significant penalties), criminal and civil liability for us and our officers and directors, and/or adverse publicity that negatively affect our business.

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. 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, Alexion received a request from the DOJ for the voluntary production of documents and other information pertaining to Alexion's compliance with the FCPA. For information concerning the risks

associated with the investigation, see our Risk Factor - "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." 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 considered to constitute off-label promotion and is 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, and the only approved complement inhibition therapy for the treatment of AChR antibody-positive gMG. 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, 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, 2017, we had 2,525 full-time, world-wide employees, of which 832 were engaged in research, product development, manufacturing, and clinical development, 1,226 in sales and marketing, and 467 in administration, human resources, information technology and finance. Our U.S. employees are not represented by any collective bargaining unit, and we regard the relationships with all our employees as satisfactory.

EXECUTIVE OFFICERS OF THE COMPANY

The executive officers of the Company and their respective ages and positions as of February 8, 2018 are as follows:

Name	Position with Alexion	Age
Ludwig Hantson, Ph.D.	Chief Executive Officer	55
Paul J. Clancy	Executive Vice President, Chief Financial Officer	56
Indrani Franchini, J.D.	Executive Vice President, Chief Compliance Officer	46
Brian Goff	Executive Vice President, Chief Commercial Officer	48
Anne-Marie Law	Executive Vice President, Chief Human Resources Officer	50
John Moriarty, J.D.	Executive Vice President, General Counsel	50
Julie O'Neill	Executive Vice President, Global Operations	51
John Orloff, M.D.	Executive Vice President, Head of Research and Development	60
Heidi L. Wagner, J.D.	Senior Vice President, Global Government Affairs	53

John Moriarty, Executive Vice President, General Counsel, and Heidi Wagner, Senior Vice President, Global Government Affairs, have chosen not to relocate to Alexion's new headquarters in Boston, Massachusetts and will be leaving the Company in February of 2018. Effective February 12, 2018, Ellen Chiniara, J.D. will assume the role of Executive Vice President, General Counsel.

Ludwig N. Hantson, Ph.D., is Chief Executive Officer of Alexion. Dr. Hantson is an accomplished healthcare executive with more than 30 years of experience in the biopharmaceutical industry.

Prior to joining Alexion in March 2017, Dr. Hantson was President and Chief Executive Officer of Baxalta and also served on the company's Board of Directors. He led Baxalta's successful spin-off as a public company from Baxter in July 2015 where he was President of Baxter BioScience. Dr. Hantson joined Baxter in May 2010 and established the BioScience division as one of the most innovative specialty and rare disease companies by building a robust pipeline of 25 new product candidates, and launching 13 new products.

Dr. Hantson held several leadership roles during his decade-long tenure at Novartis from 2001-2010, including CEO of Pharma North America, CEO of Europe, and President of Pharma Canada. Prior to Novartis, he spent 13 years with Johnson & Johnson in roles of increasing responsibility in marketing, and research and development.

Dr. Hantson received his Ph.D. in motor rehabilitation and physical therapy, master's degree in physical education, and a certification in high secondary education, all from the University of Louvain in Belgium.

Paul J. Clancy is Executive Vice President, Chief Financial Officer of Alexion. Mr. Clancy is responsible for global financial management, treasury, internal audit, corporate strategy, business development, investor relations, information technology, and security activities.

Prior to joining Alexion in July 2017, Mr. Clancy served as the Executive Vice President, Finance and Chief Financial Officer and a member of the Executive Committee of Biogen, where he led the financial performance of the company. Prior to joining Biogen, Mr. Clancy spent 13 years at PepsiCo, serving in a range of finance, strategy and general management positions. Mr. Clancy serves on the Board of Directors of the biopharmaceutical companies Agios Pharmaceuticals, Inc. and Incyte Corporation.

Mr. Clancy holds an MBA from Columbia University and a Bachelor of Science in Finance from Babson College.

Brian Goff is Executive Vice President, Chief Commercial Officer of Alexion. Mr. Goff leads commercial operations globally with responsibility for country operations in each of Alexion's affiliates in North America, EMEA, Japan, Asia Pacific, and Latin America.

Mr. Goff is a proven global biopharmaceutical executive with a 25-year track record of consistently delivering sustainable growth through multiple business cycles. Prior to joining Alexion in June 2017, Mr. Goff was Chief Operating Officer and a Member of the Board of Directors of Neurovance from December 2016 until its acquisition by Otsuka Pharmaceuticals in March 2017. Prior to joining Neurovance, Mr. Goff served as Baxalta's Executive Vice President & President — Hematology Division from January 2015 to July 2016. He previously served with Baxter Healthcare Corporation as Global Hemophilia Franchise Head from June 2012 to December 2014. Earlier in his career, Mr. Goff held positions of increasing responsibility in sales and marketing roles with Novartis Pharmaceuticals, and the pharmaceutical division of Johnson & Johnson.

Mr. Goff holds an MBA from Wharton at the University of Pennsylvania and a Bachelor of Arts in Economics from Skidmore College.

Indrani Franchini, J.D., is Executive Vice President, Chief Compliance Officer of Alexion. Ms. Franchini is responsible for leading Alexion's global compliance program and co-leads the Global Corporate Compliance Committee.

Ms. Franchini has extensive experience developing and building the infrastructure and company-wide standards for global compliance programs. Prior to joining Alexion in June 2017, Ms. Franchini served as Chief Compliance Officer at Hess Corporation from July 2012 to June 2017. She previously spent nearly ten years with Pfizer overseeing all compliance elements for the development, marketing, and promotion of its global business. Earlier in her career, Ms. Franchini served as an attorney with Milbank, Tweed, Hadley & McCloy in the firm's New York and Tokyo offices.

Ms. Franchini earned her J.D. from the University of Michigan Law School and a Bachelor of Arts from Princeton University. In addition, she spent a year as a Fulbright Fellow at the Kyushu University Graduate School in Fukuoka, Japan.

Anne-Marie Law is Executive Vice President, Chief Human Resources Officer of Alexion. She is responsible for Human Resources on a global basis, with the goal of continuing to build the organization capabilities to advance Alexion's strategy.

Ms. Law brings more than 25 years of experience at global corporations to the organization. Prior to joining Alexion in June 2017, she served as Chief Human Resources Officer at Hyatt Hotels Corporation from October 2016 to May 2017, where she was responsible for building the strategy to support the company's 100,000 employees worldwide, and designing talent systems to create world class leadership and customer connectivity capabilities. From January 2015 to July 2016, she served as Executive Vice President and Head of Human Resources for Baxalta Incorporated, and from April 2009 to December 2014 she held various senior human resources positions at McKesson Corporation, including the Specialty Health Division, VeriSign, and Xilinx, Inc.

Ms. Law is a graduate of Leicester University with a degree in Art History in the United Kingdom and the National College of Ireland, Dublin.

John B. Moriarty, J.D. is Executive Vice President and General Counsel. From December 2012 to September 2014, Mr. Moriarty served as Senior Vice President and General Counsel.

Prior to joining Alexon in December 2012, he 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 from March 2010 to December 2012. 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 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.is Executive Vice President of Global Operations. 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 in February 2014, 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 a member of the Boards of DBV Technologies, 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).

John Orloff, M.D., is Executive Vice President, Head of Research & Development of Alexion. Dr. Orloff is focused on strengthening Alexion's clinical pipeline and research programs, enhancing research and development productivity, overseeing regulatory and medical affairs, and supporting business development. Dr. Orloff has 20 years of experience in the biopharmaceutical industry and deep expertise spanning various stages of clinical and non-clinical development, including developing medicines for rare diseases.

Prior to joining Alexion in June 2017, Dr. Orloff served as Executive Vice President, Head of Research & Development at Novelion from November 2016 to May 2017, where he currently sits on the Board of Directors. From July 2015 to July 2016, he served with Baxalta as Global Head of R&D and Chief Scientific Officer, where he advanced the company's pipeline and oversaw regulatory approval of 10 unique products and two devices. He also held executive R&D roles with Baxter International from July 2014 to June 2015, Merck Serono from January 2014 to May 2014, Novartis from April 2003 to October 2013 and Merck Research Laboratories. Prior to joining the biopharmaceutical industry in 1997, Dr. Orloff was with the Yale School of Medicine for seven years.

Dr. Orloff received a Bachelor of Arts from Dartmouth College, and a M.D. from the University of Vermont College of Medicine. He completed his medical training at the University of Pittsburgh Medical Center and Yale University School of Medicine.

Heidi L. Wagner, J.D., is 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 in September 2009, 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 U.S. 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 Strensiq are small and have not been definitively determined, we must be able to successfully identify patients in order to maintain growth.

Kanuma and Strensiq 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 Strensiq, 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. 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 heading “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”.

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, gMG or all indications. In 2017, Soliris was approved in the U.S., EU and Japan as a treatment for adult patients with gMG who are anti-acetylcholine receptor antibody-positive. 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 gMG, or provide a lower level of coverage or reimbursement than anticipated or currently in effect.

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 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. In September 2017, we announced our intention to close ARIMF. 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 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 all 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 of 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. In October 2017, the FDA notified Alexion that the Warning Letter has been resolved. If we had failed to address the FDA's concerns, the FDA or other regulatory authorities could have taken 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 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. 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 whom we do not control, 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, which we have commenced.

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, 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 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, aHUS and gMG 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. Soliris for the treatment of gMG was approved in 2017. 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 FCA, the anti-kickback provisions of the federal Social Security Act, and other related federal and state laws and regulations. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind to induce, or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any 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. 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. Other related federal and state laws and regulations that may affect our ability to operate include, among others, the federal False Statements Statute, the federal Civil Monetary Penalties Law, HIPAA, the federal Open Payments program, state anti-kickback and false claims acts, and state and local disclosure requirements and marketing restrictions. Additional information about the scope of these requirements is offered in the "Fraud and Abuse" section.

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). Any action against us for violation of these laws, even if we successfully defend against it, could require the expenditure of significant resources and generate negative publicity, which could materially

adversely affect our ability to operate our business and our financial results.

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.

The EU and EU Member States impose 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.

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 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, Alexion’s provision of free drug to Medicare patients and

Alexion’s related compliance policies and training materials. We understand that the U.S. Attorney's Office is coordinating its inquiry with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services. In May 2017, Brazilian authorities seized records and data from our Sao Paulo, Brazil offices as part of an investigation being conducted into Alexion's Brazilian operations. 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 ongoing investigations of our compliance with the FCPA, Medicare patient assistance rules, regulations in Brazil, 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, including exclusion from Medicare, Medicaid, and other governmental healthcare programs. Additionally, remediation of any such findings could have an adverse effect on our business operations, and 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 requests for information in connection with these ongoing investigations, 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 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. 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 is dependent on the availability of meaningful legal remedies in each country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or loss of such rights, could be material to our business. In some countries, patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents or we did not file patents in those markets. Also, the patent environment is unpredictable and the validity and enforceability of patents cannot be predicted with certainty. Absent relevant patent protection for a product, once regulatory exclusivity periods expire, biosimilar or generic versions of the product can be approved and marketed. Even prior to the expiration of regulatory exclusivity, a competitor could seek to obtain marketing approval by submitting its own clinical trial data.

The market exclusivity of our products may be impacted by competitive products that are either innovative or biosimilar or generic copies. In our

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

Risks Related to Our Operations

We may not accurately forecast demand for our products, including our new products, which may cause our operating results to fluctuate, and we cannot guarantee that we will achieve our financial goals, including our ability to maintain profitability on a quarterly or annual basis in the future.

We have maintained profitability on a quarterly basis since the quarter ended June 30, 2008 and on an annual basis beginning with the year ended December 31, 2008. Our quarterly revenues, expenses and net income (loss) may fluctuate, even significantly, due to the risks described in these "Risk Factors" as well as the timing of charges and expenses that we may take. We believe that we formulate our annual operating budgets with reasonable assumptions and targets, however we may not generate sufficient revenues or control expenses to achieve our financial goals, including continued profitability. We may not be able to sustain or increase profitability on a quarterly or annual basis. You should not consider our financial performance, including our revenue growth, in recent periods as indicative of our future performance. We may not accurately forecast demand for our products, especially Strensiq and Kanuma and Soliris for the treatment of gMG. 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. Soliris for the treatment of gMG was approved in 2017. 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 pipeline and continue to launch our second and third products and our third indication for Soliris 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.

Other than Soliris for the treatment of gMG, 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, and is the only approved complement inhibition therapy for the treatment of AChR antibody-positive gMG. We are in advanced clinical studies of Soliris for the treatment of NMOD, and there are currently no approved drugs for this indication. 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, aHUS, MG and NMOSD, 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 achieve the expected financial and operating benefits of our corporate restructuring, our business and financial results may be harmed.

We have undertook broad corporate restructuring activities in 2017 to re-align our global organization with the Company's re-focused strategy, reduce costs, and realize operational efficiencies. These activities, including a work force reduction of more than 20.0% and plans to close certain operational sites, subject the Company to many risks, including loss of business continuity, unanticipated costs, and higher than usual employee turnover. The expected cost savings and operational efficiencies from the restructuring activities are based on assumptions and expectations, which are reasonable in our judgment but may not be achieved due to unforeseen difficulties and challenges that are beyond

our control. If these assumptions and expectations are incorrect or if we experience delays or unforeseen events in realizing the benefits of the restructuring activities, our business operations and financial results may be harmed.

As we implement the restructuring, we must execute on our re-focused strategy, including growing and maximizing our rare disease business and pursuing disciplined business development to expand our pipeline. If we are unable to effectively execute with fewer human resources and/or attract, retain or motivate key employees, our business may be adversely affected.

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 March 2017, our Board appointed a new CEO and we have experienced other recent management changes. In addition, in 2017, we announced a relocation of the Company’s global headquarters from New Haven, CT to Boston, MA in 2018 and we began a company-wide restructuring to re-align our global organization with the Company's re-focused strategy. We will need to fill open positions resulting from employees who do not relocate to Boston. The relocation and restructuring have the potential to adversely impact our ability to recruit and/or retain key employees as well as to disrupt our business operations, financial conditions, programs, plans and strategies.

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 (as defined below) 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, 2017, the net carrying value of our goodwill and other intangible assets totaled $8,991.8. As required by generally accepted accounting principles, we periodically assess these assets to determine if there are indicators of impairment. Impairment of intangible assets may be

triggered by developments both within and outside our control. Deteriorating economic conditions, technological changes, disruptions to our business, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in use of the assets, intensified competition, divestitures, market capitalization declines and other factors may impair our goodwill and other intangible assets. Any charges relating to such impairments could adversely affect our results of operations in the periods in which an impairment is recognized.

As part of our standard quarterly procedures, we reviewed the Kanuma asset as of December 31, 2017 and determined that there were no indicators of impairment. We will continue to review the related valuation and accounting of this asset in future quarters as new information becomes available to us. Changes to assumptions used in our net cash flow projections may result in impairment charges in subsequent periods. The net book value of the Kanuma intangible asset as of December 31, 2017 is $3,512.8.

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 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. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief, and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations. In addition, 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,

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 certain current and former executives and Board members, and we could also become subject to legal proceedings and government investigations relating to matters addressed in the Audit Committee Investigation. In May 2017, Brazilian authorities seized records and data from our Sao Paulo, Brazil offices as part of an investigation being conducted into Alexion's Brazilian operations. 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 IRS, 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, certain governments are considering and may adopt tax reform measures that significantly increase our worldwide tax liabilities. The Organization for Economic Co-operation and Development and other government bodies have focused on issues related to the taxation of multinational corporations, including, in the area of "base erosion and profit shifting," where payments are made from affiliates in jurisdictions with high tax rates to affiliates in jurisdictions with lower tax rates. It is possible that these reform measures could increase our effective tax rate and harm our financial position and results of operations over the next several years.

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. Any determination that our operation or activities are not in compliance with existing laws or regulations, including the FCPA, could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief, and/or other sanctions against us, and remediation of such findings could have an adverse effect on our business 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. 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.

Certain legislative changes to and regulatory changes under PPACA have occurred in the 115th U.S. Congress and under the Trump Administration. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate, beginning in 2019. Additional legislative changes to and regulatory changes under PPACA remain possible.

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.

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate Program and we have obligations to report the average sales price

under the Medicare program. Under the Medicaid Drug Rebate Program, 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, in the case of innovator products, the best price for each drug. Any failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results.

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. 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 our products-from the ceiling price requirements for these newly-eligible entities. 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, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Any changes to the definition of average manufacturer price and the Medicaid rebate amount also could affect our 340B ceiling price calculation for our products and could negatively impact our results of operations.

PPACA obligates the Secretary of the Health and Human Services (HHS) to update the agreement that manufacturers must sign to participate in the 340B pricing program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration (HRSA) recently updated the agreement with participating manufacturers. PPACA also obligates the Secretary of HHS to create regulations and processes to improve the integrity of the 340B program. On January 5, 2017, HRSA issued

a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The effective date of the regulation has been delayed until July 1, 2018. Implementation of this final rule and the issuance of any other final regulations and guidance could affect our obligations under the 340B pricing program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B pricing program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

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. 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 pricing 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, civil monetary penalties can be applied if we are found to have knowingly submitted any false pricing information to the government, if we are found to have made a misrepresentation in the

reporting of our average sales price, or if we fail to submit the required pricing data on a timely basis. Such conduct 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.

Federal law requires that a company must participate in the VA 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., numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Each of these laws is 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 or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by 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 imposes strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from different EU Member States 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 in all EU Member States on 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, “hacktivists,” 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, 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 of Directors, the President, the Secretary, or a majority of the Board of Directors, or upon the written request of stockholders who together own of record 25.0% 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 15.0% 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 15.0% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Item 1B. UNRESOLVED STAFF COMMENTS.

None.

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Item 2. PROPERTIES.

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

Location	Operations Conducted	Approximate Square Feet	Lease Expiration Dates
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
Bogart, Georgia	Commercial, research and development manufacturing	70,000	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 April 2014, we purchased a fill/finish facility in Athlone, Ireland, which has been refurbished to become our first company-owned fill/finish facility. In July 2016, we announced plans to construct a new biologics manufacturing facility at this site, which is expected to be completed and receive regulatory approval in 2019.

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 and receive regulatory approval in 2020.

In September 2017, we entered into a lease agreement for approximately 150,000 square feet of office space that is currently being constructed in Boston, Massachusetts which will be the Company’s new corporate headquarters once completed. The term of the lease will commence upon the landlord's substantial completion of our premises and will expire on the thirteenth anniversary of commencement, with an option to renew for up to an additional ten years. Construction is expected to be completed in the second quarter of 2018. We are currently leasing temporary office space in Boston until our new corporate headquarters is complete.

In September 2017, we announced our intention to close ARIMF. During the fourth quarter 2017, we began to actively market the facility to potential buyers. We do not expect the closing of the ARIMF facility to impact our clinical or commercial supply of inventory.

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.

The investigations have focused on operations in various countries, including Brazil, Colombia, Japan, Russia and Turkey, and Alexion's compliance with the FCPA and other applicable laws.

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 any such loss or range of loss, or the cost of the ongoing investigation. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief, and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Alexion is committed to strengthening its compliance program and has initiated a comprehensive company-wide transformation plan to enhance and remediate its business processes, structures, controls, training, talent and systems across Alexion's global operations. For information concerning the risks associated with the investigation, see our Risk Factor - "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."

As previously reported, on December 29, 2016, a 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. On April 12, 2017, the court appointed a lead plaintiff. On July 14, 2017, the lead plaintiff filed an amended putative class action complaint against the Company and seven current or former employees. The complaint alleges that defendants made misrepresentations and omissions about Soliris, including alleged misrepresentations regarding sales practices, management changes, and related investigations, between January 30, 2014 and

May 26, 2017, and that the Company's stock price dropped upon the purported disclosure of the misrepresentations. Defendants moved to dismiss the amended complaint on September 12, 2017. Plaintiffs filed an opposition to defendants' motion to dismiss on November 13, 2017, and defendants' filed a reply brief in further support of their motion on December 28, 2017. Defendants' motion to dismiss is now fully briefed and pending before the court. 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. We understand that the U.S. Attorney's Office is coordinating its inquiry with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services. Other companies have disclosed similar inquiries. We are cooperating with this inquiry.

In May 2017, Brazilian authorities seized records and data from our Sao Paulo, Brazil offices as part of an investigation being conducted into Alexion's Brazilian operations. We are cooperating with this inquiry.

In June 2017, we received a demand to inspect certain Company books and records pursuant to Section 220 of the General Corporation Law of the State of Delaware on behalf of a purported stockholder. Among other things, the demand sought to determine whether to institute a derivative lawsuit against certain of the Company's directors and officers in relation to the investigation by our Audit and Finance Committee announced in November 2016 and the investigations instituted by the SEC, DOJ, U.S. Attorney's Office for the District of Massachusetts, and Brazilian law

enforcement officials that are described above. The Company has responded to the demand. Given the early stages of this matter, 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.

On September 22, 2017, a shareholder filed a derivative suit on behalf of the Company, in the U.S. District Court for the District of Delaware against

eighteen current and former employees and members of the Board of Directors, naming the Company as a nominal defendant. The complaint, which asserts federal and state law claims, alleges that between January 30, 2014 and September 22, 2017 defendants made misrepresentations and omissions about Soliris-including alleged misrepresentations regarding sales practices, management changes, and related investigations-in violation of federal securities law and in breach of their fiduciary duties to the Company. The litigation is in the early stages, and defendants have not yet responded to the complaint.

On September 27, 2017, a hearing panel of the Canadian Patented Medicine Prices Review Board (PMPRB) issued a decision in a previously pending administrative pricing matter that Alexion had excessively priced Soliris in a manner inconsistent with the Canadian pricing rules and guidelines. In its decision, the PMPRB ordered Alexion to decrease the price of Soliris to an upper limit based upon pricing in certain other countries, and to forfeit excess revenues for the period between 2009 and 2017. The amount of excess revenues was not material amount. In October 2017, Alexion filed an application for judicial review of the PMPRB's decision in the Federal Court of Canada. At this time, we cannot predict the duration, scope or outcome of these judicial review proceedings or any appeals that may follow and cannot reasonably estimate the amount of any potential impact to Soliris revenues in Canada relating to any potential future price reduction.

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, 2016.

Fiscal 2016	High	Low
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
Fiscal 2017	**High**	**Low**
First Quarter (January 1, 2017 to March 31, 2017)	$145.00	$115.58
Second Quarter (April 1, 2017 to June 30, 2017)	$133.67	$96.18
Third Quarter (July 1, 2017 to September 30, 2017)	$149.34	$117.17
Fourth Quarter (October 1, 2017 to December 31, 2017)	$144.91	$105.01

As of January 31, 2018, we had approximately 103 stockholders of record of our common stock and an estimated 165,638 beneficial owners. The closing sale price of our common stock on January 31, 2018 was $119.32 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 2017:

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, 2017	—	$—	—	701.5
November 1-30, 2017	—	—	—	701.5
December 1-31, 2017	1.5	113.85	1.5	536.4
Total	1.5	$113.85	1.5	

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 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 8, 2018, there is a total of $451.4 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	5.3	$124.71	5.30	19.5
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 2017 Incentive Plan. Does not include 3.6 restricted shares outstanding that were issued under the 2017 Incentive plan and the previous Amended and Restated 2004 Incentive Plan.

(2) Of these shares, 18.7 remain available for future issuance under the 2017 Incentive Plan and 0.8 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, 2012 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

	12/12	12/13	12/14	12/15	12/16	12/17
Alexion Pharmaceuticals, Inc.	100.00	141.76	197.39	203.49	130.52	127.58
Nasdaq Composite	100.00	141.63	162.09	173.33	187.19	242.29
Nasdaq Biotechnology	100.00	174.05	230.33	244.29	194.95	228.29

Item 6. SELECTED FINANCIAL DATA.
(amounts in millions, except per share amounts)

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.

Consolidated Statements of Operations Data:

	Year Ended December 31,				
	2017	2016	2015	2014	2013
Net product sales [1]	$3,549.5	$3,081.7	$2,602.5	$2,233.7	$1,551.3
Other revenue	1.6	2.4	1.5	—	—
Total revenues	3,551.1	3,084.1	2,604.0	2,233.7	1,551.3
Cost of sales:					
Cost of sales [2]	454.2	258.3	233.1	173.9	168.4
Change in contingent liability from intellectual property settlements		—	—	—	9.2
Total cost of sales	454.2	258.3	233.1	173.9	177.6
Operating expenses:					
Research and development	878.4	757.2	709.5	513.8	317.1
Selling, general and administrative	1,094.4	953.0	862.6	630.2	489.7
Amortization of purchased intangible assets [3]	320.1	322.2	116.6	—	0.4
Change in fair value of contingent consideration	41.0	35.7	64.2	20.3	4.0
Acquisition-related costs	—	2.3	39.2	—	1.0
Restructuring expenses [2]	104.6	3.0	42.1	15.3	—
Impairment of intangible assets	31.0	85.0	—	11.5	33.5
Total operating expenses	2,469.5	2,158.4	1,834.2	1,191.1	845.7
Operating income	627.4	667.4	536.7	868.7	528.0
Other income (expense)	(79.6)	(91.2)	(38.6)	3.4	(1.7)
Income before income taxes	547.8	576.2	498.1	872.1	526.3
Income tax expense [4] [5] [6] [7]	104.5	176.8	353.7	215.2	273.4
Net income	$443.3	$399.4	$144.4	$656.9	$252.9
Earnings per common share					
Basic	$1.98	$1.78	$0.68	$3.32	$1.29
Diluted	$1.97	$1.76	$0.67	$3.26	$1.27
Shares used in computing earnings per common share					
Basic	223.9	224.3	213.4	198.1	195.5
Diluted	225.4	226.3	215.9	201.6	199.7

Consolidated Balance Sheet Data:

	As of December 31,				
	2017	2016	2015	2014	2013
Cash, cash equivalents and marketable securities	$1,474.1	$1,293.4	$1,385.0	$1,961.6	$1,514.9
Total assets [8]	13,583.3	13,253.3	13,097.9	4,202.0	3,317.7
Long-term debt (current and noncurrent) [9]	2,888.1	3,055.1	3,420.9	57.5	113.0
Contingent consideration (current and noncurrent)	168.9	152.9	177.2	163.0	142.7
Facility lease obligation (current and noncurrent)	353.3	243.4	151.3	107.1	32.2
Total stockholders' equity[10]	8,893.1	8,693.8	8,258.6	3,302.0	2,382.1

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

[1] In March 2014, we entered into an agreement with the French government which positively impacted prospective reimbursement of Soliris and also provided for reimbursement for shipments made in years prior to January 1, 2014. As a result of the agreement, in 2014 we recognized $87.8 of net product sales from Soliris in France relating to years prior to January 1, 2014.
[2] In 2017, we committed to an operational plan to re-align the global organization with its refocused corporate strategy. As a result of this re-alignment, in 2017, we recorded additional asset related charges of $152.1 associated with the planned closure of the ARIMF facility to cost of sales. These charges primarily relate to accelerated depreciation and the impairment of manufacturing assets. Additionally, the re-alignment in 2017 resulted in restructuring expenses of $104.6, primarily related to employee separation costs.
[3] 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.
[4] In 2017, we recognized tax expense of $45.8 as a result of the Tax Cuts and Jobs Act. Certain impacts of the Tax Act have been recorded on a provisional basis. See Note 11, "Income Taxes" for additional information.
[5] In 2016, we recognized deferred tax expense of $119.3 associated with the distribution of earnings from our captive foreign partnership.
[6] In connection with the integration of the Synageva business with and into the Alexion business, we incurred a one-time tax expense of $315.6 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.
[7] In 2013, we recognized tax expense of approximately $95.8 resulting from the centralization of our global supply chain and technical operations in Ireland.
[8] In connection with the acquisition of Synageva, we acquired $4,236.0 of intangible assets and $4,783.4 of goodwill.
[9] In connection with the acquisition of Synageva, we borrowed $3,500.0 under our term loan under a new credit facility.
[10] In connection with the acquisition of Synageva, we issued $4,917.8 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

Alexion Pharmaceuticals, Inc. (Alexion, the Company, we, our or us) is a global biopharmaceutical company focused on serving patients and families affected by rare diseases through the innovation, development and commercialization of life-changing therapies.

We are the global leader in complement inhibition and have developed and commercialize the first and only approved complement inhibitor to treat patients with paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), and anti-acetylcholine receptor (AChR) antibody-positive generalized myasthenia gravis (gMG). In addition, Alexion has two highly innovative enzyme replacement therapies for patients with life-threatening and ultra-rare metabolic disorders, hypophosphatasia (HPP) and lysosomal acid lipase deficiency (LAL-D).

As the leader in complement biology for over 20 years, Alexion focuses its research efforts on novel molecules and targets in the complement cascade, and its development efforts on the core therapeutic areas of hematology, nephrology, neurology, and metabolic disorders.

Recent Developments

In the first half of 2017, we announced the following key additions to our executive leadership team.

- Ludwig N. Hantson, Ph.D., Chief Executive Officer
- Paul Clancy, Chief Financial Officer
- Indrani Franchini, J.D., Chief Compliance Officer
- Brian Goff, Chief Commercial Officer
- Anne-Marie Law, Chief Human Resource Officer
- John Orloff, M.D., Head of Research & Development

In the first quarter of 2017, we initiated a company-wide restructuring designed to help position the Company for sustainable, long-term growth that we believe will further allow us to fulfill our mission of serving patients and families with rare diseases. The initial restructuring activities primarily focused on a reduction of the Company's global workforce. In September 2017, we committed to an operational plan to re-align the global organization with its refocused corporate strategy. The re-alignment focuses investments in priority growth areas to maximize leadership in complement and grow the rare disease business. The re-alignment also includes the relocation of the Company's headquarters to Boston, Massachusetts in 2018. Our New Haven, Connecticut site will continue to support employees working in the research and process development laboratories, the clinical supply and quality teams, nurse case management and a number of important enterprise business services. The plan is expected to further reduce the Company's global workforce by approximately 20.0% over the next twelve months. The restructuring will achieve cost savings by focusing the development portfolio, simplifying business structures and processes across the Company's global operations, and closing of multiple Alexion sites, including the Company's Rhode Island manufacturing facility (ARIMF) and certain regional and country-based offices.

In March 2013, we received a Warning Letter (Warning Letter) from the U.S. Food and Drug Administration (FDA) regarding compliance with current Good Manufacturing Practices (cGMP) at ARIMF. In October 2017, Alexion received a notification from the FDA that the Warning Letter had been resolved. As previously announced, we plan to close ARIMF to align our manufacturing facilities with our ongoing multi-product network manufacturing strategy, which utilizes manufacturing operations in the U.S. and Ireland, and manufacturing capacity through manufacturing partners.

In October 2017, the FDA approved Soliris as a treatment for adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine

receptor (AchR) antibody-positive. Additionally, in August 2017, the European Commission (EC) approved the extension of the indication for Soliris to include the treatment of refractory gMG in adults who are AchR antibody-positive.

In December 2017, the Ministry of Health, Labour and Welfare (MHLW) in Japan approved Soliris as a treatment for patients with gMG who are AChR antibody-positive and whose symptoms are difficult to control with high-dose intravenous immunoglobulin therapy or plasmapheresis.

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 our customers. 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.

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.

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.

Historically, we deferred revenue recognition for sales to certain international customers, mainly distributors, until the product was received by the end customer due to various factors, including our inability to estimate product returns. On a regular basis, we review revenue arrangements, including our distributor relationships, to determine whether any changes in these arrangements or historical experience with these customers have an impact on revenue recognition. In the first quarter 2017, we determined that we had sufficient sales experience with certain customers to estimate product returns from such customers. We accounted for this prospectively as a change in estimate and began to recognize revenue for these customers when title to the product and the associated risk of loss passed to the customer. Some customers purchase larger quantities of product less frequently, which may result in revenue fluctuations from

quarter to quarter. We do not believe these buying patterns increase the risk of product returns or our ability to estimate such returns.

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 have provided balances and activity in the rebates payable account for the years ended December 31, 2017, 2016 and 2015 as follows:

	Rebates Payable
Balance at December 31, 2014	$ 36.8
Current provisions relating to sales in current year	89.3
Adjustments relating to prior years	(1.8)
Payments/credits relating to sales in current year	(42.8)
Payments/credits relating to sales in prior years	(25.9)
Balance at December 31, 2015	$ 55.6
Current provisions relating to sales in current year	114.6
Adjustments relating to prior years	(1.7)
Payments/credits relating to sales in current year	(50.3)
Payments/credits relating to sales in prior years	(48.7)
Balance at December 31, 2016	$ 69.5
Current provisions relating to sales in current year	193.8
Adjustments relating to prior years	(4.5)
Payments/credits relating to sales in current year	(97.4)
Payments/credits relating to sales in prior years	(62.3)
Balance at December 31, 2017	$ 99.1

Current provisions relating to sales in the current year increased by $79.2 in 2017 compared to 2016 and $25.3 in 2016 compared to 2015. These increases were primarily due to increased unit volumes in the U.S. and Europe which were subject to rebates. The increase in 2017 was also attributable to increases in rebate rates in certain geographical regions and on certain product sales as compared to the prior year.

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.

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.

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 2017 Incentive Plan (2017 Plan) and (ii) the 2015 Employee Stock Purchase Plan (ESPP). The 2017 Plan replaced the Amended & Restated 2004 Incentive Plan, effective May 10, 2017. Under the 2017 Plan, restricted stock, restricted stock units, stock options and other stock-related awards may be granted to our directors, officers, employees and consultants or advisors of the Company or any subsidiary. Under the ESPP, eligible employees can purchase shares of common stock at a discount semi-annually through payroll deductions. To date, share-based compensation issued under the plans consists of incentive and non-qualified stock options, restricted stock and restricted stock units, including restricted stock units with market and non-market performance conditions, and shares issued under our ESPP.

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

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

On December 22, 2017, the Tax Cuts and Jobs Act (Tax Act) was enacted into law. The Tax Act decreased the U.S. statutory corporate tax rate for years beginning after December 31, 2017, and included other domestic and international tax provisions that affect the measurement of our deferred tax assets and liabilities. As a result, we revalued our deferred tax assets and liabilities as of December 31, 2017 and recorded a deferred tax benefit of $292.4. Other impacts of the Tax Act have been recorded on a provisional basis, see Note 11, “Income Taxes” for additional information.

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 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 IRS 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. We will adopt the new standard in the first quarter 2018 using the modified retrospective method. We have reviewed the new standard and have not identified any accounting changes that will materially impact the recognition of our net product sales. We have also completed our review and analysis of customer contracts and determined that the impact of adopting the new standard in the first quarter 2018 will not be material to our financial position and results of operations. We are implementing changes to our accounting policies, internal controls and disclosures to support the new standard; however, these changes will not be significant.

In January 2016, the FASB issued a new standard that changes accounting for equity investments, financial liabilities under the fair value option, and presentation and disclosure requirements for financial instruments. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. Equity investments with readily determinable fair values will be measured at fair value with changes in fair value recognized in net income. Companies have the option to either measure equity investments without readily determinable fair values at fair value or at cost adjusted for changes in observable prices minus impairment. We have elected to measure equity investments without readily determinable fair values at cost adjusted for changes in observable prices minus impairment, which will be recognized in net income. This standard is effective for interim and annual periods beginning after December 15, 2017. The guidance related to equity investments without readily determinable fair values should be applied prospectively to equity investments that exist as of the date of adoption. The adoption of this standard may increase volatility in our net income as changes in observable prices of equity investments without readily determinable fair values

will be recorded in net income and could have a material impact on our consolidated financial statements and related disclosures.

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. 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. The amendments also require recognition of excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. 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 early adopt this standard in the third quarter of 2016. We 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 income tax standard that eliminates the exception for an intra-entity asset transfer other than inventory. Under

the new standard, entities should recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. Any deferred tax asset that arises in the buyer's jurisdiction would also be recognized at the time of the transfer. We elected to early adopt this standard in the first quarter 2017. As a result of the adoption, in the first quarter of 2017, we recorded an $18.8 decrease in retained earnings, primarily resulting from the elimination of previously recorded prepaid tax assets.

In January 2017, the FASB issued a new standard that clarifies the definition of a business and determines when an integrated set of assets and activities is not a business. This framework requires that if substantially all of the fair value of gross assets acquired or disposed of is concentrated in a single asset or group of similar identifiable assets, the assets would not represent a business. The standard is effective for interim and annual periods beginning after December 15, 2017 with early adoption permitted. We anticipate that the adoption of this new standard will result in more transactions being accounted for as asset acquisitions.

In August 2017, the FASB issued a new standard intended to improve and simplify certain aspects of the accounting for hedges. The new standard is intended to more closely align hedge accounting with companies’ risk management strategies, simplify the application of hedge accounting, and increase transparency as to the scope and results of hedging programs. It also amends the presentation and disclosure requirements and changes how companies assess effectiveness. The standard is effective for interim and annual periods beginning after December 15, 2018 with early adoption permitted. 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,		
	2017	2016	2015
Net product sales	$3,549.5	$3,081.7	$2,602.5
Other revenue	1.6	2.4	1.5
Total revenues	3,551.1	3,084.1	2,604.0
Cost of sales	454.2	258.3	233.1
Operating expenses:			
Research and development	878.4	757.2	709.5
Selling, general and administrative	1,094.4	953.0	862.6
Amortization of purchased intangible assets	320.1	322.2	116.6
Change in fair value of contingent consideration	41.0	35.7	64.2
Acquisition-related costs	—	2.3	39.2
Restructuring expenses	104.6	3.0	42.1
Impairment of intangible assets	31.0	85.0	—
Total operating expenses	2,469.5	2,158.4	1,834.2
Operating income	627.4	667.4	536.7
Other expense	(79.6)	(91.2)	(38.6)
Income before income taxes	547.8	576.2	498.1
Income tax expense	104.5	176.8	353.7
Net income	$443.3	$399.4	$144.4
Earnings per common share:			
Basic	$1.98	$1.78	$0.68
Diluted	$1.97	$1.76	$0.67

Comparison of the Years Ended December 31, 2017, 2016, and 2015

Net Product Sales

Net product sales by product and significant geographic region are as follows:

	Year Ended December 31,			% Change	
	2017	2016	2015	2017 compared to 2016	2016 compared to 2015
Soliris					
United States	$1,235.0	$1,058.5	$943.6	16.7 %	12.2 %
Europe	985.2	939.7	838.3	4.8 %	12.1 %
Asia Pacific	328.1	303.8	274.0	8.0 %	10.9 %
Rest of World	595.8	541.2	534.3	10.1 %	1.3 %
	$3,144.1	2,843.2	2,590.2	10.6 %	9.8 %
Strensiq					
United States	$280.1	$177.5	$7.7	57.8 %	**
Europe	35.6	15.3	1.7	132.7%	**
Asia Pacific	18.6	13.0	2.4	43.1 %	**
Rest of World	5.5	3.6	0.1	52.8 %	**
	339.8	209.4	11.9	62.3 %	**
Kanuma					
United States	$42.4	$20.4	$—	107.8%	N/A
Europe	14.6	6.3	0.4	131.7%	**
Asia Pacific	2.7	1.3	—	107.7%	N/A
Rest of World	5.9	1.1	—	**	N/A
	$65.6	29.1	0.4	125.4%	**
Total Net Product Sales	$3,549.5	$3,081.7	$2,602.5	15.2 %	18.4 %

** Percentages not meaningful

Net Product Sales (consolidated)

United States Asia Pacific
Europe Rest of World

Soliris net product sales

United States Asia Pacific
Europe Rest of World

Strensiq net product sales
United States Asia Pacific
Europe Rest of World

Kanuma net product sales
United States Asia Pacific
Europe Rest of World

The components of this increase in net product sales for December 31, 2017 as compared to 2016 are as follows:

The increase in net product sales for fiscal year 2017, as compared to the same period in 2016, was primarily due to an increase in unit volumes of 16.8%. This increase in unit volumes is due to increased global demand for Soliris therapy for patients with PNH or aHUS, as well as increased sales of Strensiq and Kanuma during 2017 as a result of our continuing efforts to identify and reach more patients with HPP and LAL-D globally.
The components of this increase in revenues for the year ended December 31, 2016 as compared to the same period in 2015 are as follows:

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 21.8% 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 offset by the negative impact on foreign exchange of 2.9%, for the year ended December 31, 2016, as compared to the same period in 2015. The negative impact on foreign exchange of $74.2, or 2.9%, 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 $73.0 and $117.9 related to our foreign currency cash flow hedging program, for the years ended December 31, 2016 and 2015, respectively.

We have historically deferred revenue recognition for sales to certain international customers, mainly distributors, until the product was received by the end customer due to various factors, including our inability to estimate product returns. On a regular basis, we review revenue arrangements, including our distributor relationships, to determine whether any changes in these arrangements or historical experience with these customers have an impact on revenue recognition. In the first quarter 2017, we determined that we had sufficient sales experience with certain customers to estimate product returns from such customers. As a result, we began to recognize revenue for these customers when title to the product and the associated risk of loss passed to the customer. Some customers may purchase larger quantities of product less frequently, which may result in revenue fluctuations from quarter to quarter.

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 years ended December 31, 2017, 2016 and 2015:

The increase in cost of sales for the year ended December 31, 2017, as compared to the same periods in 2016, was primarily due to additional asset related charges of $152.1 associated with the planned closure of the ARIMF facility that was announced in the third quarter of 2017 as part of the restructuring. These charges primarily relate to accelerated depreciation and the impairment of manufacturing assets.

In the first quarter 2015, we recorded an expense of $24.4 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.

Exclusive of the items mentioned above, cost of sales as a percentage of net product sales were

8.5%, 8.4% and 8.0% for the years ended December 31, 2017, 2016 and 2015, respectively.

We expect our cost of sales to decrease as a percentage of sales in 2018 as compared to 2017 due to the impact of the restructuring related additional asset charges in 2017.

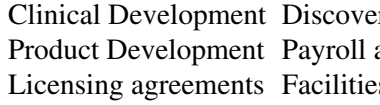
Research and Development Expense

Our research and development expense includes personnel, facility and direct costs associated with the research and development (R&D) of our product candidates, as well as product development costs.

Direct expenses are comprised of costs paid 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, ALXN1210 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 and other administrative costs incurred during product development. 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.

Other R&D expenses consist of costs to compensate personnel, to maintain our facilities and equipment, and other occupancy costs associated with 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 graph provides information regarding research and development expenses:



During the year ended December 31, 2017, we incurred R&D expenses of $878.4, an increase of $121.2, or 16.0%, versus the $757.2 incurred during the year ended December 31, 2016. The increase was primarily related to the following:

- Increase of $23.0 in direct clinical development expenses relates primarily to the expansion of studies for ALXN1210.
- Increase of $37.2 in direct product development expenses related primarily to an increase in costs associated with the manufacturing of material for ALXN1210 and ALXN6000 clinical research activities.
- Increase of $39.9 in licensing agreement expenses related to upfront payments made in the fourth quarter of 2017 related to a collaboration and license agreement with Halozyme Therapeutics, Inc.
- Increase of $16.9 in payroll and benefits related primarily to increased bonus performance and stock compensation expense.
- Increase of $17.4 in facilities and other expenses related primarily to accelerated depreciation on assets that support R&D activities associated with the 2017 restructuring activities.

During the year ended December 31, 2016, we incurred research and development expenses of $757.2, an increase of $47.7, or 6.7%, versus the $709.5 incurred during the year ended December 31, 2015. The increase was primarily related to the following:

- Increase of $52.6 in direct clinical development expenses related primarily to an expansion of studies for ALXN1210, sebelipase alfa, and eculizumab.
- Increase of $47.8 in direct 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 $9.8 in discovery research expenses primarily related to increases in external research expenses associated with our collaboration agreements.
- Increase of $55.7 in payroll and benefit 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.
- Decrease of $120.2 in licensing agreement expenses related to upfront payments made in the first quarter 2015.

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

2017 2016 2015

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

(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) Unallocated 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 decrease as a percentage of sales in 2018 as compared to 2017. For additional information on our development 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:
Salary, benefits and other labor expense
External selling, general and administrative expense

During the year ended December 31, 2017, we incurred selling, general and administrative expenses of $1,094.4, an increase of $141.4, or 14.8%, versus the $953.0 incurred during the year ended December 31, 2016. The increase was primarily related to the following:
- Increase in salary, benefits and other labor expenses of $81.5, primarily related to increase of commercial activities to support the continued global launches of Strensiq and Kanuma and the launch of Soliris for gMG. Employee related costs associated with executive leadership changes and incentive compensation also increased.
- Increase in external selling, general and administrative expenses of $59.9. The increase was primarily due to an increase in charitable contributions and additional professional services, offset in part by decreases in advertising and promotional cost as compared to 2016. The increase was also due to asset impairment charges that were recorded in 2017 related to restructuring activities.

During the year ended December 31, 2016, we incurred selling, general and administrative expenses of $953.0, an increase of $90.4, or 10.5%, versus the $862.6 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 $83.9. 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 decrease as a percentage of sales in 2018 as compared to 2017.

Amortization of Purchased Intangible Assets

Amortization expense associated with purchased intangible assets was $320.1, $322.2 and $116.6 for the years ended December 31, 2017, 2016 and 2015, respectively. Amortization expense is primarily associated with intangible assets related to Strensiq and Kanuma. In the third quarter 2015, we received regulatory approval for Strensiq and Kanuma.

Change in Fair Value of Contingent Consideration

For the years ended December 31, 2017, 2016 and 2015, the change in fair value of contingent consideration expense associated with our prior business combinations was $41.0, $35.7 and $64.2, respectively. The change in the fair value of contingent consideration will fluctuate based on the timing of recognition of changes in the probability of achieving and the expected timing of milestone payments. For

the year ended December 31, 2017, changes in the fair value of contingent consideration expense primarily reflect changes in the expected timing of payments of contingent consideration, as well as the interest component of contingent consideration related to the passage of time.

Acquisition-related Costs

For the years ended December 31, 2017, 2016 and 2015, acquisition-related costs associated with our business combinations included the following:

Transaction Costs Integration Costs

Acquisition-related costs for the years ended December 31, 2016 and 2015 resulted from the acquisition of Synageva in 2015.

Restructuring Expenses

In the first quarter of 2017, we initiated a company-wide restructuring designed to help position the Company for sustainable, long-term growth that we believe will further allow us to fulfill our mission of serving patients and families with rare diseases. The initial restructuring activities primarily focused on a reduction of the Company's global workforce. In September 2017, we committed to an operational plan to re-align the global organization with its refocused corporate strategy. The re-alignment focuses investments in priority growth areas to maximize leadership in complement and grow the rare disease business. The re-alignment also includes the

relocation of the Company's headquarters to Boston, Massachusetts in 2018. Our New Haven, Connecticut site will continue to support employees working in the research and process development laboratories, the clinical supply and quality teams, nurse case management and a number of important enterprise business services. The plan is expected to further reduce the Company's global workforce by approximately 20.0%. The restructuring will achieve cost savings by focusing the development portfolio, simplifying business structures and processes across the Company's global operations, and closing of multiple Alexion sites, including ARIMF and certain regional and country-based offices. For the year ended December 31, 2017, we recorded restructuring expenses of $104.6. We expect to pay substantially all accrued amounts related to the 2017 restructuring activities by the end of 2018. We currently estimate incurring additional restructuring and related expenses of approximately $30.0 to $70.0 in 2018 related to the 2017 restructuring activities, primarily related to other costs. As we continue to execute our strategic business plan and global footprint, we may incur restructuring expenses in 2018 that are materially different from our current estimate.

In connection with the previous 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 $11.2 in restructuring expense in the fourth quarter of 2015.

In conjunction with the acquisition and integration of Synageva, we recorded restructuring expense of $13.3, primarily related to employee costs, during 2015. Synageva restructuring charges were not material for the year ended December 31, 2016.

In the fourth quarter of 2014, we announced plans to relocate our European headquarters from Lausanne, Switzerland to Zurich, Switzerland. The relocation of our European headquarters supports our operational needs based on growth in the European region. During the years ended December 31, 2016 and 2015, we incurred restructuring costs of $3.6 and $17.6 respectively, related to this event.

Impairment of Intangible Assets

During the fourth quarter of 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 was determined to be $31.0, which was lower than the carrying amount of the asset. As a result, in the fourth quarter 2016, we recognized an impairment charge of $85.0 to write-down this asset to fair value. In the second quarter 2017, due to clinical results, we recognized an impairment charge of $31.0 related to our SBC-103 acquired in-process research and development asset to write-down the asset to fair value, which was determined to be de minimis.

As of December 31, 2017, we reviewed the Kanuma asset for impairment and determined that there were no indicators of impairment. We will continue to review the related valuation and accounting of this asset in future quarters as new information becomes available to us. Changes to assumptions used in our net cash flow projections may result in impairment charges in subsequent periods. The net book value of the Kanuma intangible asset as of December 31, 2017 is $3,512.8.

Other Income and (Expense)

The following table provides information regarding other income and expense:

Investment Income			
Interest Expense			
Other Income (expense)			

The increase in interest expense for the year ended December 31, 2016 as compared to the year ended December 31, 2015 was due to us borrowing $3,500.0 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

The income tax expense for the years ended December 31, 2017, 2016, and 2015 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. During the year ended December 31, 2017, we recorded an income tax expense of $104.5 and an effective tax rate of 19.1%, compared to an income tax expense of $176.8 and $353.7 and an effective tax rate of 30.7% and 71.0% for the years ended December 31, 2016 and 2015, respectively. In December 2017, the Tax Act was enacted into law. The Tax Act decreased the U.S. federal corporate tax rate to 21.0%, imposed a minimum tax on foreign earnings and incorporated a one-time transition tax on previously unremitted foreign earnings. We have incorporated the impact of the Tax Act in our results of operations or have calculated provisional amounts for the tax effects of the Tax Act that can be reasonably estimated for the year ended December 31, 2017.

The Tax Act resulted in an increase to tax expense of $45.8 for the year ended December 31, 2017. This increase includes a transition tax expense of $177.9 and deferred tax expense related to the new GILTI minimum tax of $165.4, partially offset by the $297.5 benefit of re-measuring balance sheet taxes to the new 21.0% US federal tax rate. The re-measurement benefit includes $292.4 related to decreases to our net deferred tax liability and $5.1 related to decreases to income taxes payable. The deferred tax expense related to the GILTI minimum tax

includes incremental deferred tax of $236.9, net of a related $71.5 decrease for uncertain tax positions.

The decrease in the effective tax rate during 2017, from 30.7% for the year ended December 31, 2016 to 19.1% for the year ended December 31, 2017 is primarily attributable to the net increase to tax expense in 2017 of $45.8 attributable to the Tax Act, offset by decreases attributable to the deferred tax cost of $119.3 associated with the distribution of earnings from our captive foreign partnership in 2016 and the conclusion of the IRS examination of our 2013 and 2014 tax years in 2017. The impact of the enactment of the Tax Act increased our effective tax rate in 2017 by 8.4%. The 2016 distribution increased our 2016 effective tax rate by 20.7%. Conclusion of the IRS examination resulted in a decrease to our 2017 effective tax rate of approximately 3.6% for the year ended December 31, 2017.

The decrease in the effective tax rate during 2016, from 71.0% for the year ended December 31, 2015 to 30.7% for the year ended December 31, 2016 was primarily attributable to the $315.6 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 the $119.3 of deferred tax expense we recognized in 2016 attributable to first quarter distributions from our foreign captive partnership, which increased our 2016 effective tax rate by 20.7%.

We continue to maintain a valuation allowance against certain other deferred tax assets where realization is not certain. We periodically evaluate the likelihood of realizing 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, 2017 and 2016:

	December 31, 2017	December 31, 2016
Cash and cash equivalents	$ 584.4	$ 966.0
Marketable securities	889.7	327.4
Long-term debt (includes current portion)	2,906.3	3,081.3
Current assets	$ 2,953.9	$ 2,578.2
Current liabilities	952.5	822.9
Working capital	$ 2,001.4	$ 1,755.3

The aggregate increase in cash and cash equivalents and marketable securities was primarily attributable to cash generated from operations and net proceeds from the issuance of common stock under share-based compensation arrangements. Partially offsetting these increases was cash utilized to repurchase shares of common stock, principal payments on our term loan, and purchases of property, plant, and equipment.

We expect our operating expenses to decrease as a percentage of sales in 2018. We also expect reduced capital investment in 2018 as compared to 2017. 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, reverse repurchase agreements, and high-quality marketable securities in accordance with our investment policy. The stated objectives of our investment policy are 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, 2017, four customers accounted for 57.7% of the accounts receivable balance, with these individual customers accounting for 10.2% to 18.9% of the accounts receivable balance. At December 31, 2016, three customers accounted for 47.0% of the accounts receivable balance, with individual customers accounting for 13.7% to 19.1% of the accounts receivable balance.
For the year ended December 31, 2017, three customers accounted for 37.0% of our product sales, with these individual customers ranging from 10.8% to 15.0% of product sales. For the year ended December 31, 2016, three customers accounted for

36.7% of our product sales, with these individual customers ranging from 10.0% to 16.0% of product sales. For the year ended December 31, 2015, three customers accounted for 38.2% of our product sales, with these individual customers ranging from 10.0% to 17.5% 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. Substantially all of our accounts receivable are due from wholesale distributors, public hospitals and other government entities. We monitor the financial performance of our customers so that we can appropriately respond to changes in their credit worthiness. We operate in certain jurisdictions where weakness in economic conditions can result in extended collection periods. We continue to monitor these conditions and assess their possible impact on our business. To date, we have not experienced any significant losses with respect to collection of our accounts receivable.

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, 2017, we had foreign exchange forward contracts with notional amounts totaling $2,708.1. These outstanding foreign exchange forward contracts had a net fair value liability of $47.5, of which $27.0 is included in other current assets and noncurrent assets and $74.5 is included in other current liabilities and noncurrent liabilities. As of December 31, 2017, we had interest rate swap contracts with notional amounts totaling $2,331.3. These outstanding interest rate swap contracts had a net fair value of $21.8 included in other current assets and 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, 2017, 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, reverse repurchase agreements, 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 $741.0 that will become payable if and when certain development and commercial milestones are achieved. Of these milestone amounts, $451.0 and $290.0 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 do not expect to make any milestone payments 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.

License Agreements

In December 2017, we entered into a collaboration and license agreement with Halozyme Therapeutics, Inc. that allows us to use drug-delivery technology in the development of subcutaneous formulations for our portfolio of products for up to four targets. Due to the early stage of the assets we are licensing, we recorded expense for the upfront payment of $40.0 during the fourth quarter 2017. In addition, as of December 31, 2017, we could be required to pay an additional $160.0 for each target developed, subject to achievement of specified development, regulatory and sales-based milestones, 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 $50.0 during the first quarter 2015. In addition, as of December 31, 2017 we could be required to pay up to an additional $822.0 if certain development, regulatory, and commercial milestones are met over

time, as well as royalties on commercial sales.

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 $47.0 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 $15.0 during the first quarter 2015. In the third quarter of 2017 we terminated our agreement with this third party.

In addition, we have entered into other license agreements under which we would be required to pay up to an additional $488.0 if certain development, regulatory and commercial milestones are met.

We do not expect the payments associated with milestones under our licensing agreements 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 $20.0.

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. Associated with this arrangement we recognized interest expense of $14.2, $14.0, and $4.9 for the year ended December 31, 2017, 2016, and 2015, respectively. As of December 31, 2017 and 2016, our total facility lease obligation was $134.6 and $136.5, respectively, recorded within other current liabilities and facility lease obligation on our consolidated balance sheets.

During the third quarter 2015, we entered into an 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. 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. The completion of the facility, including obtaining regulatory approval, is expected in the first half of 2019. As of December 31, 2017 and 2016, we recorded a construction-in-process asset of $180.6 and $118.4, respectively, and an offsetting facility lease obligation of $159.1 and $106.9, respectively, within other current liabilities and facility lease obligation on our consolidated balance sheets.

In September 2017, we entered into a lease agreement for approximately 150,000 square feet of office space that is currently being constructed in Boston, Massachusetts. The term of the lease will commence upon the landlord's substantial completion of our premises and will expire on the thirteenth anniversary of commencement, with an option to renew for up to an additional ten years. Although we will not legally own the premises, due to our involvement during the construction period, we are deemed to be the owner of the portion of the building that we will lease 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. The landlord's construction of the building is in process and is expected to be completed during the first half of 2018. As of December 31, 2017, we recorded a construction-in-process asset of $64.1 and an offsetting facility lease obligation of $59.6 associated with our relative portion of the building within our consolidated balance sheets.

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 $3,500.0 term loan facility and a $500.0 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 $100.0 in the form of letters of credit and borrowings on same-day notice, referred to as

swingline loans, of up to $25.0. Borrowings can be used for working capital requirements, acquisitions and other general corporate purposes.

As of December 31, 2017, we had $2,906.3 outstanding on the term loan. As of December 31, 2017, we had open letters of credit of $2.2 that offset our borrowing availability on the revolving facility.

Manufacturing Obligations

We have supply agreements with Lonza 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 $1,098.9 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 $27.3 through 2019 with other third party manufacturers.

Taxes

We have recorded tax on the undistributed earnings of our controlled foreign corporation (CFC) subsidiaries. In the fourth quarter 2017, we recorded a one-time U.S. federal transition tax of $177.9 imposed on the undistributed earnings of our CFC subsidiaries as required by the Tax Act. In addition, we recorded an immaterial tax expense related to the incremental withholding, foreign local, and U.S. state taxes we would expect to incur on a dividend distribution of these earnings to the U.S. To the extent CFC earnings may not be repatriated to the U.S. as a dividend distribution due to limitations imposed by law, we have not recorded the related potential tax. Other impacts of the Tax Act have been recorded on a provisional basis, see Note 11, “Income Taxes” for additional information.

Common Stock Repurchase Program

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 February 2017, our Board of Directors authorized the future acquisition of shares with an aggregate value of up to $1,000.0 under the repurchase program, which superseded all prior repurchase programs. Under the program, we repurchased 4.0 and 3.1 shares of our common stock at a cost of $463.6 and $430.6 during the years ended December 31, 2017 and 2016, respectively. As of December 31, 2017, there is a total of $536.4 remaining for repurchases under the program.

Cash Flows

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

	Year Ended December 31,		
	2017	2016	$ Change
Net cash provided by operating activities	$ 1,115.6	$ 1,086.3	$29.3
Net cash used in investing activities	(918.3)	(287.6)	(630.7)
Net cash (used in) provided by financing activities	(596.6)	(836.2)	239.6
Effect of exchange rate changes on cash	17.7	(6.6)	24.3
Net change in cash and cash equivalents	$ (381.6)	$ (44.1)	$(337.5)

Operating Activities

Cash flows provided by operations in 2017 were $1,115.6 compared to $1,086.3 in 2016. The increase was driven by an increase in gross margin on product sales of $424.0 resulting primarily from an increase in global demand for Soliris as well as

increased sales of Strensiq and Kanuma during 2017 as a result of continuing efforts to identify and reach more patients with HPP and LAL-D globally. Partially offsetting this increase was employee separation payments in connection with the 2017 restructuring activities, as well as increases in clinical R&D, product

development and selling, general, and administrative expenses during 2017.

We expect increases in cash flows from operations which will be highly dependent on sales levels, and the related cash collections from sales of our products.

Investing Activities

Cash used for investing activities in 2017 was $918.3 compared to $287.6 in 2016. The increase in cash used for investing activities was primarily attributable to purchases and maturities of available-for-sale marketable securities, which resulted in a net cash outflow of $558.9 in 2017 compared to a net cash inflow of $50.7 in 2016.

During 2017, we also had higher cash outlays associated with the purchase of property, plant and

equipment of $357.3, compared to $332.7 in 2016. The significant spending on property, plant and equipment in 2017 relates primarily to the construction of our new biologics manufacturing facilities in Ireland.

Financing Activities

Cash flows used in financing activities in 2017 were $596.6 compared to $836.2 in 2016. The decrease in cash used for financing activities was primarily due to principal payments on our credit facility of $175.0 in 2017, compared to $375.0 in 2016.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2017 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	$2,906.3	$ —	$2,906.3	$ —	$ —
Interest expense [1]	221.0	89.1	131.9	—	—
Facility lease obligations [2]	296.6	15.2	42.0	45.7	193.7
Operating leases	78.4	22.3	25.0	13.2	17.9
Total contractual obligations	$3,502.3	$ 126.6	$3,105.2	$ 58.9	$ 211.6
Commercial commitments:					
Clinical and manufacturing development [3]	$1,126.2	$ 234.0	$343.6	$ 176.6	$ 372.0
Total commercial commitments	$1,126.2	$ 234.0	$343.6	$ 176.6	$ 372.0

[1] Interest on variable rate debt calculated based on interest rates at December 31, 2017. Interest that is fixed, associated to our interest rate swaps, is calculated based on the fixed interest swap rate at December 31, 2017.

[2] Facility lease obligations include the lease agreement signed in November 2012, for office and laboratory space in New Haven, Connecticut and the lease agreement signed in September 2017 for office space in Boston, Massachusetts. Although we do not legally own these premises, we were deemed to be the owner of the buildings 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, 2017.

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 $60.9 at December 31, 2017 was not included within the table above. The timing of the settlement of these amounts was not reasonably estimable at December 31, 2017. 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, 2017. Contingent payments associated with these business combinations total up to $741.0 which will become payable if and when certain development and commercial milestones are achieved. During the next 12 months, we do not expect to make milestone payments 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. During the next 12 months, we expect to make milestone payments related to our license agreements of approximately $20.0.

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, 2017. The total unfunded obligation on our defined benefit plans as of December 31, 2017 was $19.2. 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 $3,500.0 term loan facility and a $500.0 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 $100.0 in the form of letters of credit and borrowings on same-day notice, referred to as swingline loans, of up to $25.0. 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 facilities, together with third party manufacturing facilities, will be adequate for our on-going activities.

In addition to the minimum rental commitments on our operating leases we may also be required to pay amounts for taxes, insurance, maintenance and other operating expenses.

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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, 2017, we invested our cash in a variety of financial instruments, principally money market funds, corporate bonds, repurchase agreements, 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 1.00%, the fair value of our investment portfolio would (decrease) increase by approximately $(1.9) and $1.9, 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 a number of interest rate swap agreements that qualified for and are designated as cash flow hedges. We currently have cash flow hedges with aggregate amounts of approximately 70.0% of our current outstanding term loan covering periods over the next twelve months. If interest rates were to increase or decrease by 1.00%, interest expense, over the next year would increase or decrease by $8.8, 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. 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, the Ruble 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, and payables denominated in foreign currencies. Approximately 49.0% of our net product sales were denominated in foreign currencies during 2017, 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 Europe and accordingly, our expenses are impacted by fluctuations in the value of the 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 up to 6 months and 2) hedge a portion of our forecasted product sales (in some currencies), including intercompany sales, and certain forecasted expenses using contracts with durations of up to 60 months. The objective of this program is to reduce the volatility of our operating results due to fluctuation of foreign exchange. 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, 2017 and 2016, we held foreign exchange forward contracts with notional amounts totaling $2,708.1 and $2,389.2, respectively. As of December 31, 2017 and 2016, our outstanding foreign exchange forward contracts had a net fair value of $(47.5) and $140.2, 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, 2017, 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 $149.6 at December 31, 2017. 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 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, 2017. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of December 31, 2017, our disclosure controls and procedures were effective at the reasonable assurance level.

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, 2017 based on the framework in Internal Control-Integrated Framework (2013) issued by the

Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, management has concluded that the Company maintained an effective internal control over financial reporting as of December 31, 2017.

The effectiveness of our internal control over financial reporting as of December 31, 2017 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Remediation of Previous Material Weakness in Internal Control Over Financial Reporting

Management previously identified and disclosed a material weakness in the Company's internal control over financial reporting 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.

The Company has completed the documentation and testing of the corrective actions described below and, as of December 31, 2017, our management has concluded that as a result of the remediation activities implemented the previously disclosed material weakness has been remediated as of December 31, 2017.

The Board of Directors reinforced 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, increased communication with, and trained 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;

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

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.

The Board of Directors, together with management, evaluated certain Company practices and procedures, including those related to compensation, planning and forecasting, as well as the Company's organizational structure, modified or terminated practices and procedures and reassigned roles and responsibilities to enhance controls and compliance. In addition, in December 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 Board of Directors subsequently appointed Dr. Hantson as Chief Executive Officer in March 2017 and Paul J. Clancy as Chief Financial Officer in July 2017. In May 2017,

David Brennan was appointed Chairman of the Board of Directors.

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, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9A(T). CONTROLS AND PROCEDURES.

Not applicable

Item 9B. OTHER INFORMATION.

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

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

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

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

CODE OF ETHICS

We have adopted the Alexion Pharmaceuticals, Inc. Code of Conduct, or code of ethics, that applies to directors, officers and employees of Alexion and its subsidiaries and complies with the requirements of Item 406 of Regulation S-K and the listing standards of the Nasdaq Global Select Market. Our code of ethics is located on our website (http://ir.alexionpharm.com/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	Employment Agreement, dated as of March 27, 2017, by and between Ludwig N. Hantson and Alexion Pharmaceuticals, Inc. (28)**
10.5	

	Employment Agreement, dated as of June 11, 2017, by and between Paul J. Clancy and Alexion Pharmaceuticals, Inc. (29)**
10.6	Employment Agreement, dated as of June 1, 2017, by and between Brian Goff and Alexion Pharmaceuticals, Inc. **
10.7	Employment Agreement, dated as of December 11, 2016, by and between David Brennan and Alexion Pharmaceuticals, Inc. (30)**
10.8	Employment Agreement, dated as of December 12, 2016, by and between David J. Anderson and Alexion Pharmaceuticals, Inc. (30)**
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)

10.31 Alexion Pharmaceuticals, Inc. 2017 Incentive Plan (31)**

10.32 Form of 2017 Incentive Plan Restricted Stock Unit Agreement**

10.33 Form of 2017 Incentive Plan Nonqualified Stock Option Agreement.**

10.34	Form of 2017 Incentive Plan Performance Stock Unit Agreement (TSR)**
10.35	Form of 2017 Incentive Plan Performance Stock Unit Agreement (R&D Units)**
10.36	Alexion Pharmaceuticals, Inc. 2017 Incentive Plan Rules for Awards Granted to Participants in France**
10.37	Form of 2017 Incentive Plan Restricted Stock Unit Agreement for French Participants**
10.38	Form of 2017 Incentive Plan Global Stock Option Agreement**
10.39	Form of 2017 Incentive Plan Restricted Stock Unit Agreement for Non-U.S. Participants**
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, 2017 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.
(28) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017.
(29) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.
(30) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.
(31) Incorporated by reference to our Registration Statement on Form S-8 (Reg. No. 333-217905) filed on May 5, 2017.

+Confidential treatment was granted for portions of such exhibit.

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

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

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

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/ Ludwig N. Hantson, Ph.D.
Ludwig N. Hantson, Ph.D.
Date: February 8, 2018 Chief Executive Officer
(principal executive officer)

By: /s/ Paul J. Clancy
Paul J. Clancy
Date: February 8, 2018 Executive Vice President and Chief Financial Officer
(principal financial officer)

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/ Ludwig N. Hantson Ludwig N. Hantson	Chief Executive Officer and Director (principal executive officer)	February 8, 2018
/s/ Paul J. Clancy Paul J. Clancy	Executive Vice President and Chief Financial Officer (principal financial officer)	February 8, 2018
/s/ Daniel A. Bazarko Daniel A. Bazarko, C.P.A.	Senior Vice President and Chief Accounting Officer (principal accounting officer)	February 8, 2018
/s/ David R. Brennan David R. Brennan	Chairman	February 8, 2018
/s/ Felix J. Baker Felix J. Baker, Ph.D.	Director	February 8, 2018
/s/ M. Michele Burns M. Michele Burns	Director	February 8, 2018
/s/ Christopher J. Coughlin Christopher J. Coughlin	Director	February 8, 2018
/s/ Deborah Dunsire, M.D. Deborah Dunsire, M.D.	Director	February 8, 2018
/s/ Paul A. Friedman Paul A. Friedman, M.D.	Director	February 8, 2018
/s/ John T. Mollen John T. Mollen	Director	February 8, 2018
/s/ Francois Nader Francois Nader, M.D.	Director	February 8, 2018
/s/ Alvin S. Parven Alvin S. Parven	Director	February 8, 2018

/s/ Judith A. Reinsdorf, J.D. Judith A. Reinsdorf, J.D.	Director	February 8, 2018
/s/ Andreas Rummelt Andreas Rummelt, Ph.D.	Director	February 8, 2018
/s/ Ann M. Veneman Ann M. Veneman	Director	February 8, 2018

Alexion Pharmaceuticals, Inc.
Contents
For the Years Ended December 31, 2017, 2016 and 2015

Report of Independent Registered Public Accounting Firm

Report of Independent Registered Public Accounting Firm
To the Board of Directors and Stockholders of Alexion Pharmaceuticals, Inc.
Opinions on the Financial Statements and Internal Control over Financial Reporting
We have audited the accompanying consolidated balance sheets of Alexion Pharmaceuticals, Inc. and its subsidiaries as of December 31, 2017 and 2016, and the related consolidated statements of operations, comprehensive income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).
In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.
Basis for Opinions
The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.
Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. 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.
Definition and Limitations of Internal Control over Financial Reporting
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 8, 2018

We have served as the Company's auditor since 2002

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

	December 31,	
	2017	2016
Assets		
Current Assets:		
Cash and cash equivalents	$584.4	$966.0
Marketable securities	889.7	327.4
Trade accounts receivable, net	726.5	649.6
Inventories	460.4	374.7
Prepaid expenses and other current assets	292.9	260.5
Total current assets	2,953.9	2,578.2
Property, plant and equipment, net	1,325.4	1,035.6
Intangible assets, net	3,954.4	4,303.1
Goodwill	5,037.4	5,037.4
Other assets	312.2	299.0
Total assets	$13,583.3	$13,253.3
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$70.8	$64.1
Accrued expenses	639.4	508.0
Deferred revenue	15.9	36.6
Current portion of long-term debt	167.4	167.0
Current portion of contingent consideration	—	23.8
Other current liabilities	59.0	23.4
Total current liabilities	952.5	822.9
Long-term debt, less current portion	2,720.7	2,888.1
Contingent consideration	168.9	129.1
Facility lease obligations	342.9	233.4
Deferred tax liabilities	365.0	395.5
Other liabilities	140.2	90.5
Total liabilities	4,690.2	4,559.5
Commitments and contingencies (Note 10)		
Stockholders' Equity:		
Common stock, $.0001 par value; 290.0 shares authorized; 234.3 and 231.9 shares issued at December 31, 2017 and 2016, respectively	—	—
Additional paid-in capital	8,290.3	7,957.0
Treasury stock, at cost, 12.0 and 8.0 shares at December 31, 2017 and 2016, respectively	(1,604.9)	(1,141.3)
Accumulated other comprehensive (loss) income	(34.4)	60.5
Retained earnings	2,242.1	1,817.6
Total stockholders' equity	8,893.1	8,693.8
Total liabilities and stockholders' equity	$13,583.3	$13,253.3

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,		
	2017	2016	2015
Net product sales	$3,549.5	$3,081.7	$2,602.5
Other revenue	1.6	2.4	1.5
Total revenues	3,551.1	3,084.1	2,604.0
Cost of sales	454.2	258.3	233.1
Operating expenses:			
Research and development	878.4	757.2	709.5
Selling, general and administrative	1,094.4	953.0	862.6
Amortization of purchased intangible assets	320.1	322.2	116.6
Change in fair value of contingent consideration	41.0	35.7	64.2
Acquisition-related costs	—	2.3	39.2
Restructuring expenses	104.6	3.0	42.1
Impairment of intangible assets	31.0	85.0	—
Total operating expenses	2,469.5	2,158.4	1,834.2
Operating income	627.4	667.4	536.7
Other income and expense:			
Investment income	18.5	10.9	8.5
Interest expense	(98.4)	(96.9)	(47.8)
Other income (expense)	0.3	(5.2)	0.7
Income before income taxes	547.8	576.2	498.1
Income tax expense	104.5	176.8	353.7
Net income	$443.3	$399.4	$144.4
Earnings per common share			
Basic	$1.98	$1.78	$0.68
Diluted	$1.97	$1.76	$0.67
Shares used in computing earnings per common share			
Basic	223.9	224.3	213.4
Diluted	225.4	226.3	215.9

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,		
	2017	2016	2015
Net income	$443.3	$399.4	$144.4
Other comprehensive (loss) income, net of tax:			
Foreign currency translation	8.4	(4.3)	(6.3)
Unrealized gains (losses) on marketable securities	0.6	0.4	(0.6)
Unrealized gains on pension obligation	1.9	2.9	7.0
Unrealized (losses) gains on hedging activities, net of tax of $(59.0), $(0.2) and $5.6, respectively	(105.8)	(0.8)	5.4
Other comprehensive (loss) income, net of tax	(94.9)	(1.8)	5.5
Comprehensive income	$348.4	$397.6	$149.9

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, 2014	201.9	—	$2,592.2	2.9	$(383.0)	$ 56.8	$1,036.0	$ 3,302.0
Repurchase of common stock	—	—	—	2.0	(327.7)	—	—	(327.7)
Issuance of common stock, net of issuance costs of $4.1	26.1	—	4,913.8	—	—	—	—	4,913.8
Issuance of common stock under stock option and stock purchase plans	1.4	—	82.0	—	—	—	—	82.0
Issuance of restricted common stock	1.1	—	—	—	—	—	—	—
Excess tax benefit from stock options		—	(89.7)	—	—	—	—	(89.7)
Share-based compensation expense	—	—	228.3	—	—	—	—	228.3
Net income	—	—	—	—	—	—	144.4	144.4
Other comprehensive income	—	—	—	—	—	5.5	—	5.5
Balances, December 31, 2015	230.5	—	$7,726.6	4.9	$(710.7)	$ 62.3	$1,180.4	$ 8,258.6
Repurchase of common stock	—	—	—	3.1	(430.6)	—	—	(430.6)
Issuance of common stock under stock option and stock purchase plans	0.6	—	37.1	—	—	—	—	37.1
Issuance of restricted common stock	0.8	—	—	—	—	—	—	—
Share-based compensation expense	—	—	193.3	—	—	—	—	193.3
Net income	—	—	—	—	—	—	399.4	399.4
Other comprehensive loss	—	—	—	—	—	(1.8)	—	(1.8)
Adoption of new share-based compensation guidance	—	—	—	—	—	—	237.8	237.8
Balances, December 31, 2016	231.9	—	$7,957.0	8.0	$(1,141.3)	$ 60.5	$1,817.6	$ 8,693.8
Repurchase of common stock	—	—	—	4.0	(463.6)	—		(463.6)
Issuance of common stock under stock option and stock purchase plans	1.3	—	85.9	—	—	—	—	85.9
Issuance of restricted common stock	1.1	—	—	—	—	—	—	—
Share-based compensation expense	—	—	247.4	—	—		—	247.4
Net income	—	—	—	—	—	—	443.3	443.3
Other comprehensive loss	—	—	—		—	(94.9)	—	(94.9)
Adoption of new intra-entity tax guidance	—	—	—	—	—	—	(18.8)	(18.8)
Balances, December 31, 2017	234.3	—	$8,290.3	12.0	$(1,604.9)	$ (34.4)	$2,242.1	$ 8,893.1

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,		
	2017	2016	2015
Cash flows from operating activities:			
Net income	$443.3	$399.4	$144.4
Adjustments to reconcile net income to net cash flows from operating activities:			