

ALEXION PHARMACEUTICALS, INC.
Form 10-K
February 06, 2019
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

Annual report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2018

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.)

121 Seaport Boulevard, Boston Massachusetts 02210

(Address of Principal Executive Offices) (Zip Code)

475-230-2596

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: Common Stock, par value \$0.0001

Name of each exchange on which registered: The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

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

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 No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes 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 Accelerated filer Non-accelerated filer

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

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 29, 2018, was \$26,514,235,288.⁽¹⁾

The number of shares of Common Stock outstanding as of January 31, 2019 was 223,469,381.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement to be used in connection with its 2019 Annual Meeting of Stockholders currently anticipated to be held on May 14, 2019, are incorporated by reference into Part III of this report.

(1) Excludes 9,186,789 shares of common stock held by directors, executive officers and their respective affiliates at June 29, 2018. 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. Words such as “anticipates,” “may,” “forecasts,” “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 UTLOMIRIS™, SOLIRIS®, STRENSIQ® and KANUMA® for approved indications and any expanded uses, sales of our products in various markets worldwide, pricing for our products, level of insurance coverage and reimbursement for our products, timing regarding development and regulatory approvals for additional indications or in additional territories;

plans for clinical trials (and proof of concept trials), status of our ongoing clinical trials for our product candidates, commencement dates for new clinical trials, clinical trial results and evaluation of our clinical trial results by regulatory agencies;

potential benefits offered by product candidates, including improved dosing intervals;

the medical and commercial potential of additional indications for our products;

the expected timing for the completion and/or regulatory approval of our facilities and facilities of our third-party manufacturers;

future expansion of our commercial organization;

future governmental and regulatory decisions regarding pricing (and discounts) and the adoption, implementation and interpretation of healthcare laws and regulations (and the impact on our business);

plans and prospects for future regulatory approval of products and product candidates;

competitors, potential competitors and future competitive products (including biosimilars);

plans to grow our product pipeline (and diversify our business, including through acquisitions) and anticipated benefits to the Company;

future objective to expand business and sales;

future plans to retain earnings and not pay dividends;

expected decisions to appeal certain litigation and intellectual property decisions;

expectations to realize the carrying value of product inventory;

impact of accounting standards;

future costs, operating expenses (including research and development, sales, general and administrative and restructuring expenses) and capital requirements, capital investment, sufficiency of cash to fund operations, the sufficiency of our existing capital resources and projected cash needs, price approval and funding processes in various countries;

- anticipated future milestone, contingent and royalty payments (and expected impact on liquidity);

timing and anticipated amounts of future tax payments and benefits, as well as timing of conclusion of tax audits;

collection of accounts receivable;

the safety and efficacy of our products and our product candidates;

the adequacy of our pharmacovigilance and drug safety reporting processes;

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;

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; and

estimates of the capacity of manufacturing and other service facilities to support our business, operations, products and product candidates.

Such risks and uncertainties include, but are not limited to, increased competition, actions by regulatory agencies, product candidates not receiving regulatory approvals, 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, the investigation by the MHLW in Japan, risks related to 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.

Note Regarding Trademarks

We have proprietary rights to a number of registered and unregistered trademarks that we believe are important to our business, including but not limited to: Alexion Pharmaceuticals, Inc., Alexion, ULTOMIRIS, SOLIRIS, STRENSIQ and KANUMA. We have, in certain cases, omitted the ®, © and ™ designations for these and other trademarks used in this Annual Report on Form 10-K. Nevertheless, all rights to such trademarks are reserved. These and other trademarks referenced in this Annual Report on Form 10-K are the property of their respective owners.

Item 1. BUSINESS.

(dollars and shares in millions)

Overview

Alexion 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 only two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH), as well as the first and only approved complement inhibitor to treat 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 products and development programs on life-transforming therapeutics for rare diseases for which we believe the current treatments are either non-existent or inadequate. We have developed or are developing innovative products for the following indications:

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). 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).
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.
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.
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.
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.

Relapsing Neuromyelitis Optica Spectrum Disorder Relapsing NMOSD is a severe and ultra-rare autoimmune disease of the central nervous system that primarily affects the optic nerves and the spinal cord. Each relapse of the

(NMOSD) disorder results in a stepwise accumulation of disability, including blindness and paralysis, and sometimes premature death.

Wilson Disease Wilson disease is a rare disorder that can lead to severe liver disease, including cirrhosis and acute liver failure, as well as debilitating neurological morbidities such as impaired movement, gait, speech, swallowing, and psychiatric disorders.

WAIHA is a rare autoimmune disorder caused by pathogenic Immunoglobulin G (IgG) antibodies Warm Autoimmune that react with and cause the premature destruction of red blood cells at normal body temperature. Hemolytic Anemia The disease is often characterized by profound, and potentially life-threatening anemia and other (WAIHA) acute complications, including severe and life-threatening hemolysis, severe weakness, enlarged spleen and/or liver, rapid heart rate (tachycardia), chest pain, heart failure and fainting (syncope).

Marketed Products

Our marketed products include the following:

Product	Therapeutic Area	Approved Indication
	Hematology	PNH
	Hematology	PNH
	Hematology/Nephrology	aHUS
	Neurology	gMG
	Metabolic Disorders	HPP
	Metabolic Disorders	LAL-D

ULTOMIRIS (ALXN1210/ravulizumab-cwvz)

ULTOMIRIS 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. As of the date hereof, ULTOMIRIS has only been approved as a therapy in the US for adult patients with PNH. ULTOMIRIS is a humanized monoclonal antibody that effectively blocks terminal complement activity at the doses currently prescribed. ULTOMIRIS is the first and only long-acting C5 inhibitor that provides immediate and complete inhibition for eight weeks.

In December 2018, ULTOMIRIS was approved by the U.S. Food and Drug Administration (FDA) as a new treatment option for adult patients living with PNH.

In June 2018, we submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for approval of ULTOMIRIS for the treatment of patients with PNH and in July 2018 the MAA was accepted for review in the European Union (EU). In September 2018, we also filed an application with the Japan Pharmaceuticals and Medical Devices (PDMA) for the approval of ULTOMIRIS for patients with PNH.

ULTOMIRIS has received Orphan Drug Designation (ODD) for the treatment of patients with PNH in the U.S., EU and Japan.

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.

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.

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 FDA and European Commission (EC) have granted SOLIRIS orphan drug designation for the treatment of patients with aHUS.

In 2017, the FDA and EC approved SOLIRIS for the treatment of refractory gMG in adults who are anti-acetylcholine receptor (AChR) antibody-positive. Additionally, in 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 (PLEX). 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.

STRENSIQ (asfotase alfa)

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. STRENSIQ is approved in the U.S. for patients with

perinatal-, infantile- and juvenile-onset HPP, Europe for the treatment of patients with pediatric-onset HPP, and Japan 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)

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. KANUMA is approved in the U.S. for the treatment of patients with LAL-D, Europe for long-term enzyme replacement therapy in patients with LAL-D, and Japan for the treatment of patients 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 ongoing clinical development programs include the following:

Product	Development Area	Indication	Phase	Phase	Phase	Filed
			I	II	III	
ULTOMIRIS (ALXN1210/ravulizumab-cwvz) (Intravenous)	Hematology/Nephrology	aHUS			1	
	Neurology	gMG			1	
ULTOMIRIS (ALXN1210/ravulizumab-cwvz) (Subcutaneous)	Hematology/Nephrology	PNH/aHUS			1	
ALXN1810 (Subcutaneous)	Next Generation Subcutaneous Complement Inhibitor		1			
SOLIRIS (eculizumab)	Neurology	NMOSD				1
ALXN1840 (WTX101)	Metabolic Disorders	Wilson disease			1	
ALXN1830 (SYNT001)	Hematology	WAIHA		1		

ULTOMIRIS (ALXN1210/ravulizumab-cwvz)

ALXN1210 (ravulizumab-cwvz) 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 clinical studies, ALXN1210 demonstrated

rapid, complete, and sustained reduction of free C5 levels for eight weeks.

Intravenous (IV)

Enrollment was completed in late May 2018 in a Phase III, single arm, multicenter study to evaluate the safety and efficacy of ALXN1210 administered by IV infusion every 8 weeks to adult patients with aHUS who have never been treated with a complement inhibitor. In January 2019, we announced the results of the Phase

III study with ALXN1210 meeting its primary objective in complement inhibitor-naïve patients with aHUS. In the initial 26 week treatment period in this study, 53.6 percent of patients demonstrated complete thrombotic microangiopathy (TMA) response. A second Phase III, single arm, multicenter study to evaluate the safety, efficacy, pharmacokinetics (PK), and pharmaco-dynamics (PD) of ALXN1210 administered by IV infusion every 8 weeks in pediatric patients (including adolescents) with aHUS who have never been treated with a complement inhibitor (inhibitor-naïve patients) is ongoing.

Alexion plans to initiate a Phase III study with ALXN1210 administered by IV infusion every 8 weeks to adult patients for the treatment of gMG in 2019.

In addition to aHUS and gMG, Alexion plans to initiate clinical studies of ALXN1210 in NMOSD. In addition, in 2019 we also plan to initiate proof of concept trials for ALXN1210 as a therapy for Amyotrophic Lateral Sclerosis (ALS), and Primary Progressive Multiple Sclerosis (PPMS).

Subcutaneous (SC) Delivery

In late 2018, Alexion initiated a single, PK-based Phase III study of ALXN1210 delivered subcutaneously once per week to PNH patients to support regulatory approval submissions in both PNH and aHUS.

In October 2017, the FDA granted orphan drug designation to the subcutaneous formulation of ALXN1210 for the treatment of aHUS.

ALXN1810 Subcutaneous (SC) Delivery

ALXN1810 combines ALXN1210 with recombinant human hyaluronidase enzyme (rHuPH20) from Halozyme Therapeutics, Inc. to potentially further extend the dosing interval for ALXN1210 SC to once every two weeks or once per month. A SC healthy volunteer study with ALXN1810 was initiated in August 2018.

SOLIRIS (eculizumab)

In September 2018, we announced the results of the Phase III global, randomized, double-blind, placebo-controlled study to evaluate eculizumab as a treatment for patients with relapsing NMOSD. The study met its primary endpoint of time to first adjudicated on-trial relapse, demonstrating that treatment with eculizumab reduced the risk of NMOSD relapse by 94.2 percent compared to placebo. At 48 weeks, 97.9 percent of patients receiving eculizumab were free of relapse compared to 63.2 percent of patients receiving placebo. Eculizumab had a safety profile consistent with that seen in previous clinical studies. The FDA, EC, and MHLW have each granted orphan designation for eculizumab as a treatment for patients with relapsing NMOSD.

In December 2018, we submitted our requests for regulatory approval to the FDA and our MAA in the EU for eculizumab for the potential treatment of NMOSD.

ALXN1840 (WTX101)

ALXN1840 (WTX101), an innovative product candidate that addresses the underlying cause of Wilson disease, is a first-in-class oral copper-binding agent with a unique mechanism of action and ability to access and bind copper from serum and promote its removal from the liver.

ALXN1840 is in Phase III development as a treatment for Wilson disease. In addition, ALXN1840 has received Fast Track designation in the U.S. and Orphan Drug Designation for the treatment of Wilson disease in the U.S. and EU.

ALXN1830 (SYNT001)

ALXN1830 (SYNT001) is a humanized monoclonal antibody that is designed to inhibit the interaction of the neonatal Fc receptor (FcRn) with IgG and IgG immune complexes and has the potential to improve treatment in a number of rare IgG-mediated diseases. ALXN1830 (SYNT001) is currently being evaluated in Phase 1b/2a studies in patients with warm autoimmune hemolytic anemia (WAIHA) and in patients with pemphigus vulgaris (PV) or pemphigus foliaceus (PF). In 2019, Alexion plans to initiate two pivotal trials, one in WAIHA and one in gMG.

Manufacturing

We utilize both internal manufacturing facilities and third party contract manufacturers to supply clinical and commercial quantities of our products and product candidates. Our internal manufacturing capability includes our Ireland facilities, a fill/finish facility in Athlone and a packaging facility in Dublin, as well as facilities in Massachusetts and Georgia. Third party contract manufacturers, including Lonza Group AG and its affiliates (Lonza), provide bulk drug substance as well as other manufacturing services like purification, product filling, finishing, packaging, and labeling.

We have various agreements with Lonza through 2029, with remaining total non-cancellable commitments of approximately \$1,084.6. 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, we pay Lonza a royalty on sales of SOLIRIS that was previously manufactured at the Alexion Rhode Island Manufacturing Facility (ARIMF) and a payment with respect to sales of SOLIRIS manufactured at Lonza facilities. The ARIMF site was sold in 2018. Lonza is in the process of qualifying a new manufacturing facility dedicated to Alexion products and commitments entered into under this arrangement are included in the non-cancellable commitments amount noted above.

In addition, we have non-cancellable commitments of approximately \$104.1 through 2020 with other third party manufacturers.

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, the construction of this facility is on-going and, based on current expectations, we anticipate this facility will receive regulatory approval in 2020.

In May 2015, we announced plans to construct a new biologics manufacturing facility on our existing property in Dublin, Ireland, the construction of this facility has commenced and, based on current

expectations, we anticipate this facility will 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 those for other pharmaceutical companies 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. In addition, we have recently announced that, in an effort to align the structure of our commercial organization with our re-focused corporate strategy and to realize operational efficiencies, certain portions of our international commercial operations will transition to a new operating model in which sales and marketing efforts in the designated countries will rely to a greater extent on third-party entities and alliances to promote and sell our products, and our direct sales presence will decrease in these regions (as we focus our direct sales resources on those regions where it can have a more cost-effective impact).

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. For the year ended December 31, 2018, four customers accounted for 50.3% of our product sales, with these individual customers ranging from 10.0% to 16.4% of product sales. 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.

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 19 “Segment Information” of the Consolidated Financial Statements included in this Annual Report on Form 10-K, for financial information by geographic areas.

Intellectual Property Rights and Market Exclusivity

Patents and other intellectual property rights protect our 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 we believe are or may become meaningful to our business. In addition to patents, we rely on trade secrets, know-how, trademarks, other forms of intellectual property and regulatory exclusivity. Our intellectual property rights have material value and we act to protect them.

Patent rights and regulatory protections are the two principal considerations that determine the period of market exclusivity for our products. 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 biopharmaceutical 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

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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 Annual Report on Form 10-K titled Government Regulation. For information regarding lawsuits alleging that ULTOMIRIS infringes patents held by a third party, see Note 11 "Commitments and Contingencies" to the notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

SOLIRIS Exclusivity

With respect to SOLIRIS, we own an issued U.S. patent that covers the eculizumab composition of matter that 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 that will expire in March 2019. SOLIRIS also benefits from orphan drug exclusivity for treating gMG until 2024 (orphan drug exclusivity for SOLIRIS for treating PNH and aHUS previously expired). 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, through late 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.

ULTOMIRIS Exclusivity

With respect to ULTOMIRIS, we own issued U.S. patents that cover the composition, use and formulation of ravulizumab which will expire in 2035. ULTOMIRIS is also protected in the U.S. by regulatory data exclusivity until 2030 and we have applied for orphan drug exclusivity for treating PNH, which, if granted, would protect that indication through 2025. Although ULTOMIRIS is not yet approved for any indication in Europe or Japan, it is also protected in those regions by patents that cover ravulizumab which will expire in 2035. If ULTOMIRIS is approved in Europe or Japan, we also expect regulatory protections to apply in those regions. In addition to the foregoing patent and regulatory protections, we own other patents and pending patent applications that are directed to various aspects of ravulizumab and which may provide additional protection

for ULTOMIRIS 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 that will expire in 2026. We have applied for an extension of this 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.

Investigational Compounds

We also own U.S. and foreign patents and patent applications that protect our investigational compounds and product candidates. At present, we do not know 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.

Importance of Intellectual Property Exclusivities and Rights

The pharmaceutical industry places considerable importance on obtaining and enforcing patent (including licensed patents), trade secret and other intellectual property protection for new therapies, technologies, products, services and processes. Our success therefore depends, in part, on our ability to obtain and enforce our patents (including licensed patents) and other intellectual property rights necessary to protect our current and future products, to obtain and preserve our trade secrets and other confidential intellectual property and to avoid or neutralize intellectual property threats from third parties. The existence of patents does not guarantee our right to practice the patented technology or commercialize the patented product. Litigation, oppositions, inter partes reviews or other proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our patents, regulatory exclusivities or other proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. We may also face challenges to our patents, regulatory exclusivities and other proprietary rights covering our products by manufacturers of biosimilars. For additional information, see Item 1A “Risk Factors - Risks Related to Intellectual Property” elsewhere in this Annual Report on Form 10-K (including a recent European Patent Office ruling to revoke a previously issued patent relating to the formulation of SOLIRIS).

Government Regulation

Drug Development and Approval in the United States

The preclinical studies and clinical testing, manufacture, labeling, storage, record keeping, advertising, promotion, pharmacovigilance reporting, export, and marketing, among other things, of our products and product candidates, including ULTOMIRIS, SOLIRIS, STRENSIQ and KANUMA, are subject to extensive regulation by governmental authorities in the U.S., the EU, Japan 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 four 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 and state 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 NIH. The results information is posted to the website unless the drug has not yet been approved, in which case the NIH 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 current Good Manufacturer Practice (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 BLA may include many delays and requests for additional information 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. The FDA has also released final guidance documents on the assignment of clearly distinguishable nonproprietary product names for both biologic and biosimilar products, labeling for biosimilar products, and questions and answers on issues involving biosimilar development, as well as 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 2018, sixteen (16) biosimilar products have been approved in total. The agency continues to refine the procedures and standards it will apply in implementing this approval pathway. In July 2018, the FDA issued a Biosimilars Action Plan, asserting its

intent to take steps to facilitate biosimilars competition. We anticipate that the 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, including SOLIRIS, 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 an 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 (OIG) of the Department of Health and Human Services (HHS), 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. If 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.

In the EU, 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. The application for orphan designation must be submitted to the EMA and approved before an application is made for marketing authorization for the product. Once authorized, orphan medicinal products are entitled to up to ten years of market exclusivity (which may be extended for an additional two years if pediatric data have been produced in accordance with an agreed pediatric investigational plan). 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 efficacious 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 criteria for orphan designation are no longer met or if the orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity.

ULTOMIRIS has received orphan drug designation for the treatment of patients with PNH in the U.S., EU and Japan, and for the subcutaneous treatment of patients with aHUS in the U.S. 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 gMG in the U.S., Japan, and the EU; (d) the prevention of graft rejection and delayed graft rejection following solid organ transplantation in the EU and (e) and for the treatment of NMOSD in the U.S., EU, and Japan. 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. As noted above, 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; and for KANUMA in the treatment of LAL-D presenting in infants. 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 those 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, promotion, 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 and is mandatory for certain categories of medicinal products, such as orphan medicinal products. A centralized marketing authorization is valid for all EU Member States and the European Economic Area states. 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. The EC may agree upon recommendation of the EMA to grant for medicines designated as orphan medicines a (i) conditional marketing authorization in the interest of public health under certain conditions; namely that unmet medical needs will be fulfilled, the benefit-risk balance of the product is positive, the benefit to public health of the medicinal product's immediate availability on the market outweighs the risks due to need for further data and it is likely that the applicant will be able to provide comprehensive data; or (ii) marketing authorization under "exceptional circumstances" when the applicant can show that it is unable to provide

comprehensive data on the efficacy and safety under normal conditions of use and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles.

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 companies within the EU legal framework (i.e., GCP, GLP, cGMP and pharmacovigilance rules, which govern quality control of the manufacturing process and require documentation policies and procedures). We and our third party manufacturers are required under regulations to ensure that all of our processes, methods, and equipment are compliant with GCP, GLP, cGMP and pharmacovigilance rules. The EMA and national competent authorities may arrange inspections to ensure that we adhere to these principles and regulations. Any adverse findings from such inspections, depending on their severity, may result in significant delays in obtaining a marketing authorization, may impose penalties or may result in other action by regulatory authorities.

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, pre-approval promotion of products, reporting of adverse health events, both before and after grant of marketing authorization, and marketing/promotion 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 third party payers, including government programs such as Medicare and Medicaid in the U.S, as well as private health insurers. 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, biologics, and other health care products and services. For example, governments may regulate reimbursement, pricing, and coverage of products in order to control costs or to affect utilization levels of certain products. In addition, private health insurance plans may restrict coverage of some products, such as by using drug formularies under which only select drugs or uses of select drugs are covered, through the implementation of variable patient co-payment obligations that make non-preferred drugs more expensive for patients, and by employing utilization management controls, such as requirements for prior authorization or prior failure on another type of treatment before the insurer will cover and reimburse a particular therapy. Payers may especially impose these obstacles to coverage for higher-priced drugs such as those we sell. Consequently, all of 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 patients 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. Our products are primarily reimbursed by Medicare under Medicare Part B, which generally covers physician services and outpatient care, including some outpatient prescription drugs under limited conditions, and Medicare Part D, which provides an outpatient prescription drug benefit for Medicare beneficiaries.

Generally speaking, Medicare Part B provides limited coverage of certain outpatient drugs and biologics that are reasonable and necessary for diagnosis or treatment of an illness or injury. Under Part B, reimbursement 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 within HHS that administers Medicare and the Medicaid Drug Rebate Program, on a quarterly basis. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare

pays physicians and suppliers ASP + 6.0% for most Part B-covered drugs and biologics (Medicare payments for ULTOMIRIS will also be based on the ASP formula commencing with the period two quarters after approval). Medicare payment for separately payable Part B drugs reimbursed through the hospital outpatient prospective payment system is generally under the discretion of CMS, meaning it can be changed without legislative action from Congress. The current reimbursement rate for most separately payable Part B drugs used in the hospital outpatient setting is ASP plus 6.0%. One exception, however, is that, effective January 1, 2018, Medicare pays 340B hospital covered entities ASP minus 22.5% for separately payable Part-B covered drugs and biologics that were purchased under the 340B Program in an outpatient clinic setting, as discussed further below. In addition, the sequester that is currently in place through 2027, reduces payments providers receive for Part B-Covered drugs by 1.6%, which results in a net payment equivalent to ASP plus 4.3%. The sequester affects other Medicare payments and is also discussed in more detail below. In both settings (i.e., physician office and hospital outpatient), the amount of reimbursement is updated quarterly based on the manufacturer's submission of new ASP information.

Medicare Part D is an outpatient prescription drug benefit available to all Medicare beneficiaries. It is a benefit that is implemented through private insurance plans under contractual arrangements between the plans and the federal government. Similar to pharmaceutical coverage through private health insurance, Part D plans develop formularies, impose utilization controls (such as prior authorization, step therapy, and quantity limits), and negotiate discounts from drug manufacturers. Because of this, the list of prescription drugs covered by Part D plans varies by plan. However, with limited exceptions, individual plans are required by statute to cover certain therapeutic categories and classes of drugs or biologics and to have at least two drugs in each unique therapeutic category or class.

Our products can also be provided under Medicare Parts A and C (Medicare Advantage). Medicare Part A generally 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 biologics administered to patients during an inpatient hospital stay. As a result, hospitals may not have a financial incentive to utilize our products for inpatients where lower cost alternative therapies are available. Finally, Medicare beneficiaries can receive their Part A, B, and D benefits through a Medicare Advantage organization plan that is administered by a private insurance company pursuant to Medicare Part C. Similar to private health

insurance plan, Medicare Advantage organization plans negotiate discounts with health care providers and implement utilization controls, including, most notably, step therapy for Part B drugs beginning January 1, 2019.

Beginning April 1, 2013, the Budget Control Act of 2011, Pub. L. No. 112-25, as amended, requires Medicare payments for all items and services, including drugs and biologics, to be reduced by up to 2.0% under sequestration (i.e., automatic spending reductions, calculated each year by the Office of Management and Budget). Subsequent legislation extended the 2.0% reduction, on average, to 2027. This 2.0% reduction in Medicare payments affects all Parts of the Medicare program and could impact sales of our products. Additional sequestration orders could also be triggered, potentially resulting in up to a 4% reduction in Medicare payments.

Pursuant to the Medicaid Drug Rebate Statute (42 U.S.C. § 1396r-8(a)(1)), we are required to participate in the Medicaid Drug Rebate Program in order for federal payment to be available for our products under Medicaid and Medicare Part B. Medicaid is a government health insurance program for eligible low-income adults, children, families, pregnant women, and people with certain 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. As a result, coverage and reimbursement requirements for drugs and biologics vary by state. For example, drugs and biologics may be covered under the medical or pharmacy benefit, and state Medicaid programs may impose different utilization management controls, such as prior authorization, step therapy, or quantity limits on drugs and biologics, subject to federal limitations for such controls. But all states must generally provide coverage and reimbursement for a manufacturer's covered outpatient drugs, as that term is defined by applicable law, if a manufacturer participates in the Medicaid Drug Rebate Program.

Under the Medicaid Drug Rebate Program, we are required to, among other things, pay a rebate to each state Medicaid program for quantities of our products utilized on an outpatient basis (with some exceptions) that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. Medicaid Drug Rebate Program Rebates are calculated using a statutory formula, state-reported utilization data, and pricing data that are calculated and 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.

In addition to participating in the Medicaid Drug Rebate Program, federal law requires manufacturers like us to 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 drug 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 only include health care organizations that have certain federal designations or receive funding from specific federal programs, including Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and certain types of hospitals and specialized clinics, as well as certain hospitals that serve a disproportionate share of low-income patients. PPACA expanded the 340B program to include additional types of covered entities: certain children's hospitals, certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by PPACA. However, "orphan drugs" i.e., those designated under section 526 of the FDCA, such as each of our products that have received market authorization are exempted from the ceiling price requirements for these newly-eligible entities when used for the rare disease or condition for which they received an orphan designation. 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 the Medicaid Drug Rebate Program are also subject to the 340B ceiling price calculation and discount requirement. Any changes to the definition of Medicaid 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. In addition, after multiple delays, the final rule implementing civil monetary penalties against manufacturers for instances of overcharging 340B covered entities became effective on January 1, 2019. Accordingly, we could be subject to such penalties if the government finds that we knowingly and intentionally overcharged a 340B covered entity.

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 and other agreements with the VA for our products, which qualify as “covered drugs.” Under these agreements, we must make our products available to the “Big Four” federal agencies the VA, the Department of Defense (DoD), the Public Health Service (including the Indian 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. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to a penalty for each item of false information and could result in other potential liability as well, including liability under the False Claims Act (which is discussed in more detail below).

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 to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, each of our covered drugs is listed on an agreement with the Defense Health Agency (DHA) under which we have agreed to honor the “Big Four” pricing for our products when they are dispensed to TRICARE beneficiaries by TRICARE retail network pharmacies. More specifically, we have agreed to provide rebates (or refunds) on such utilization. Companies are required to enter into a DHA Agreement for “covered drug” products in order for the covered drug to be eligible for DoD formulary inclusion and available to TRICARE beneficiaries without preauthorization. The formula for determining the rebate is established in the regulations and our DHA 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).

As noted in the foregoing, pricing and rebate calculations vary among products and programs. The calculations can be very 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 or other governmental agencies 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. For example, if we become aware that certain Medicaid Drug Rebate Program price 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 consider restatements for earlier periods as well depending on the circumstance. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program. Any corrections to our Medicaid rebate calculations could result in an increase or decrease 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 under the 340B drug pricing program.

Any failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results. 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, as well as provide a basis for other potential liability under other federal laws such as the False Claims Act.

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.

Further, in the U.S., there is increased focus on drug pricing, and the President, policy officials (including the FDA) and lawmakers have expressed a clear interest in efforts to reduce prices for drugs and biologics, further increase transparency around prices and price increases, lower out-of-pocket costs for consumers, and decrease spending on drugs by government programs. In addition, members of Congress have launched an investigation into the pricing practices of the prescription drug industry (and hearings may be held in 2019 in connection with this investigation). We expect

regulatory changes and continued Congressional investigations and negative media attention in the coming months with respect to drugs reimbursed by federal healthcare programs, like ours, which could have a negative impact on our operations.

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. Pricing of prescription only medicinal products is a national prerogative. Therefore the relevant 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 participation in 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 individuals such as 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 (which is discussed below). A conviction for violation of the Anti-Kickback Statute results in criminal fines and requires mandatory exclusion from participation in federal health care programs.

Although there are a number of statutory exceptions and regulatory safe harbors to the federal Anti-Kickback Statute that protect certain common, industry practices from prosecution, the exceptions and safe harbors are drawn narrowly, and arrangements may be subject to scrutiny or penalty if they do not fully satisfy all elements of an available exception or safe harbor. The discount safe harbor is currently the subject of possible reform. Any changes to the discount safe harbor may cause us to review our arrangements and pricing strategies with payers.

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 to the government 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. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of eleven thousand one hundred eighty-one to twenty-two thousand three hundred sixty-three dollars per false claim or statement for penalties assessed after January 29, 2018, with respect to violations occurring after November 2, 2015 (and penalties of five thousand five hundred to eleven thousand dollars with respect to violations occurring before that date). Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged inappropriate promotional and marketing activities, including those involving the provision of free product or other items of value to customers, certain financial arrangements with

healthcare providers, misstated government pricing information, and purported “off-label” promotion of products, among other things.

Under the federal criminal statute on false statements relating to health care matters, it is a crime to knowingly and willfully falsify, conceal, or cover up a material fact, make any materially false, fictitious, or fraudulent statements or representations, or make or use any materially 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 federally funded healthcare benefits, items, or services.

Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) criminal federal health care fraud statute, it is a crime to knowingly and willfully execute, or attempt to execute, a scheme or artifice to defraud any health care benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items, or services.

The federal Civil Monetary Penalties Law authorizes the imposition of substantial civil monetary penalties against an entity, such as a pharmaceutical manufacturer, that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal healthcare programs to provide items or services reimbursable by a federal healthcare program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment.

The majority of states also have statutes similar to the federal Anti-Kickback Statute and FCA that apply to items and services reimbursed under Medicaid and other state health care programs, or, in several states, apply regardless of the payer.

The federal Physician Payments Sunshine Act requires “applicable manufacturers” of products, including biologics, for which payment is available under Medicare, Medicaid or the State Children’s Health Insurance Program, among others, to track and report annually to the federal government (for disclosure to the public) certain payments and other transfers of value they make to “covered recipients.” The term covered recipients includes physicians, teaching

hospitals, and, for reports submitted on or after January 1, 2022, physician assistances, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. In addition, several U.S. states and localities have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports, 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. In addition, several recently passed state laws require disclosures related to state agencies and/or commercial purchasers with respect to certain price increases that exceed a certain level as identified in the relevant statutes. 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. Any of the foregoing would be expected to have a negative impact on our business which may be material.

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, 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 and Note 11 "Commitments and Contingencies" to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K 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.

Outside the U.S., other countries have implemented similar laws and regulations relating to fraud and abuse in the sale of pharmaceutical products and requirements for disclosure of financial interactions with healthcare providers and additional countries may consider or implement such laws.

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

PPACA was adopted in the U.S. in March 2010. This law substantially changes the way healthcare is financed in the U.S. by both governmental and private insurers, and significantly impacts the pharmaceutical industry. PPACA contains a number of provisions that have and 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 have an impact on 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 percentage 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 aggregate branded prescription drug fee paid by all covered entities (\$2,800 in 2019 and each ensuing year), based on, among other things, its applicable 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 and biologics are required to provide a 50.0% discount on branded prescription drugs and biologics dispensed to beneficiaries within this donut hole. This discount was recently increased to 70.0%, beginning January 1, 2019, by the Bipartisan Budget Act of 2018.

As noted above, PPACA also expanded the Public Health Service’s 340B drug pricing discount program by including additional types of covered entities. 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 as described above. PPACA exempts “orphan drugs” designated under section 526 of the

FDCA, such as our products, from the ceiling pricing requirements for these newly-eligible covered entities. Moreover, certain legislative changes to and regulatory changes under PPACA have occurred under the Trump Administration. For example, the Tax Cuts and Jobs Act enacted in 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. In December 2018, a federal district court in Texas ruled the individual mandate was unconstitutional and could not be severed from the PPACA. As a result, the court ruled the remaining provisions of the PPACA were also invalid, though the court declined to issue a preliminary injunction with respect to the PPACA. However, it remains unclear whether the court’s ruling will be upheld by appellate courts. In addition, further legislative changes to and regulatory changes under PPACA remain possible.

Privacy, Data Protection and Information Security

Numerous international, federal, and state laws, including state security breach notification and information security laws, state 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 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. In addition, in December 2018, HHS issued cybersecurity guidance for all healthcare organizations that addresses organizations’ enterprise-level information security generally, including individually identifiable health information. Failure to comply with current and future laws and regulations

could result in governmental enforcement actions (including the imposition of significant penalties), criminal and civil liability for our Company and our officers and directors, and/or adverse publicity that negatively affects our business. Further, the EU's General Data Protection Regulation (GDPR) and implementing laws in the EU member states govern the collection and processing of EU residents' personal data and, among other requirements, imposes certain consent and data access rights. Such laws may impact our ability to conduct clinical trials that involve EU personal data and engage in other activities that require the processing of EU personal data. Outside of the U.S.

and the EU, there are numerous other jurisdictions that have their own privacy and information security laws, and new laws and regulations are being considered and/or enacted globally, which may affect our ability to collect, process, and store their residents' personal data. Two such examples are the California Consumer Privacy Act of 2018 and the Brazilian Data Protection Law, which both go into effect in early 2020, and may impact our collection and use of personal information related to their jurisdictions.

Moreover, we rely on our and third-party provided information technology systems and applications to support our operations and to maintain and process company information including personal information, confidential business information and proprietary information. If these information technology systems are subject to cybersecurity attacks, or are otherwise compromised, due to cyberattacks, human error or malfeasance, system errors or otherwise, it may adversely impact our business, disrupt our operations, or lead to the loss, theft, destruction, corruption or compromise of company information and personal information. Such information technology or security events could also lead to legal liability, regulatory investigations or actions, loss of business, negative media coverage, and reputational damage. While we maintain an information security program with technical controls to mitigate these risks and training to educate and prepare our employees, the healthcare sector continues to see a high frequency of cyberattacks and threat actors that continue to become more sophisticated and better resourced, and our systems and the information maintained within those systems remain potentially vulnerable to data security incidents. Moreover, losses from such events may not be completely covered by insurance coverage. Finally, as cyber threats continue to evolve and privacy and cybersecurity laws and regulations continue to develop, we may need to invest additional resources to implement new compliance measures, strengthen our information security posture, or respond to cyber threats and incidents.

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 and interactions with foreign government officials. The FCPA prohibits U.S. companies and their employees, officers, and 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 U.K. Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances. Liability in relation to breaches of the U.K. 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 this investigation see Note 11 "Commitments and Contingencies" to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K and, with respect to the the risks associated with the investigation, see our Risk Factors, including "Our business and operations may be materially adversely affected by government investigations."

The EU also imposes strict restrictions 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. Increasing regulatory scrutiny of the promotional activities of pharmaceutical companies also has been observed in a number of EU Member States. 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. Under the new Clinical Trial Regulation there is an obligation to publish clinical trial within a certain timeframe. A breach of this obligation would constitute non-compliance with an EU Regulation and may be met with penalties set by each Member State, including civil and criminal liability.

Japan and other countries in which we operate also have strict regulations and requirements regarding the promotion of pharmaceutical products.

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

ULTOMIRIS and SOLIRIS are currently the only approved therapies for the treatment of PNH (although several companies are currently evaluating other complement inhibitors for the treatment of PNH in clinical trials). SOLIRIS is currently the only approved therapy for the treatment of aHUS, and the only approved complement inhibitor therapy for the treatment of AChR antibody-positive gMG (although similar to PNH, there are companies evaluating other complement inhibitors in both aHUS and gMG clinical trials). We have recently announced the results of our SOLIRIS Phase III PREVENT trial in patients with anti-aquaporin-4 (AQP4) auto antibody-positive NMOSD. Based on these results, we submitted applications for marketing authorization for SOLIRIS as a treatment for NMOSD in the US and the E.U. and expect additional marketing authorization applications to be submitted in other jurisdictions in the future. While we are unable to assess our competitive position with respect to potential NMOSD competitors, as we have not yet received regulatory approval in any jurisdiction, we are aware that others companies are also developing and testing therapies for NMOSD. We are also in advanced clinical studies of ULTOMIRIS and SOLIRIS for the treatment of other indications, and we believe there are competitors for the patient segments we target with respect to these products. 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,

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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 addition, we are aware that companies are conducting clinical trials for biosimilars of SOLIRIS and we expect to compete with biosimilars in the future.

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, 2018, we had 2,656 full-time, world-wide employees, of which 954 were engaged in research, product development, manufacturing, and clinical development, 1,299 in sales and marketing, and 403 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 6, 2019 are as follows:

Name	Position with Alexion	Age
Ludwig Hantson, Ph.D.	Chief Executive Officer	56
Paul J. Clancy	Executive Vice President, Chief Financial Officer	57
Ellen Chiniara, J.D.	Executive Vice President, General Counsel and Corporate Secretary	60
Indrani Franchini, J.D.	Executive Vice President, Chief Compliance Officer	47
Brian Goff	Executive Vice President, Chief Commercial Officer	49
Anne-Marie Law	Executive Vice President, Chief Human Resources Officer	51
John Orloff, M.D.	Executive Vice President, Head of Research and Development	61

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. Mr. Hantson serves on the Board of Directors of Hologic Inc., which is a medical technology company.

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.

Ellen Chiniara is Executive Vice President, General Counsel and Corporate Secretary of Alexion. In this role, she is responsible for overseeing all global legal matters for the Company.

Prior to joining Alexion in January 2018, Ms. Chiniara was Senior Vice President and General Counsel of Alere Inc., a point-of-care diagnostics company, from October 2006 to October 2017 where she was responsible for all legal matters and, from June 2014 to October 2017 she had oversight of compliance and government affairs matters. She managed the legal aspects of the company's numerous acquisitions and dispositions and was also the executive sponsor of Alere's corporate social responsibility efforts.

Prior to joining Alere, Ms. Chiniara served as Associate General Counsel for Serono's Neurology division from 2002 to 2006. Earlier in her career, Ms. Chiniara was a partner at the law firm Hale and Dorr LLP (now Wilmer Cutler Pickering Hale and Dorr LLP).

Ms. Chiniara received her J.D. from Stanford University's School of Law and her Bachelor's Degree from Bryn Mawr College. She also was a graduate fellow at Yale University in Slavic Languages.

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 (a leading independent energy company) from June 2012 to July 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 Graduation School in Fukuoka, Japan.

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. He has deep expertise in commercial operations across multiple therapeutic areas, as well as broad expertise managing global cross-functional teams, including R&D, Medical Affairs, Manufacturing and Quality with a number of industry-leading biopharmaceutical companies.

Prior to joining Alexion in June 2017, Mr. Goff was Chief Operating Officer and a Member of the Board of Directors of Neurovance Inc. 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 has a MBA from the Wharton School at the University of Pennsylvania and a Bachelor of Arts from Skidmore College.

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. She previously served as Executive Vice President and Head of Human Resources for Baxalta Incorporated from April 2009 to December 2014, and 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 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.

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 (or that may be accessed through links 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., 121 Seaport Boulevard, Boston Massachusetts 02210. In addition, any document we file may be viewed 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).

The company intends to use its website <http://www.alexion.com> as a means of disclosing material non-public information and for complying with its disclosure obligations under SEC Regulation FD. Such disclosures will be included on the company's website under the heading "Investors". Accordingly, investors should monitor such portions of the company's website, in addition to following the company's press releases, SEC filings and public conference calls and webcasts.

Item 1A. Risk Factors.

(amounts in millions, except percentages)

You should carefully consider the following risk factors before you decide to invest in Alexion securities and our business, because the risks described below may have a material 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 and Product Candidates

We depend on the success of, and revenue from, Soliris.

Since 2007, our revenue has depended primarily on the sales of Soliris. Unless we are able to develop or acquire new products and technologies, successfully commercialize ULTOMIRIS as described in the following risk factor, and/or materially increase sales of Strensiq and Kanuma (two of our other currently approved products), we will remain dependent on sales of Soliris as a source of our revenue.

The commercial success of SOLIRIS and our ability to generate revenue depends on several factors, including: the safety and efficacy of SOLIRIS; coverage or reimbursement by government or third-party payers for SOLIRIS; pricing for SOLIRIS; the analysis by doctors and patients of the cost of SOLIRIS relative to the perceived benefits; manufacturing and uninterrupted supply; the introduction of and success of competing products by competitors (including novel products and biosimilars to SOLIRIS); the size of patient populations and the number of patients diagnosed who may be treated with SOLIRIS; the impact of legal, administrative, regulatory or legislative developments; and our ability to develop, obtain regulatory approval for and commercialize SOLIRIS for new indications.

While SOLIRIS has been studied for indications beyond PNH, aHUS and gMG (which are the current approved indications of SOLIRIS), there is no guarantee that we can obtain regulatory approval or achieve any commercial sales of SOLIRIS for other indications. Despite positive topline results from the Phase 3 PREVENT study of SOLIRIS in patients with anti-aquaporin-4 (AQP4) auto antibody-positive neuromyelitis optica spectrum disorder (NMOSD), we may not be able to obtain regulatory approval to sell SOLIRIS as a treatment for NMOSD due to the failure to meet applicable regulatory requirements. Additionally, even if we obtain regulatory approval, physicians and patients

may not accept SOLIRIS as a treatment for NMOSD or payers may not be willing to pay for or reimburse the costs of SOLIRIS as a therapy for NMOSD.

If we are not able to maintain revenues from sales of SOLIRIS, or our SOLIRIS revenues decrease, our operating results would be negatively impacted and our ability to fund research and development programs for the discovery and commercialization or acquisition of new products would be harmed, which would limit our ability to diversify our revenue base and our stock price could be adversely affected.

If PNH patients do not switch from SOLIRIS to ULTOMIRIS or ULTOMIRIS does not gain market acceptance, our future operating results may be adversely impacted.

In December 2018, ULTOMIRIS was approved by the FDA for use in the U.S. for adult patients with PNH (and applications for approval of ULTOMIRIS are under review by the European Medicines Agency (EMA) and the Ministry of Health, Labour and Welfare (MHLW) in Japan for patients with PNH).

One of our principal business objectives is to facilitate the conversion of PNH patients from SOLIRIS to ULTOMIRIS. While clinical trials demonstrated that ULTOMIRIS is non-inferior to SOLIRIS at an 8 week dosing interval (compared to a 2 week dosing interval for SOLIRIS), existing PNH patients taking SOLIRIS and their physicians may decline to switch to ULTOMIRIS for many reasons including: reluctance to try a new therapy, lack of clinical evidence that ULTOMIRIS is superior to SOLIRIS, no (or limited) reimbursement by government or third-party payers (including as a result of SOLIRIS being available as an alternative therapy), or our inability to manufacture quantities necessary to meet demands.

If we achieve our goal of promptly facilitating the conversion of current PNH patients from SOLIRIS to ULTOMIRIS, we anticipate that revenue from SOLIRIS, which accounted for approximately \$3,563.0, or 86.3%, of our revenues in 2018, will decline as we move patients to ULTOMIRIS. We have established a price for ULTOMIRIS in the U.S. that, on an annual basis, represents an approximate 10% discount to the cost of current labeled maintenance therapy for SOLIRIS for adult PNH patients of average weight. However, this represents an approximate 10% premium to the cost of SOLIRIS in a patient's first year of switching due to the loading doses required.

We may not obtain marketing approval for ULTOMIRIS as a treatment for PNH in any jurisdictions beyond the U.S. or for any indications beyond PNH.

There is no guarantee that the EMA or the MHLW (or any other regulatory authority) will promptly approve the use of ULTOMIRIS in PNH patients or that they will approve the use of ULTOMIRIS in PNH patients at all. We believe that the EU and Japan may be important

potential markets for ULTOMIRIS and if we are not able to sell ULTOMIRIS in these geographies, our business may be adversely impacted.

Subject to successful completion of clinical trials, we intend to pursue marketing approval for ULTOMIRIS in the U.S., the EU, Japan and other jurisdictions for indications in addition to PNH and, potentially, other delivery mechanisms. The FDA, the EMA or the MHLW could reject our applications for indications beyond PNH (and the EMA and the MHLW could reject our application for ULTOMIRIS for PNH) or for a subcutaneous delivery mechanism for many reasons, including due to a finding of inadequate safety, tolerability, potency or efficacy profiles. Additionally, these and other regulatory agencies may request that we provide additional safety or efficacy data, which may require significant additional time and expense to generate prior to a decision on approval.

If ULTOMIRIS is not approved for use in PNH patients in the EU or Japan (or other jurisdictions) or for any other indications or for subcutaneous administration in the U.S., the EU, Japan or elsewhere or if any such approval is delayed, our future business and results of operations may be harmed. In the event of any of the foregoing, while we would continue to sell SOLIRIS in the jurisdictions and for the indications authorized by the appropriate authorities, certain of the patents and regulatory exclusivities related to SOLIRIS expire earlier than patents and regulatory exclusivities we hold on ULTOMIRIS, which may allow competitors to enter those markets at an earlier date utilizing SOLIRIS or biosimilar technology.

Our future commercial success depends on gaining regulatory approval for new products and obtaining approvals for existing products for new indications.

We have invested, and continue to invest, significant amounts in acquiring new products and technologies and advancing our existing product candidates and technologies. Our long-term success and revenue growth will depend upon the successful identification, acquisition (including licenses from third parties), development and commercialization of new products and technologies, and approval of additional indications for our existing products and products under development. Product development (including products acquired in connection with acquisitions) is very expensive, takes significant time to obtain regulatory approval 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, the novelty of the product candidates involved and the indications to be treated. Further, success in early clinical trials, which may lead to further investment in a product candidate by us, may not result in success in later stage

trials. In addition, our recent acquisitions have focused on new technologies with which we have very limited experience, including antibody therapeutics targeting the neonatal Fc receptor, which may make the development, approval and commercialization of such potential products challenging.

Our ability to maintain or grow revenues may be adversely affected if we are delayed or unable to successfully develop the products in our pipeline, if we are unable to gain approval for SOLIRIS and ULTOMIRIS for additional indications and in new jurisdictions, obtain marketing approval for STRENSIQ and KANUMA in additional territories, obtain approval for additional delivery systems for our therapies (such as subcutaneous administration) or acquire or license products and technologies from third parties.

If we do not obtain regulatory approval of new products or additional indications for existing products or additional delivery systems, or are significantly delayed or limited in doing so, our revenue may be adversely affected, we may experience surplus inventory, we may be required to write down certain assets, our business may be materially harmed and we may need to significantly curtail operations.

We develop therapies for rare diseases with limited patient populations that have not been definitively determined, and our success will depend on our ability to identify patients in the disease areas we target.

The therapies that we have developed and that are in our product pipeline target diseases that have a limited number of patients and for which, in many cases, there are either no or limited diagnostics tools. For example, KANUMA and STRENSIQ are currently approved to treat ultra-rare diseases with small patient populations that have not been definitively determined. Our development pipeline programs that may be the basis for future revenue growth also focus on rare (and ultra-rare) diseases for which there are a very limited number of patients. The lack of diagnostic tools, coupled with the fact that there is frequently limited awareness among certain health care providers concerning

the rare diseases we treat, often means that a proper diagnosis can, and frequently does, take years to identify (or an appropriate diagnosis may never be made for certain patients). As a result, we may not be able to grow our revenues (even as we introduce new products or as existing products are approved for additional indications). There can be no guarantee that any of our programs will be effective at identifying patients, and even if we can identify patients that our therapies can help, the number of patients that our therapies treat may turn out to be lower than we expect, may not be otherwise amenable to treatment with our products (such as KANUMA and STRENSIQ), or new patients may become increasingly difficult to identify, all of which may adversely affect our results of operations and our business. In addition, even in instances where we do

add patients, the number may be less than the number of patients that discontinue use of the applicable product in a given period resulting in a net loss of patients and potentially decreased revenue.

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

Our products may not gain or maintain market acceptance among physicians, patients, healthcare payers and others. Although we have received regulatory approval for certain 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 and that the benefits are meaningful relative to the cost. Nor can we predict whether patients, physicians or payers will continue use of SOLIRIS or elect to convert to ULTOMIRIS in the U.S. (or other jurisdictions if and when approved for use by the appropriate regulatory authorities) or alternative treatments that may become available. 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 and biosimilars;

• demonstrated clinical safety and efficacy compared to other drugs;

• perceived cost-effectiveness and/or evaluations in HTAs;

• pricing and availability of reimbursement from third-party payers, including governmental entities;

• convenience and ease of administration;

• effectiveness of our marketing strategy;

• publicity concerning our products and our other product candidates (and those of competitive products); and

• availability of alternative treatments.

The likelihood of physicians to prescribe SOLIRIS for patients with aHUS (and ULTOMIRIS, if approved for use by aHUS patients) 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 some healthcare providers have determined not to continue SOLIRIS treatment for some patients with aHUS. While SOLIRIS as a treatment for aHUS is recommended by some regulatory authorities to be used for the duration of a patient's lifetime, we are aware that some healthcare providers prescribe SOLIRIS for aHUS for a shorter time

period and, in some cases, may prescribe SOLIRIS for aHUS in emergency or acute situations only. Decisions such as this by aHUS patients and healthcare providers to use our products for a period that is less than the remaining lifetime of the patient or in only acute circumstances can cause our SOLIRIS revenues, and revenues for our other products, to fluctuate and past sales of our products may not be indicative of future sales for such products.

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 may limit our ability to generate revenue and could harm our overall business.

If our products harm patients, or are 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 biologics for use in humans may cause harm to patients, which exposes us to product liability risks and regulatory penalties.

Our products and our product candidates treat patients with rare diseases and, as a result, we generally are able to test our products in only a small number of 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. Under pharmacovigilance guidelines, we are required to timely report any adverse events any patient using our products experiences and any clinical evaluations of outcomes in the post-marketing setting are required to be reported to appropriate regulatory agencies in accordance with relevant

regulations, as a result any potential adverse events will be promptly brought to the attention of regulators that may likely require prompt remedial action (and any failure to report these adverse events or report such events in a timely manner may result in penalties being imposed by regulators). In the event 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. If we experience any of the foregoing actions, it may harm our reputation and, particularly given that we rely on a very limited number of products for our revenue, our business and results of operations could be materially and adversely impacted. Further, any investigation into the circumstances surrounding an adverse event may be costly and time consuming (even if it is ultimately determined that the adverse event is not the result of the use of our product) or the investigation may not be sufficiently conclusive to prevent a regulatory authority from taking one of the foregoing actions against us.

In addition, many patients who use our products are already very ill and may suffer adverse events, including death, during treatment for reasons that may or may not be related to our products. Also, there are risks associated with our products; for example, use of C5 Inhibitors, such as SOLIRIS and ULTOMIRIS, is associated with an increased risk for certain types of infection, including meningococcal infection. In certain cases, 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, which could result in the patient using SOLIRIS or ULTOMIRIS experiencing a life-threatening meningococcal infection (and even in certain cases in which a vaccination can be delivered to the patient, it may not, eliminate all risk of meningococcal infection). Patients using our products and product candidates have died or suffered potentially life-threatening conditions either during or after ending their treatments, and these include patients who have died while participating in a clinical trial (for example, four patients died during the ULTOMIRIS Phase III clinical trial for aHUS, although none of these were considered related to the treatment with ULTOMIRIS). We may be sued by patients who are harmed during the course of using our products, whether as a prescribed therapy, during a clinical trial, during an investigator initiated study, or otherwise. Any such product liability lawsuit or injury claim, which could include class actions, could harm our reputation among patients, physicians, payers and others and require us to pay substantial amounts of money to injured patients, and even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations due to the expense of defending any such claim. While we do have product liability insurance, it 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, or at all.

We anticipate that we may face increased competition from companies that will enter into the markets we currently serve and as our product pipeline expands into markets that are currently served by other companies.

We expect that the business environment in which we operate will become increasingly competitive.

Currently, certain of our products are the only approved therapy for the indication they treat. For example, SOLIRIS and ULTOMIRIS (in the U.S.) are the only approved treatments of PNH. In the future, we expect that SOLIRIS and ULTOMIRIS may compete with new, novel drugs and pharmaceuticals currently in development. For example, several companies are developing and engaged in clinical trials for therapies to treat PNH, aHUS, and gMG. If SOLIRIS is approved for treatment of NMOSD, we expect there may be competition in that market as well. Since other companies are also operating clinical trials in this disease state. Additionally, other pharmaceutical companies have publicly stated that they are developing and intend to commercialize a SOLIRIS biosimilar and these biosimilars may be commercially available in the future. STRENSIQ and KANUMA may also experience competition in the future. We are also aware of companies that are planning to initiate studies for diseases that we are also targeting with our product pipeline. 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. Other pharmaceutical companies have publicly announced intentions to establish or develop rare disease programs and may introduce products that compete with ours (or products that are in our pipeline). 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, have less frequent dosing schedules, or easier to administer than our products. Our current and future competitors may develop products that are more broadly accepted or may receive patent protection that dominates, blocks or adversely affects our product development or business. These competitive products, including any biosimilars approved under alternative regulatory pathways, may significantly reduce both the price that we receive for such marketed products and the volume of products that we sell, which may negatively impact our revenues and profitability. Given that a significant portion of our 2018 revenue was attributable to SOLIRIS, one or more competitive products or biosimilar could have a significant impact on our entire business. In

addition, 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 may 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

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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.

Risks Related to Pricing and Reimbursement

Sales of our products depend on reimbursement by government authorities, private health insurers and other organizations, each of which are subject to pressures to contain costs. If we are unable to obtain, or maintain at anticipated levels, reimbursement for and access to our products, or coverage is reduced, our pricing may be adversely affected or our product sales, results of operations or financial condition could be harmed.

Our products are significantly more expensive than traditional drug treatments and almost all patients require governmental payers, such as Medicare and Medicaid in the U.S. or country specific governmental organizations in foreign countries, and/or private third-party payers to pay all or a portion of the cost of our products. There is also a significant trend in the health care industry by public and private payers to contain or reduce their costs. As a result, payers have in the past (i) decreased the portion of costs they will cover, (ii) ceased providing adequate payment for our products or (iii) not covered our products at all, each of which payers may continue to do in the future (or other payers who have not taken such actions in the past may do so in the future). Any of the foregoing may have an adverse impact on our revenue and results of operations.

Our ability to set the price for our products varies significantly from country to country, including in those countries where pricing, coverage, 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 at all), 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, which could delay market entry (or, if pricing is not approved, we may be unable to sell at all in a country where we have received regulatory approval for a product). In addition, authorities in some countries impose additional obligations, such as HTAs, which assess how well a pharmaceutical works in relation to its cost. Additionally, U.S. payers are increasingly considering new metrics as the basis for reimbursement rates. If our products do not meet or surpass these metrics, including any HTAs and other metrics imposed on our products, these payers may not reimburse for use of our products or may reduce the rate of reimbursement for our products and as a result we expect revenue from such product may decrease. We may also, in some

cases, elect to reduce prices or reimbursement with third parties which we believe provides value in the long term.

Further, 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 other countries or in new markets. In Canada, for example, the Patented Medicine Prices Review Board (PMPRB) issued a decision in an administrative pricing matter that we had excessively priced SOLIRIS in a manner inconsistent with the Canadian pricing rules and guidelines and ordered that the price be decreased to no higher than the lowest price in seven comparator countries (we filed an application for judicial review of the PMPRB's decision in the Federal Court of Canada, and a hearing on the matter was held in November 2018, but we are unable to determine the outcome of this review at this time since the court has not yet issued its opinion). In addition, the current U.S. presidential administration recently unveiled a number of proposals, among these was a recommendation to move from the current U.S. pricing and reimbursement regime to one that would establish pharmaceutical pricing by reference to a target price derived from the international price index (such a change may be expected to result in significant savings for the government for purchases of certain pharmaceuticals). If the U.S., which accounted for a significant portion of our revenue in 2018, were to move to a pricing system based on the international price index (or similar model) that were to apply to our products, we expect that our revenues for sales in the U.S. (or any other country adopting such a price index) may decrease, and such decrease may be material in amount.

Due to the cost of our therapies, any potential increase in the number of patients receiving our products (for example, we expect there may be increases in sales of SOLIRIS for patients with NMOSD, if approved by regulatory authorities for that indication), may cause third-party payers to modify, limit or eliminate coverage or reimbursement for our

products because they may require an allocation of a greater percentage of the potential financial resources of any public or private payer for our products.

Further, health insurance programs may utilize coverage incentives and obstacles to discourage beneficiaries from using higher priced products such as ours, including:

- establishing formularies under which only selected drugs are covered;
- utilizing variable co-payments that make drugs that are not preferred by the payer more expensive for patients; and

utilizing management controls, such as requirements for prior authorization or failure first on another type of treatment.

Any of these actions may subject our products to payer-driven restrictions.

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 use of our products or adoption of new treatment options, such as ULTOMIRIS. The continuation of the use of these types of limits or barriers by insurers or the imposition of similar limitations or barriers in the future may have an adverse impact on our revenue and results of operations. In some cases, we have financially supported non-profit organizations that assist patients in accessing treatment for PNH and aHUS, including SOLIRIS, among other therapies. 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 (or limited 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. As third-party payers attempt to contain health care costs they are demanding price discounts or rebates and limiting both the types and variety of drugs that they may cover and the amounts that they will pay for drugs. As a result, they may not cover or provide adequate payment to patients for our products or they may demand discounts or rebates from us, which may be material.

Our commercial success depends on obtaining and maintaining pricing for our products, which is directly tied to reimbursement for our products at anticipated levels for our products. It is difficult to project the impact of evolving reimbursement mechanics on the willingness of payers to cover our products, but we expect pharmaceutical pricing to continue to be subject to intense payer, political and societal pressures on a global basis. If we are unable to obtain or maintain coverage for our products, or coverage is reduced or eliminated in one or more countries or if the U.S. (or other countries) were to move to an international price index for our products, our pricing, product sales, results of operations or financial condition could be harmed.

Risks Related to Business Operations

We rely on a limited number of facilities to produce our products and 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 majority of our products and product candidates are biologics, which cannot be manufactured synthetically and must be produced from biologic sources. As a result, the production of biologic therapeutics that meet all product specification and regulatory requirements is particularly complex. Even slight deviations at any point in the production process may lead to production failures or recalls. For example, in 2013 and 2014 we undertook a voluntary recall of SOLIRIS due to the presence of visible particles in a limited number of vials. In addition, because the production process involves the use of materials that are derived from biological sources, the process can be affected by contaminants that could impact those biological micro-organisms. Therefore, the manufacture of our products and our product candidates is highly regulated, complex and difficult, and, as noted above, even minor technical problems or deviations could result in significant defects or failures and regulatory action against us. These manufacturing challenges are coupled with the fact that we have limited experience manufacturing commercial quantities of ULTOMIRIS, STRENSIQ and KANUMA (so we may have limited previous experience resolving any issues in connection with the manufacture of these products and it may take significant time to remediate or we may be unable to solve any manufacturing problems) and we rely on a limited number of facilities to manufacture our products for our development, clinical and commercialization needs, some of which we own and some of which are owned by third parties.

If we and/or our third party suppliers fail to meet the highly technical requirements of manufacturing our biologic products and our strict quality and control specifications, we (or they) may be unable to manufacture or supply our products. We depend on our third party manufacturers to perform effectively on a timely basis and to comply with regulatory requirements and meet our product specifications. If they are unable to do so, our contractual rights to

address any failures and right to recover damages are limited. Our failure or the failure of our third-party manufacturers 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, delay regulatory approval, result in the rejection of our product candidates or result in supply shortages for our patients, which may lead to lawsuits,

loss of revenue or could accelerate introduction of competing products to the market.

As noted above, 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, which may 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, or the facilities of our third party manufacturers, we or our third party manufacturers may need to close our or their manufacturing facilities for an extended period of time to investigate and remediate the contaminant.

If we underestimate demand for ULTOMIRIS, 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 Annual Report on Form 10-K, we may not be able to increase our revenues and alternative therapies may gain greater market acceptance.

We also face external factors, many of which are beyond our control, that 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 risks to our business of any manufacturing stops or interruptions (whether the result of internal or external factors) are amplified because we rely on a limited number of facilities to produce our products and product candidates. For example, each of our products is manufactured at only one to two facilities. Sales of SOLIRIS, which accounted for 86.3% of our revenue for the fiscal year ended December 31, 2018, in the U.S., the EU, Japan and certain other territories were manufactured exclusively by Lonza at its facilities in Singapore and Spain.

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. We expect that we will continue to rely on a very limited number of manufacturing facilities in the future for all of our products, including ULTOMIRIS.

We and our third party providers are required to maintain compliance with cGMP and other stringent operation and manufacturing requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. Governmental authorities will generally not permit products manufactured at a facility that is not registered by the applicable government agency to enter into the country and such products may be returned for failure to comply with such regulation, which may decrease or delay sales and result in the loss of inventory. 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 or comply with on-going operating regulations 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.

Our efforts to bring more of our manufacturing operations under our control present additional challenges. 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 certain of our other clinical and commercial products. We also completed construction of a 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 are also constructing new biologics manufacturing facilities at both sites. Despite the significant investment we have made in these facilities and operations, we cannot guarantee that we will be able to successfully and timely complete the construction of the biologics facilities or the appropriate validation processes or obtain the necessary regulatory approvals for these and other facilities, or that we will be able to perform the intended manufacturing and supply chain services at these facilities for commercial or clinical use. Prior to such time, we may continue to rely on third parties for these services.

If we experience any manufacturing issues, we may be unable to timely identify alternative manufacturers, and if we are able to timely identify alternative manufacturers, such alternative manufactures may not be able to satisfy our requirements. 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. The payment of a substantial penalty could harm our financial condition and may restrict our ability to transition to internal manufacturing or manufacturing by other third parties. In addition, the terms and conditions to engage an additional third party manufacturer may not be as favorable to us as our current arrangements and may likely reduce the profit on the sales of any products to which they relate.

In addition, KANUMA is a transgenic product and the facilities on which we rely to produce raw material for KANUMA are the only animal facilities in the world that produce 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 our animal operations altogether. If our animal operations are disrupted, it may be extremely difficult to set up another animal facility to supply the unpurified KANUMA.

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. Each of these could have an adverse material impact on our business individually or in the aggregate. Such manufacturing issues could increase our cost of goods, cause us to lose revenue, reduce our profitability or damage our reputation.

We rely on a limited number of providers for our raw materials and supply chain services, which could result in our being unable to continue to successfully commercialize our products and our product candidates (if approved) and to advance our clinical pipeline.

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 and materially limit our ability to generate revenues.

We also 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.

These third party raw material providers and supply chain service providers operate as independent entities and we do not exercise control over any such third party provider's operations or their 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 contractual remedies we may have under agreements with these parties may not protect us from the harm suffered by our business or our patients if they fail to provide material or perform services that meet our specifications. Due to the highly specialized nature of the services performed by these third parties, particularly the supply of our raw materials, we do not believe that we could quickly find replacement suppliers or service providers and, even if we were able to identify additional third parties, the terms of any such arrangement may not be favorable to us. In either of these cases, our revenue, results of operations, business and reputation may be harmed and we may not be able to provide the therapies that our patients require.

The success of our business may also depend on the security of our products while in the supply chain for delivery to patients, which, as noted above, is dependent on third-party providers. For example, if our products are not fully and adequately secured from unauthorized access by third parties, any of our products may be tampered with or contaminated. If our products were exposed to any tampering or contamination, or if they are not transported in accordance with the required specifications, our patients may be harmed through use of our products, and such harm may be severe. In addition, if the supply chain is not secure (or our distributors do not exercise control over our products while in their possession), we are also at risk for our products to be diverted to patients other than those who are the intended recipient or to patients who do not have a prescription to receive our therapies (or it may be used for treatment by physicians who have not completed the necessary REMs protocols in order to treat patients) or it may be sold by distributors, channels or other entities that are not authorized by Alexion to sell our products. In addition, an unauthorized distributor may not properly store or ship our products, thereby exposing patients to potential harm from use of the product that was not handled in accordance with our standards. In any of the foregoing were to happen, we

could be subject to costly litigation, significant monetary penalties, harm to our reputation and investigation by regulatory authorities (and potentially subject to regulatory action, including recall, product withdrawals, suspensions and monetary penalties).

The sale and use of counterfeit versions of our products could result in significant harm to patients, reduced sales of our products and harm to our reputation.

We are aware that counterfeit versions of our products have been sold by entities that are not affiliated with Alexion using product packaging suggesting that the product was manufactured by Alexion. If unauthorized third parties illegally distribute and sell

counterfeit versions of our products, those products may not meet our very stringent product specifications (or the manufacturing, handling and distribution requirements for our products) and any patient that takes any counterfeit product may suffer serious adverse health consequences, including death. Our reputation and business could suffer harm as a result of counterfeit drugs sold under our brand name and could result in lost sales for us and decreased revenues.

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 may be unable to successfully commercialize our products.

We currently market and sell our products in the U.S., the EU Japan and several other territories through a direct sales force. Most of our products are relatively new to the market (ULTOMIRIS for the treatment of PNH was approved by the FDA in December 2018, for example), and we have recently hired several senior members of our sales and commercial team. In addition, in order to gain greater efficiencies in our operations, we have begun to implement a plan pursuant to which certain portions of our international commercial operations will transition to a new operating model in which sales and marketing efforts in the designated countries will rely to a greater extent on third-parties to promote and sell our products, and our direct sales presence will decrease in these regions.

Due to the fact that many of our products are new to the market, we do not have significant experience in marketing and selling these productions to patients, healthcare providers and payers (for example, we are new to certain therapy areas, such as neurology (gMG), and our sales force has had very limited exposure in educating and targeting sales to patients and physicians in neurology practices). This challenge is coupled with the fact that many of our sales and marketing team are new to Alexion and we are transitioning to third parties to market and sell our product in certain countries. If we are unable to successfully market and sell our new products and to successfully sell our products in new therapy areas, as well as successfully implement the transition to third parties to distribute and market our products in certain countries, our business and sales may be harmed. One of our objectives is to expand our business and sales in the future. If we are unable to establish and/or expand our capabilities to sell, market and distribute our products in those jurisdictions where we will continue to rely on our direct sales force and, at the same time, effectively transition from a direct sales force model (or maintain such distributor capabilities in countries where we have already commenced commercial sales), we may not be able to successfully sell our products. In that event, we may not be able to maintain or increase revenues and achieve our goal of expanding our business. 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, or that we will be able to manage the transition to distributors in the relevant jurisdictions that will not cause any interruption or disruption in our business and sales of our products.

Even if we hire the qualified sales and marketing personnel necessary to support our objectives, or enter into marketing and distribution agreements with third parties on acceptable terms, we may not hire such employees or enter into such agreements in an efficient manner or on a timely basis. We may not be able to forecast accurately 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. In addition, as we launch new products, such as ULTOMIRIS for the treatment of PNH, and we move into new therapeutic areas (such as neurology), and, if and when, the products we acquire in connection with acquisitions and development agreements with third parties move closer to regulatory approval, we may have a larger product portfolio and address more therapeutic areas and the foregoing risks may continue to apply and may even increase. Our expenses associated with building up and maintaining the sales force and distribution capabilities around the world, and in transitioning from direct sales to third party marketers and distributors, may be disproportionate compared to the revenues we may be able to generate on sales or any savings or efficiencies we gain through use of such third-parties. We cannot guarantee that we will be successful in commercializing any of our products for the above referenced or other reasons.

Completion of proof of concept trials, preclinical studies or clinical trials does not guarantee advancement to the next phase of development or regulatory approval or successful commercialization.

Completion of preclinical studies or clinical trials does not guarantee that we will initiate additional studies or trials for our product candidates, if further studies or trials are initiated, what the scope and phase of the trial will be or that

they will be completed, or if these further studies or trials are completed, that the design or results may 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, we could be materially adversely affected. Failure of a clinical trial to achieve its pre-specified primary endpoint

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generally increases the likelihood that additional studies or trials may 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.

We are currently planning and conducting several clinical trials of products and product candidates that we anticipate may be important to our goal of expanding our business and diversifying our product portfolio. These trials may not yield the anticipated results for a number of reasons. For example, the fact that we have obtained marketing authorization in the U.S. for ULTOMIRIS as a treatment for PNH does not mean that ULTOMIRIS will be approved as a treatment for aHUS, gMG and NMOSD or that any clinical trials may achieve its designated endpoints and prove to be safe and effective for use in patients with these indications. In addition, we are also conducting clinical trials in therapeutic areas with which we have limited experience (for example, in 2018 we acquired ALXN1840 (WTX101), a therapy for Wilson's disease acquired from Wilson Therapeutics and are currently in Phase III clinical trials) and with technology platforms with which we also have limited experience (for example, in 2018 we acquired Syntimmune that develops humanized monoclonal antibody that inhibits the interaction of FcRn with Immunoglobulin G (IgG) and IgG immune complexes). Each of these clinical trials is subject to the risks highlighted in the preceding paragraph and the investments we have made in these technologies may not generate the expected returns if the clinical trials do not produce results that will meet the requirements of regulators and the needs of patients and their healthcare providers. In addition, we intend to further increase the number of products in our preclinical and early-stage clinical pipeline and the number of indications that our products address. For example, in 2019 we plan to initiate proof of concept clinical trials for ULTOMIRIS as a treatment for Amyotrophic Lateral Sclerosis (ALS) and Primary Progressive Multiple Sclerosis (PPMS). There is no guarantee that any proof of concept trial will provide sufficient evidence to advance our research beyond the proof of concept stage, and we may expend significant resources in an effort to establish proof of concept that ULTOMIRIS is a potential therapy for ALS or PPMS or that any other product in development will meet the standard for proof of concept for other indications. In the event that a product does satisfactorily establish proof of concept, and it does advance into preclinical or clinical trials, such product may face the risks and challenges identified in the preceding paragraph.

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 effects 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, including if there are concerns about patient safety. We may have to spend considerable resources repeating clinical trials or conducting additional trials, either of which may increase costs and delay revenue from those product candidates, if any. We may open clinical sites and enroll patients in countries where or for indications in which we have little experience.

We rely on a small number of clinical research organizations to carry out our clinical trial related activities, and one contract research organization (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. In addition, we may be responsible for any errors in clinical trials by a CRO as a result of the performance of services in connection with a clinical trial on our behalf. And regulatory agencies, in connection with a potential product or approval or as part of on-going monitoring, will review a CROs compliance with regulatory requirements relating to clinical trials and we may be subject to findings and regulatory action (including denial or delay of product approval) if a CRO fails to comply with regulations.

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

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- 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 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;
- 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;
- failure of patients taking the placebo to continue to participate in our clinical trials;
- insufficient clinical trial data to support safety and effectiveness of the product candidates;
- lack of effectiveness or safety of the product candidate being tested;
- 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.

We may not accurately forecast demand for our products, including our new products, or the conversion of PNH patients to ULTOMIRIS, which may cause our operating results to fluctuate. Our quarterly revenues, expenses and net income (loss) may fluctuate, even significantly, due to certain risks, including those described in these “Risk Factors” as well as the timing of charges and expenses that we may take and acquisitions (such as the Wilson Therapeutics and Syntimmune acquisitions). In the future, 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. Since

we have a limited sales and operating history with certain of our products (such as ULTOMIRIS as a treatment for PNH in the US) and for new indications of existing products (such as SOLIRIS as a treatment for gMG), we may not be able to accurately forecast demand for our products. STRENSIQ and KANUMA, also relatively new products, each received marketing approval in 2015, and both products treat rare diseases for which there was no existing therapy in a new therapeutic area. We have recently filed for regulatory approval for SOLIRIS as a treatment for NMOSD. Since approval of ULTOMIRIS as a treatment for PNH in the U.S. in December 2018, we have undertaken efforts to facilitate the conversion of PNH patients in the U.S. from SOLIRIS to ULTOMIRIS. Product demand and, in the case of conversion to ULTOMIRIS, product preference and conversion, is dependent on a number of factors, many of which are beyond our control. For these reasons, we may not be able to accurately forecast demand for our products.

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.

Our investors and investment analysts may have widely varying expectations that may be materially higher or lower than actual revenues and profits and if our revenues and profits are different from these expectations, our stock price may experience significant volatility. Our revenues and profits 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.

In addition, we have in the past provided, and expect to continue to provide, financial guidance for future periods and if our actual operating results fail to meet or exceed the guidance that we have previously provided to our investors, our stock price could drop suddenly and significantly.

As we attempt to expand our pipeline, obtain regulatory approval for new products, facilitate the conversion of PNH patients from SOLIRIS to ULTOMIRIS in the U.S., seek regulatory approval for existing products in new

jurisdictions and approval of new indications for existing products (such as SOLIRIS as a treatment for NMOSD), we may have substantial expenses as we continue our research and development efforts, continue to conduct clinical trials and continue to develop and expand manufacturing, sales, marketing and distribution capabilities worldwide, some of which could be delayed, scaled-back or eliminated to achieve our financial objectives. These expenses may increase and such increases may exceed analyst and investor expectations.

If we fail to achieve the expected financial and operating benefits of our corporate restructurings, our business and financial results may be harmed.

We have undertaken corporate restructuring activities to re-align our global organization with our re-focused strategy, reduce costs, and realize operational efficiencies. We estimate that our most recent restructuring, which includes our transition in certain jurisdictions from a direct sales model to increased use of third parties, will result in a charge of up to \$25.0 in 2019. These recent restructuring activities, including work force reductions, closing certain operational sites and our increased use of third parties in certain countries to market and distribute products (and rely less on a direct sales force), subject us to many risks, including loss of business continuity, unanticipated costs, and higher than usual employee turnover. In addition, we will not exercise the same degree of control over any third parties that we do over our direct sales force and the ability to direct the third party or provide incentives for such third party to sell our products may not be as strong as in the case of a direct sales force. The expected cost savings and operational efficiencies from the restructuring activities are based on assumptions and expectations that we believe were reasonable in our judgment at the time made 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 any restructurings, 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 Chief Executive Officer (CEO) and we have experienced other recent significant management changes. In addition, since 2017, we have moved our global headquarters and undertaken company-wide restructurings with the goal of re-aligning our global organization with our re-focused strategy and to make our international operations more efficient and effective.

The relocation of our headquarters and restructurings 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 to develop, manufacture and commercialize 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 2018, we amended and restated our credit facility to, among other things, increase the amount available under the revolving credit facility from \$500.0 to \$1,000.0 and extend the maturity date of the revolving credit facility and the term loan facility to June 7, 2023. As a result, we have significant debt service obligations. In addition to the obligations to make interest and principal payments under the facility throughout the term of the loans, any changes in interest rates related to this debt could significantly increase our annual interest expense and any hedging of this interest may not be effective to control expenses.

In addition, we have substantial contingent liabilities, including milestone and royalty obligations under acquisitions and strategic transactions, and we have been, and in the future may again be, engaged in disputes with certain counterparties regarding potential milestone and royalty obligations. 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 our credit facilities and require us to use cash flow from operations to satisfy our debt obligations, which may 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 Amended and Restated Credit Agreement requires us to comply with certain financial covenants and negative covenants, 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, subject to limited exceptions. If an event of default occurs, the interest rate may increase and the administrative agent may be entitled to take various actions, including the acceleration of amounts due under the Amended and Restated Credit Agreement. If the interest rate imposed under our Amended and Restated Credit Agreement were to increase as a result of a default, our expenses may increase and we may need to allocate additional funds to this interest expense (which may limit the use of these funds for other purposes, including growing our business or responding to changes in our business and industry). If some or all of the amounts outstanding under the Amended and Restated Credit Agreement were to be accelerated by the lenders, we may not have sufficient cash on hand to pay the amounts due, we may not be able to refinance such debt on terms acceptable to us (or at all) and we may be required to sell certain assets on terms that are unfavorable to us.

Our ability to satisfy our obligations under the Amended and Restated Credit Agreement and meet our debt service obligations and our royalty and milestone 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 or at all.

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, amounts we may need to pay in connection with the resolution of any government investigation or litigation matter (including any securities class action matter or any product liability claim), the cost of obtaining and maintaining the necessary regulatory approvals for our manufacturing facilities, and the progress, timing and scope of our preclinical studies, clinical trials and product development and commercialization efforts. The capital and credit markets have experienced and may continue to experience 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 working capital, capital requirements and debt repayment obligations (or royalty and milestone obligations), we may have to delay, scale-back or

eliminate certain research, development, manufacturing, acquisition or commercial activities or sell certain assets and technologies.

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 and foreign 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. Although we believe that our safety procedures for handling and disposing of hazardous materials comply with the laws and regulations established by state, federal and foreign regulations, the risk of loss of, or accidental contamination or injury from, these materials cannot be eliminated. 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 to dedicate more resources, including substantial financial resources, to comply with such laws and regulations or purchase supplemental insurance coverage, which may not be available on acceptable terms or at all.

In order to meet one of our key business objectives of advancing and rebuilding our product pipeline, we plan to expand our business and product offerings through acquisitions of businesses and technologies. Our efforts to identify

opportunities or complete transactions that satisfy our strategic criteria may not be successful, and we may not realize the anticipated benefits of any completed acquisition or other strategic transaction.

As noted above, in 2018 a substantial portion of our total revenue was derived from SOLIRIS. We expect that there may be increased competition to SOLIRIS from, among other products and therapies, biosimilars, and we are still in the very early stages of the launch of ULTOMIRIS in the U.S. for PNH and cannot guarantee that our efforts to facilitate the conversion of patients

from SOLIRIS to ULTOMIRIS or to have new PNH patients prescribed ULTOMIRIS will be successful (or that we will obtain clearance for ULTOMIRIS for PNH in the EU, Japan and other jurisdictions). As a result, we have identified rebuilding our product pipeline as a key strategic objective and, in order to achieve this objective, we expect to purchase businesses and acquire, co-develop or license technologies and products from third parties in the future. For example, in 2018, among other transactions, we completed acquisitions of Wilson Therapeutics and Syntimmune, Inc. We anticipate that we will regularly evaluate potential merger, acquisition, partnering and in-license opportunities in an effort to expand our pipeline or product offerings, and enhance our research platforms. Acquisitions of new businesses or products and in-licensing of new technologies and products may involve numerous risks, including:

- substantial cash expenditures;
- potentially dilutive issuance of equity securities and incurrence of debt;
- assumption of material liabilities in connection with the target or purchased technology, 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 or technologies to achieve the scientific, medical, commercial or other results we anticipate;
- diverting our management's attention away from other business opportunities and concerns;
- the potential loss of our key employees or key employees of the acquired companies; and
- risks of entering disease areas and indications in which we have limited or no direct experience.

A substantial portion of our strategic efforts are focused on opportunities for rare disorders, 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. In such event, we may not be able to rebuild our pipeline and any future revenue may remain largely dependent on our existing products which, as noted above, may be subject to increasing competition from biosimilars and other competitive or novel therapies.

Even if we are able to successfully identify and complete acquisitions and other strategic transactions,

we may not be able to integrate 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, particularly if the acquired technology is preclinical trials or early-stage clinical trials.

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 may 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 and we may likely incur substantial expenses in advancing acquired products to commercialization. We may not have the necessary funds for these capital expenditures and expenses or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by incurring additional indebtedness and 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 us upon conversion.

We may incur impairment charges in the future for certain of our assets, including goodwill in connection with acquisitions, and such amounts may be material.

If the purchase price of a business acquisition exceeds the value of the assets (and liabilities) acquired, the acquirer must recognize goodwill in such amount. We may be required to recognize impairment charges for our goodwill and other intangible assets, and such charges may be material and have an adverse impact on our financial results in the period such charges are incurred.

As of December 31, 2018, the net carrying value of our goodwill and other intangible assets, net totaled \$8,678.7. As required by GAAP, we periodically assess these assets to determine if there are indicators of impairment. We have recorded charges that include inventory write-downs for failed quality specifications or recalls, impairments with respect to investments and acquisitions, 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. The impairment of tangible and 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 the 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, 2018 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, 2018 is \$3,252.6.

Our business could be adversely 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. See Note 11 “Commitments and Contingencies” to the footnotes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for information on our material legal proceedings. For example, 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. Any determination that our operations or activities are not in compliance with existing laws or regulations, by the SEC or DOJ in the above referenced matter for example, could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief, exclusion from the federal healthcare programs, healthcare debarment, product recalls, reputational damage and modifications of our business

practices and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations. Legal proceedings, government investigations, including the SEC and DOJ investigations, and enforcement actions have been and we expect may continue to be expensive and time consuming. Any future litigation or investigation may also likely be expensive and time consuming.

The 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 increase, 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 at the time made, the final taxes we owe may differ from the amounts recorded in our financial statements (and such differences may be material). 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, and from time to time we modify, 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 or other operations. 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 such increase may be material) 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 such increase may be material) 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 of our international business.

We have increased 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 or at all;
- 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;
- customs and tax officials in foreign jurisdictions may disagree with the value we set when we or others import our products (including products that are donated for charitable purposes) and we may be required to pay additional duties or fines and such amounts may be substantial;
- difficulties in establishing and 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 in the locations in which we operate our business 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, and we are currently implementing an enhanced company-wide compliance program and effort, designed to help ensure that we and our representatives, including our employees and our vendors and distributors, 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 us or our representatives. Any determination that our operations or activities are not in compliance with existing laws or regulations, including the FCPA and the UK Anti-Bribery Act, 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 a material and adverse effect on our business operations. In addition, as our international operations expand, we are likely to become subject to new anti-corruption/anti-bribery laws or existing laws may govern our activities in new jurisdictions in which we operate. In addition, as we move from a direct sales force to third-party distributors and marketers in certain countries and regions, we may also have liability under the FCPA and anti-bribery laws and regulations for their actions.

Although we can impose contractual restrictions on what they are authorized to do on our behalf, we will exercise only limited control over the actions of these third parties but may still face the same liabilities for their actions. Our failure, and the failure of others who we engage to act on our behalf, to comply, with the laws and regulations of the countries in which we operate, or will operate in the future, could materially harm our business.

Currency fluctuations and changes in exchange rates could adversely affect our revenue, 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 such fluctuations 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, Canadian dollar and Turkish Lira. 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 a portion of 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 revenue hedges is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. 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.

Risks Related to the Regulatory Environment

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 may be seriously harmed.

We and our current and future third party vendors, contract manufacturers, CROs, distributors and suppliers and logistic providers 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 the MHLW. These regulations, many of which are complex, relate to almost all aspects of our business, including GCP, GLP, cGMP and pharmacovigilance rules (for additional information on the regulations relating to our business, see “Business - Government Regulation” in Item 1 above in this Annual Report on Form 10-K). 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 (such as product contamination), or in the case of KANUMA, problems with animal operations, a regulatory agency may impose restrictions on that product, the manufacturing facility or us. We have received a Warning Letter from the FDA relating to compliance with FDA’s cGMP requirements at one of our facilities, which was remediated. If we had failed to address the FDA’s concerns or if we (or one of our third party contract manufacturers) were to receive

another Warning Letter in the future relating to cGMP or other applicable regulations, the FDA or other regulatory authorities could take regulatory action, including fines, civil penalties, recalls, seizure of product, suspension of manufacturing operations, operating restrictions, injunctions, suspension of clinical trials, 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. In addition to our manufacturing operations and those of contract manufacturers’ manufacturing operations being subject to inspection and potential regulatory action for failure to comply with (among other regulations) cGMP, our animal operations may also be subject to FDA and U.S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA APHIS) 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.). 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.

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 our products;

interruption of production;

operating restrictions, such as a shutdown of production facilities or production lines, or new manufacturing requirements;

- suspension or termination 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

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criminal prosecution.

In addition, we are subject to antitrust regulations with respect to our acquisitions, as well as our interactions with other participants in the markets we serve. In addition, these antitrust laws are vigorously enforced in the U.S. and in other jurisdictions in which we operate.

Our product candidates require extensive clinical testing and regulatory approval and failure of to satisfy regulatory requirements to meet the appropriate safety and efficacy thresholds may prevent us from being able to market our products and limit our ability to grow our business and diversify our revenue.

We believe our future success may depend on our ability to develop and commercialize our product candidates and, to this end, we have recently acquired companies and technologies in an effort to expand our product pipeline. Our product candidates are in various stages of development and must satisfy the rigid safety and efficacy requirements of the FDA and other foreign regulatory agencies before they can be approved for sale to patients. To satisfy these standards, we must ensure, among other things, that we have appropriately established our protocol designs, obtained the necessary IRB approval, provide adequate patient enrollment rates, timely and appropriately report any adverse events and serious adverse events to the appropriate authorities and ensure compliance with cGCP. If we or our third-party clinical trial providers or third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or be unsuccessful.

If we discover safety or safety reporting issues with any of our approved products, or if we fail to comply with continuing U.S. and applicable foreign regulations, our revenue may decrease, an approved product could lose its marketing approval or sales could be suspended and our business could be materially harmed.

Following marketing approval of a pharmaceutical product, the safety profile of such product continues to be closely monitored by the FDA and other foreign regulatory authorities. 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 REMS program for SOLIRIS, most recently updated by the FDA in 2015, requires prescribing information regarding the level of fever needed to seek medical attention and reporting adverse events. Future changes to the SOLIRIS REMS (or similar requirements for other products) 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, the MHLW and other health agencies. Adverse safety events involving our products may have a negative impact on our business. Discovery of safety issues with our products could result in product liability claims and could cause additional regulatory scrutiny and requirements for additional labeling or safety monitoring, withdrawal of products from the market and the imposition of fines or criminal penalties. In addition, governmental authorities are making greater amounts of safety information directly available to the public through periodic safety update reports, patient registries and other reporting requirements. The reporting of adverse safety events may also damage physician, patient and/or investor confidence in our products and our reputation. Any adverse events in connection with the use of our products could result in liabilities, loss of revenues, material write-offs of inventory, material impairments of intangible assets, goodwill and fixed assets, material restructuring charges and other adverse impacts on our results of operations.

Regulatory agencies periodically inspect our pharmacovigilance processes. If these regulatory agencies determine that we or other parties whom we do not control that perform services on our behalf, 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 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.

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. In addition, similar or more stringent post-approval requirements and obligations may be imposed by the FDA and/or other regulatory agencies with respect to our future products (such as ULTOMIRIS or SOLIRIS for the treatment of NMOSD, if approved for use by the FDA and such agencies). Compliance with these post-approval requirements could result in increased cost and expense and decrease our operating margins and, if we are unable to comply with these requirements, we may be subject to regulatory action by the applicable regulatory agency and the penalties may include fines and product withdrawals or restrictions in the use of a product.

If we fail to comply with applicable healthcare laws and regulations, including those related to healthcare fraud and abuse, we may be subject to investigations and civil or criminal penalties and our business could be adversely affected.

We are subject to healthcare “fraud and abuse” laws, such as the FCA, the anti-kickback provisions of the federal Social Security Act, laws prohibiting off-label product promotion 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.

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 of pharmaceuticals 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 Anti-Kickback Statute and FCA laws, including operating within any available safe harbors, but we cannot assure that our compliance program, policies and procedures will always protect us 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 and potential penalties is provided under “Government Regulation - Fraud and Abuse” included above in Item 1 in this Annual Report on Form 10-K.

In recent years, legislation has been adopted at the federal, state and local level requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports or make periodic public disclosures on sales, marketing, pricing, clinical trials, health care provider payments and other activities. For example, as part of the PPACA, the federal government enacted the Open Payments (commonly known as the Sunshine Act) provisions. Open Payments requires pharmaceutical manufacturers to report annually to CMS payments or other transfers of value made by that entity to physicians and teaching hospitals. We also now have similar reporting obligations throughout the EU. Failure to comply with the reporting requirements may result in significant civil monetary penalties.

Violations of U.S. federal and state fraud and abuse laws (and comparable laws in foreign jurisdictions) may result in criminal, civil and administrative sanctions, including fines, damages, civil monetary penalties (which may be material in amount) and exclusion from federal healthcare programs (including Medicare and Medicaid). Any action initiated 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.

Finally, the FDA, the EU and EU Member States and the MHLW impose restrictions on the promotion and marketing of drug products and prohibit pharmaceutical manufacturers from promoting products for indications other than those cleared or approved by regulatory authorities or for use in manner that is not consistent with the product label approved by regulatory agencies, or off-label promotion. In certain instances, physicians are, however, in their medical judgment permitted to use products for unapproved purposes and we are aware of such uses of SOLIRIS. For information regarding a recent MHLW inquiry focused on our communication efforts regarding the proper use of SOLIRIS in Japan for aHUS, see Note 11 “Commitments and Contingencies” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Although we believe our marketing materials and training programs for physicians do not constitute improper promotion, the FDA, the U.S. Department of Justice (DOJ), other federal or state government agencies, the EU, EU Member States or the MHLW may disagree. If any governmental authority determines 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, product withdrawal or recall, injunction, seizure, civil fine and criminal penalties. It is also possible that other 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 sales and marketing practices of the pharmaceutical industry have been the subject of increased scrutiny from authorities such as the DOJ, and we expect that this trend may continue and may increase. If the government or the courts determine that we breached any of these sales and marketing laws, we may be subject to penalties identified above. Any action against us for violation of these laws, even if we successfully defend against them, also could cause us to incur significant legal expenses, harm our reputation and divert our management’s attention from the operation of our business.

Our business and operations may be materially adversely affected by government investigations.

We are subject to the 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. While we have enhanced our compliance and training programs, we cannot assure that our compliance program, policies and procedures will always protect us from acts committed by employees or third-parties acting on our behalf.

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 our compliance with the FCPA. The SEC and DOJ also sought information related to our recalls of specific lots of SOLIRIS and related securities disclosures. 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 certain 501(c)(3) organizations (as described below). 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 our Brazilian operations. In October 2018, the MHLW conducted an inspection of our Japanese operations. We are cooperating with these investigations. At this time, we are 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, could result in the imposition of a broad range of civil and criminal sanctions against us 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. Any attempts to resolve some or all of these matters may not be successful. If we were to engage in settlement discussions with respect to any current or future investigation or litigation (and we

may accrue amounts due to the nature of such discussions), but the matter is not settled, the ultimate resolution may result in monetary or other penalties materially stricter or greater than the terms or amounts that we proposed in discussions (or the amount that we accrued for such matter during negotiations). For example, in connection with the investigation by the U.S. Attorney's Office for the District of Massachusetts relating generally to our support of Patient Services, Inc. (PSI) and National Organization for Rare Disorders (NORD), 501(c)(3) organizations that provide financial assistance to Medicare patients taking drugs sold by Alexion (among other matters) we have accrued approximately \$13.0 in the fourth quarter of 2018 as a result of our agreement

in principle to settle this investigation (but there is no guarantee that the steps necessary to conclusively resolve this matter will be successful or that the settlement terms will be finalized (and, if not completed, our liability in connection with this matter may exceed \$13.0)). Additionally, remediation of any such findings resulting from these and any future investigations 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., state or foreign governmental investigation or whistleblower lawsuit, has resulted and could continue to 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.

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 PPACA substantially changed the way healthcare is financed by both governmental and private insurers in the U.S., and significantly impacts the pharmaceutical industry. The 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 (and allowing biosimilars access to the market in accordance with the FDA's Biosimilars Action Plan). These changes may impact existing government healthcare programs and may 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 2016, CMS implemented changes to the Medicaid Drug Rebate Program under the PPACA. 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 may continue to increase our costs and the complexity of compliance, has been and may be time-consuming, and could have a material adverse effect on our results of operations.

Similar efforts to those in the United States, and in some cases even more aggressive efforts, are being taken by governments to control the costs of pharmaceutical drugs in countries outside the U.S. In these markets outside the U.S., the pricing and reimbursement of pharmaceutical products is subject to direct or indirect governmental control and such government authorities are increasingly attempting to limit or regulate the price of drug products and due to their control over pricing are able to move quickly to implement pricing changes.

We may face uncertainties as a result of federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. There is no assurance that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform may affect our business.

The current presidential administration has also indicated an intent to address prescription drug pricing and recent Congressional hearings have brought increased public attention to the costs of prescription drugs. These actions and the uncertainty about the future of the PPACA and healthcare laws may put downward pressure on pharmaceutical pricing and increase our regulatory burdens and operating costs.

State governments have sought to put in place limits and caps on pharmaceutical prices and have also requested rebates for certain pharmaceuticals. Attempts to decrease prices of pharmaceuticals products may lead to increased use of managed care organizations by Medicaid programs which could lead to managed care organizations influencing prescription decisions for beneficiaries and a corresponding limitation on prices and reimbursement for our products.

Governments in countries where we operate have adopted or have also 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. 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 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. Any failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results.

Pricing and rebate calculations vary among products and programs. The calculations, including those in connection with the Medicaid Drug Rebate Program and 340B drug pricing program (as described further below) 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 or other applicable government authorities 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. For example, if we become aware that our reporting to CMS 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 these programs, including 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 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. If a governmental authority, such as CMS, were to take any of the foregoing actions, our business and results of operations may be negatively impacted.

The Public Health Service's 340B drug pricing program, and other comparable government and payer regulations, may have a negative impact on the price we can charge for our products and result in a decrease in revenues.

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. The 340B pricing program is described in Pharmaceutical Pricing and Reimbursement in Item 1 Business in this Annual Report on Form 10-K. The 340B ceiling price is calculated using a statutory formula, which is based on, among other prices, the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program. We are a participant in the 340B drug pricing program and are, for the applicable covered entities, subject to the price ceiling. Any changes to the 340B drug pricing program, including:

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the method of calculating the 340B ceiling price for our products (such as the pricing regulations that have been further delayed until July 2019);

any expansion of the entities that qualify as covered entities; and

any requirement that participating manufacturers agree to provide 340B discounted pricing on drugs used in an inpatient settings;

could have a material and negative impact our revenue and results of operations.

In addition, the agreement that manufacturers must sign to participate in the 340B pricing program obligates 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. Beyond the Public Health Service's 340B drug pricing program, federal law requires that a company must participate in the Department of Veterans Affairs Federal Supply Schedule (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, may be expensive, 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 applies in all EU Member States and went into effect on May 25, 2018 and replaced the 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 increases 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 may result in notification obligations to affected individuals and government agencies, legal claims or proceedings, and liability under foreign, 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 may 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 may 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 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 may be harmed.

Our success depends 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. In addition, a patent may be issued in one country, but a counterpart patent may not be issued in another country. For example, we have applied for a certain patent in the EU that would provide protection for the composition of matter for SOLIRIS through 2027, and while a similar patent was granted in the U.S., the European patent application remains under examination by the European Patent Office and a hearing on it scheduled for February 2019 has been delayed until later in the year. Even if a patent is issued, that is not conclusive as to

inventorship, scope, validity or enforceability and therefore that patent may not afford adequate (or any) protection for our products. Third parties may challenge our patents, and have challenged our patents in the past and, in some cases have been successful in such challenges. For example, on January 21, 2019, the Opposition Division of the European Patent Office determined, following multi-party opposition proceedings, to revoke our European patent No. 2359834, which relates to the formulation of SOLIRIS. If any of our patents are narrowed, invalidated, revoked 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. Certain countries have laws that provide stronger bases for challenging third party patent rights than are available to challenge patents in other countries. Therefore, we may be able to defend our patents against a third party claim in one country but counterpart patents may be invalidated in

other countries and we may be able to invalidate a third-party patent in one country but not invalidate its counterpart patents in other countries. 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, including in connection with development efforts such as those with Complement Pharma and Dicerna. Collaboration and discussion of potential collaboration present a strong risk of exposing our trade secrets. If our trade secrets were exposed, we may lose the protection and potential exclusive rights afforded by trade secret law, and such exposure may likely help our competitors and allow them to access technology without restriction and adversely affect our business prospects.

If we are found to be infringing third party patents, 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 or product candidates, which may 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 have and may in the future receive notices claiming our products infringe third party patents and third parties have and may in the future file civil lawsuits against us claiming infringement of their intellectual property rights. Most recently, in late-2018, Chugai Pharmaceutical Co., Ltd. filed suits in the U.S. and Japan alleging that ULTOMIRIS infringes a U.S. and two Japanese patents, respectively, held by Chugai (these suits are still in the early stages). 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 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. Intellectual property disputes, such as those initiated by Chugai, can be costly and time consuming to defend. Prior to launch of a new product (or an existing product for a new indication), for various reasons, a patent owner may not be able to assert its patent rights so it is likely that any potential challenges to our products may be made after a product has been commercialized and not while the product is in development, in clinical trials or during the regulatory review process. 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 be forced to stop manufacturing, using or selling our products, which may adversely affect our business. We may seek to obtain a license prior to or during legal actions in order to reduce the risks in connection with product launches (or at a later time) and to reduce further costs and the risk of a court determination that our technology, techniques, proprietary compounds or potential product candidates infringe 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. In addition, even if we obtained a license, it would likely be non-exclusive and any competitive advantage resulting from the licensed technology may be of limited value and the same technology could be utilized by competitors.

In some instances, we believe we may prevail in a patent infringement action. There can, however, be no assurance that the court will agree with our position or that they will decide this or any other infringement case in our favor. Nor can we be certain that, if we do not prevail in litigation, that we may be able to obtain a license to any third-party patent on commercially reasonable terms or at all; successfully develop non-infringing alternatives on a timely basis (or at all); or license alternative non-infringing technology, if any exists, on commercially reasonable terms (or at all). 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 may 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 protection. 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 market exclusivity (i.e., the biosimilar product cannot be approved before 12 years after the innovative biological product). 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, Japan and Russia. Other companies are developing and advancing SOLIRIS biosimilar programs, including conducting clinical trials. Competition, including from biosimilars approved for marketing, may likely result in a decrease in prices, increased promotion efforts and lower margins for our products. In addition, approval of a biosimilar that is substitutable for one of our products may increase the risk of accelerated market penetration by that biosimilar. Further, if patients or healthcare providers do not believe that ULTOMIRIS provides a compelling profile for patient conversion from SOLIRIS, a SOLIRIS biosimilar may not only be expected to have a material and negative impact on our SOLIRIS revenues and margins (which accounted for a significant percentage of our revenue in 2018), it may also have a material impact on ULTOMIRIS revenue and margins and the ability of ULTOMIRIS to gain market acceptance.

Our other products are also at risk from biosimilars. Other than SOLIRIS for the treatment of gMG and SOLIRIS and ULTOMIRIS as a treatment for PNH, 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.

Risks Related to Our Common Stock

Our stock price is volatile.

The trading price of our common stock has been 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 and the Chugai lawsuits alleging patent infringement, 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 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 five million 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 may 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.

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
Boston, Massachusetts	Corporate headquarters and executive, sales, research and development offices	150,000	2031
New Haven, Connecticut	Research and process development laboratories, clinical supply and quality, enterprise business services	263,000	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	40,000	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, the construction of this facility is on-going and, based on current expectations, we anticipate this facility will receive regulatory approval in 2020.

In May 2015, we announced plans to construct a new biologics manufacturing facility on our existing property in Dublin, Ireland, the construction of this facility has commenced and, based on current expectations, we anticipate this facility will receive regulatory approval in 2020.

In the fourth quarter of 2018, we amended the New Haven lease agreement significantly reducing our rented square footage in the building beginning in 2019 through the expiration of the lease.

Item 3. LEGAL PROCEEDINGS.

For a discussion of legal matters as of December 31, 2018, see Note 11, "Commitments and Contingencies," Contingent Liabilities, within our notes to the consolidated financial statements included in this Annual Report on Form 10-K, which is incorporated into this item by reference.

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."

As of January 28, 2019, we had approximately 94 stockholders of record of our common stock and an estimated 210,846 beneficial owners. The closing sale price of our common stock on January 28, 2019 was \$119.21 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. In addition, restrictive covenants under our amended and restated credit agreement prohibit or limit the payment of cash dividends if we are not in compliance with certain covenants.

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 2018:

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, 2018	—	\$	—	451.5
November 1-30, 2018	—	—	—	451.5
December 1-31, 2018	—	—	—	451.5
Total	—	\$	—	

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 amount that we are authorized to expend on future repurchases to \$1,000 under the repurchase program, which superseded all prior repurchase programs. As of February 6, 2019, there is a total of \$451.5 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 outstanding options (years)	Number of shares of common stock remaining available for future issuance under equity compensation plans (2)
Equity compensation plans approved by stockholders	3.6	\$119.68	4.74	17.7
Equity compensation plans not approved by stockholders	—	\$—	—	—

(1) Reflects number of shares of common stock to be issued upon exercise of outstanding options under all our equity compensation plans, including our 2017 Incentive Plan. Does not include 3.7 of outstanding restricted stock units,

including performance-based restricted stock units, that were issued under the 2017 Incentive plan and the previous Amended and Restated 2004 Incentive Plan.

(2) Of these shares, 17.0 remain available for future issuance under the 2017 Incentive Plan and 0.7 remain available under the 2015 Employee Stock Purchase Plan.

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

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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, 2013 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

	12/13	12/14	12/15	12/16	12/17	12/18
Alexion Pharmaceuticals, Inc.	100.00	139.24	143.55	92.07	90.00	73.27
Nasdaq Composite	100.00	114.62	122.81	133.19	172.11	165.84
Nasdaq Biotechnology	100.00	131.71	140.56	112.25	133.67	121.24

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 Consolidated 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,				
	2018	2017	2016	2015	2014
Net product sales ⁽¹⁾	\$4,130.1	\$3,549.5	\$3,081.7	\$2,602.5	\$2,233.7
Other revenue	1.1	1.6	2.4	1.5	—
Total revenues	4,131.2	3,551.1	3,084.1	2,604.0	2,233.7
Cost of sales ⁽²⁾	374.3	454.2	258.3	233.1	173.9
Operating expenses:					
Research and development	730.4	878.4	757.2	709.5	513.8
Selling, general and administrative	1,111.8	1,094.4	953.0	862.6	630.2
Acquired in-process research and development ⁽³⁾	1,183.0	—	—	—	—
Amortization of purchased intangible assets ⁽⁴⁾	320.1	320.1	322.2	116.6	—
Change in fair value of contingent consideration	116.5	41.0	35.7	64.2	20.3
Acquisition-related costs	—	—	2.3	39.2	—
Restructuring expenses ⁽²⁾	25.5	104.6	3.0	42.1	15.3
Impairment of intangible assets	—	31.0	85.0	—	11.5
Total operating expenses	3,487.3	2,469.5	2,158.4	1,834.2	1,191.1
Operating income	269.6	627.4	667.4	536.7	868.7
Other (expense) income ⁽⁵⁾	(27.4)	(79.6)	(91.2)	(38.6)	3.4
Income before income taxes	242.2	547.8	576.2	498.1	872.1
Income tax expense ^{(6) (7) (8)}	164.6	104.5	176.8	353.7	215.2
Net income	\$77.6	\$443.3	\$399.4	\$144.4	\$656.9
Earnings per common share					
Basic	\$0.35	\$1.98	\$1.78	\$0.68	\$3.32
Diluted	\$0.35	\$1.97	\$1.76	\$0.67	\$3.26
Shares used in computing earnings per common share					
Basic	222.7	223.9	224.3	213.4	198.1
Diluted	224.5	225.4	226.3	215.9	201.6

Consolidated Balance Sheet Data:

	As of December 31,				
	2018	2017	2016	2015	2014
Cash, cash equivalents and marketable securities	\$1,563.8	\$1,474.1	\$1,293.4	\$1,385.0	\$1,961.6
Total assets ⁽⁹⁾	13,931.9	13,583.3	13,253.3	13,097.9	4,202.0
Long-term debt (current and noncurrent) ⁽¹⁰⁾	2,595.5	2,888.1	3,055.1	3,420.9	57.5
Contingent consideration (current and noncurrent)	280.8	168.9	152.9	177.2	163.0
Facility lease obligation (current and noncurrent)	372.2	353.3	243.4	151.3	107.1
Total stockholders’ equity ⁽¹¹⁾	9,165.3	8,893.1	8,693.8	8,258.6	3,302.0

In addition to the following notes, see “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 (which facility was subsequently sold in 2018). 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 second quarter 2018, we completed the acquisition of Wilson Therapeutics AB (publ). We acquired in-process research and development related to WTX101, an early Phase III asset in development for the treatment of Wilson Disease. Due to the stage of development of this asset, the value of this asset of \$803.7 was expensed during 2018. In the fourth quarter of 2018 we completed the acquisition of Syntimmune, Inc. We acquired in-process research and development related to SYNT001, which is in Phase 1b/2a trials and in development for the treatment of Immunoglobulin G and IgG-mediated autoimmune diseases. Due to the stage of development of this asset, the value of this asset of \$379.3 was expensed during 2018.

(4) 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.

(5) We recognized an unrealized gain of \$44.4 on our Moderna Therapeutics equity investment in 2018. Additionally, in 2016, we incurred a full year of interest expense on our credit facility entered into in 2015.

(6) We recognized tax (benefit) expense of \$(56.5) and \$45.8 in 2018 and 2017, respectively, as a result of the Tax Cuts and Jobs Act. In 2017, we recorded certain impacts of the Tax Act on a provisional basis. As of December 22, 2018, our accounting for the impact of the Tax Act was complete. See Note 12, “Income Taxes” for additional information.

(7) In 2016, we recognized deferred tax expense of \$119.3 associated with the distribution of earnings from our captive foreign partnership.

(8) 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.

(9) In 2015, in connection with the acquisition of Synageva, we acquired \$4,236.0 of intangible assets and \$4,783.4 of goodwill.

(10) In 2015, in connection with the acquisition of Synageva, we borrowed \$3,500.0 under our term loan under a credit facility. This credit facility was amended and restated in June 2018.

(11) In 2015, 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 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 only two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH), as well as the first and only approved complement inhibitor to treat 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 fourth quarter 2018, we completed the acquisition of Syntimmune, Inc. (Syntimmune), a clinical-stage biotechnology company developing an antibody therapy targeting the neonatal Fc receptor (FcRn). The lead candidate from this acquisition, ALXN1830 (SYNT001), is a monoclonal antibody that inhibits the interaction of FcRn with Immunoglobulin G (IgG) and IgG immune complexes, and is being studied in Phase 1b/2a trials for the treatment of IgG-mediated autoimmune diseases. Under the terms of the agreement, Alexion

acquired Syntimmune for an upfront payment of \$400.0, with the potential for additional milestone-dependent payments of up to \$800.0, for a total value of up to \$1,200.0.

In December 2018 ULTOMIRIS™ was approved by the FDA as a new treatment option for adult patients living with paroxysmal nocturnal hemoglobinuria (PNH). ULTOMIRIS is the first and only long-acting C5 inhibitor that provides immediate and complete inhibition for eight weeks.

In January 2019, we submitted our filings to the FDA and the EU for marketing clearance for SOLIRIS as a potential treatment of NMOSD.

On January 21, 2019, the Opposition Division of the European Patent Office determined, following multi-party opposition proceedings, to revoke our European patent No. 2359834, which relates to the formulation of SOLIRIS. Subject to our review of the final written decision of the European Patent Office, we currently expect that we will appeal this decision. While any appeal is pending at the European Patent Office, the claims in the originally granted patent remain in force.

In January 2019, we announced the results of the Phase III study with ULTOMIRIS (ALXN1210) meeting its primary objective in complement inhibitor-naïve patients with aHUS. In the initial 26 week treatment period in this study, 53.6 percent of patients demonstrated complete thrombotic microangiopathy (TMA) response.

In January 2019, we entered into a collaboration agreement with Caelum Biosciences (Caelum) to develop CAEL101 for light chain (AL) amyloidosis. Under the terms of the agreement, we acquired a minority equity interest in Caelum and an exclusive option to acquire the remaining equity in the company based on Phase II data, for pre-negotiated economics. We made an upfront payment of \$30.0 and could be required to pay up to an additional \$30.0 in contingent milestone-dependent option fees. The collaboration also provides for potential additional payments, in the

event Alexion exercises the acquisition option, for up to \$500.0, which includes an upfront option exercise payment and potential regulatory and commercial milestone payments.

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, judgments 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 and such differences may be material.

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

In May 2014, the Financial Accounting Standards Board (FASB) issued a comprehensive new standard which amends revenue recognition principles. We adopted the new standard on January 1, 2018 by applying the modified retrospective method to all contracts that were not completed as of that date. Under the new guidance, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration expected to be received in exchange for those goods or services. Revenue is recognized through a five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract, and determines those that are performance obligations. Revenue is recognized for the applicable performance element when each distinct performance obligation is satisfied.

While results for reporting periods beginning after January 1, 2018 are presented under the new guidance,

prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. The accounting policy for revenue recognition for periods prior to January 1, 2018 is described in Note 1 of the Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2017.

Nature of Products

Our principal source of revenue is product sales. Our contracts with customers generally contain a single performance obligation and we recognize revenue from product sales when we have satisfied our performance obligation by transferring control of the product to our customers. Control of the product generally transfers to the customer upon delivery. In certain countries, we sell to distributors on a consignment basis and record revenue when control of the product transfers to the customer upon sale to the end user.

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.

Revenue is recognized at the amount to which we expect to be entitled in exchange for the sale of our products. This amount includes both fixed and variable consideration and excludes amounts that are collected from customers and remitted to governmental authorities, such as value-added taxes in foreign jurisdictions. Shipping and handling costs

associated with outbound freight after control of a product has transferred to our customers are accounted for as a fulfillment cost and are included in operating expenses. The cost for any shipping and handling activities (including customs clearance activities) associated with transactions for which revenue has been recognized are accrued if not completed before the respective period end.

The timing between the recognition of revenue for product sales and the receipt of payment is not significant. Our standard credit terms, which vary based on the country of sale, generally range from 30 to 120 days and all arrangements generally are payable within one year of the transfer of the product. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between the transfer of the promised good to the customer and receipt of payment will be one year or less.

We evaluate the creditworthiness of customers on a regular basis. 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. 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 probable at the time of sale. As of December 31, 2018 and December 31, 2017, allowances on receivables were not material.

Variable Consideration

We pay distribution fees to our distributors and offer rebates and/or discounts, or enter into volume-based reimbursement arrangements with certain customers. We reduce the transaction price on our sales for these amounts. For variable amounts, we estimate the amount of consideration to which we expect to be entitled based on all available historic, current and forecast information. We primarily use the expected value method to estimate variable payments and, in limited circumstances, will apply the most likely method based on the type of variable consideration and what method better predicts the amount of consideration we expect to be entitled to. Consideration that is received from a customer that we expect will need to be refunded in the future is recorded as a refund liability to the customer within accrued expenses. Actual amounts of consideration ultimately received or refunded may differ from our estimates, and such difference may be material. If actual results in the future vary from our estimates, we adjust these estimates, which would affect net product sales and earnings in the period such variances become known, and such variances may be material.

Variability in the transaction price for our products pursuant to our contracts with customers primarily arises from the following:

Discounts and Rebates: We offer discounts and rebates to certain distributors and customers under our arrangements. In many cases, these amounts are fixed at the time of sale and the transaction price is reduced accordingly. We also provide for rebates under certain governmental programs, including Medicaid in the U.S. and other programs outside the U.S., which are payable based on actual claim data. We estimate these rebates based on an 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 (and such impact may be material). Generally, the length of time between product sale and the processing and reporting of the rebates is three to six months.

Volume-Based Arrangements: We have entered into volume-based arrangements with governments in certain countries and other customers 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 the customer as a rebate. We estimate incremental discounts resulting from these contractual limitations, based on forecasted 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, 2018, 2017 and 2016 as follows:

	Rebates Payable
Balances, 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)
Balances, 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)
Balances, December 31, 2017	\$99.1
Current provisions relating to sales in current year	235.4
Adjustments relating to prior years	(2.4)
Payments/credits relating to sales in current year	(119.3)
Payments/credits relating to sales in prior years	(90.0)
Balances, December 31, 2018	\$122.8

Current provisions relating to sales in the current year increased by \$41.6 in 2018 compared to 2017 and \$79.2 in 2017 compared to 2016. The increase in 2018 was primarily due to increased unit volumes in the U.S. which were subject to rebates as well as increases in rebate rates in the U.S. on certain product sales. The increase in 2017 was attributable to increased unit volumes in the U.S. and Europe, which were subject to rebates, as well as to increases in rebate rates in certain geographical regions and on certain product sales as compared to the prior year.

Distribution & Other Fees: We pay distribution and other fees to certain customers in connection with the sales of our products. We record distribution and other

fees paid to our customers as a reduction of revenue, unless the payment is for a distinct good or service from the customer and we can reasonably estimate the fair value of the goods or services 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.

Product Returns: Our contracts with customers generally provide for returns only if the product is damaged or defective upon delivery. We assess our sales transactions and arrangements with customers and monitor inventory within our sales channels to determine whether a provision for returns is warranted and a resulting adjustment to the transaction price is necessary. This assessment is based on historical experience and assumptions as of the date of sale and changes in these estimates could have an impact in the period in which the change occurs (and such impact may be material). 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 limited contractual return rights, our customers often carry limited inventory. The amount of variable consideration included in the transaction price is constrained by the amount that is probable will not result in a significant reversal of revenue. We consider our experience with similar transactions and expectations regarding the contract in estimating the amount of variable consideration to which we expect to be entitled, and determining whether the estimated variable consideration should be constrained. We do not have any material constraints on the variable consideration included within the transaction price of our current revenue arrangements.

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” and “Quantitative and Qualitative Disclosures About Market Risk” sections 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 (and our offers of settlement), 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 net realizable value. Cost is determined in a manner that 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

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research and development process and no longer can be used for commercial purposes and, therefore, does not have an “alternative future use”.

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

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, and such write-offs may be material.

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. We recorded other impacts of the Tax Act on a provisional basis in 2017. As of December 22, 2018, our accounting for the impact of the Tax Act was complete. See Note 12, "Income Taxes" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K 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 adjustments to income tax expense in that period, and such adjustments may be material.

New Accounting Pronouncements

In February 2016, the FASB issued a new standard that requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The standard is effective on January 1, 2019, with early adoption permitted. We adopted the new standard on January 1, 2019 and use the effective date as our date of initial application. In July 2018, the FASB issued an update that provided an additional transition option that allows companies to continue applying the guidance under the lease standard in effect at that time in the comparative periods presented in the consolidated financial statements. Companies that elect this option would record a cumulative-effect adjustment to the opening balance of retained earnings on the date of adoption. We elected this optional transition method. We also elected the "package of practical expedients", which permits us not to reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs. We continue to evaluate other practical expedients available under the standard.

We have substantially completed our assessment of the standard as well as implementation of our leasing software, including data upload and test procedures. We continue to finalize our calculations, including our discount rate assumptions, related to the new standard. We are also continuing to establish new processes and internal controls that may be required to comply with the new lease accounting and disclosure requirements set by the new standard. We expect the impact of the standard adoption to decrease our assets, liabilities and retained earnings within our consolidated balance sheet. These decreases will result from the derecognition of our existing assets and financing obligations related to our build to suit leases offset by the recognition of new ROU assets and liabilities as a result of the leasing standard.

In June 2016, the FASB issued a new standard intended to improve reporting requirements specific to loans, receivables and other financial instruments. The new standard requires that credit losses be reported based on expected losses compared to the current incurred loss model. The new standard also requires enhanced disclosure of credit risk associated with respective assets. The standard is effective for interim and annual periods beginning after December 15, 2019 with early adoption permitted. We are currently assessing the impact of this standard on our financial condition and results of operations.

In February 2018, the FASB issued a new standard that would permit entities to make a one time reclassification from accumulated other comprehensive income (AOCI) to retained earnings for the stranded tax effects resulting from the newly enacted corporate tax rates under the Tax Act, that was effective for the year ended December 31, 2017. The amount of the reclassification is calculated on the basis of the difference between the historical tax rate and newly enacted tax rate. 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.

In August 2018, the FASB issued a new standard on a customer's accounting for implementation, set-up, and other upfront costs incurred in a cloud computing arrangement (CCA). Under the new guidance, customers will assess if a CCA includes a software license and if a CCA does include a software license, implementation and set-up costs will be accounted for consistent with existing internal-use software implementation guidance. Implementation costs associated with a CCA that does not include a software license would be expensed to operating expenses. The standard also provides classification guidance on these implementation costs as well as additional quantitative and qualitative disclosures. The standard is effective for public business entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted, including adoption in any interim periods. Entities can choose to adopt the new guidance prospectively or retrospectively. We are currently assessing the impact this standard will have on our statement of financial condition and results of operations.

Recently Adopted Accounting Pronouncements

In May 2014, the 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. We adopted the new standard on January 1, 2018.

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. We adopted the new standard on January 1, 2018 and applied the new guidance prospectively to transactions occurring after adoption. We anticipate that the adoption of this new standard will likely result in more transactions, to the extent that such transactions are undertaken by the Company, being accounted for as asset acquisitions.

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 adopted the new standard on January 1, 2018, and elected to measure our existing equity investments without readily determinable fair values at cost adjusted for changes in observable prices minus impairment. In connection with the adoption of the new standard, we reclassified an immaterial amount of unrealized gains on equity securities from accumulated other comprehensive income to retained earnings. The guidance related to equity investments without readily determinable fair values was applied prospectively to equity investments that existed as of the date of adoption. We will assess equity investments without

readily determinable fair values for observable price changes and impairment on a quarterly basis. See Note 7, “Other Investments,” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further details.

In March 2017, the FASB issued a new standard that improves the presentation of net periodic pension cost and net periodic post retirement benefit cost by requiring the bifurcation of net benefit cost. Under the new standard, the service cost component of net benefit cost will be presented with other employee costs in operating expenses, while other components will be reported separately in other income and expense. We adopted the new standard on January 1, 2018. The

adoption of this standard did not have a material impact on our consolidated statements of operations.

In November 2016, the FASB issued a new standard that clarifies how entities should present restricted cash in the statement of cash flows. Under the new standard, changes in total cash, inclusive of restricted cash, should be reflected in the statement of cash flows. As a result, transfers between cash and restricted cash will no longer be reflected as activity within the statement of cash flows. We adopted the new standard on January 1, 2018. The adoption of this standard did not have a material impact on our consolidated statements of cash flows.

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 early adopted the new standard in the second quarter 2018 using the modified retrospective method. The adoption of this standard did not have a material impact on our consolidated financial statements.

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,		
	2018	2017	2016
Net product sales	\$4,130.1	\$3,549.5	\$3,081.7
Other revenue	1.1	1.6	2.4
Total revenues	4,131.2	3,551.1	3,084.1
Cost of sales	374.3	454.2	258.3
Operating expenses:			
Research and development	730.4	878.4	757.2
Selling, general and administrative	1,111.8	1,094.4	953.0
Acquired in-process research and development	1,183.0	—	—
Amortization of purchased intangible assets	320.1	320.1	322.2
Change in fair value of contingent consideration	116.5	41.0	35.7
Acquisition-related costs	—	—	2.3
Restructuring expenses	25.5	104.6	3.0
Impairment of intangible assets	—	31.0	85.0
Total operating expenses	3,487.3	2,469.5	2,158.4
Operating income	269.6	627.4	667.4
Other expense	(27.4)	(79.6)	(91.2)
Income before income taxes	242.2	547.8	576.2
Income tax expense	164.6	104.5	176.8
Net income	\$77.6	\$443.3	\$399.4
Earnings per common share:			
Basic	\$0.35	\$1.98	\$1.78
Diluted	\$0.35	\$1.97	\$1.76

Comparison of the Years Ended December 31, 2018, 2017, and 2016

Net Product Sales

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

	Year Ended December 31,			% Change			
	2018	2017	2016	2018	2017		
				compared	compared		
				to 2017	to 2016		
SOLIRIS							
United States	\$1,588.4	\$1,235.0	\$1,058.5	28.6	%	16.7	%
Europe	1,036.7	985.2	939.7	5.2	%	4.8	%
Asia Pacific	382.0	328.1	303.8	16.4	%	8.0	%
Rest of World	555.9	595.8	541.2	(6.7)	%	10.1	%
	\$3,563.0	\$3,144.1	\$2,843.2	13.3	%	10.6	%
STRENSIQ							
United States	\$374.3	\$280.1	\$177.5	33.6	%	57.8	%
Europe	61.7	35.6	15.3	73.3	%	132.7	%
Asia Pacific	27.9	18.6	13.0	50.0	%	43.1	%
Rest of World	11.2	5.5	3.6	103.6	%	52.8	%
	\$475.1	\$339.8	\$209.4	39.8	%	62.3	%
KANUMA							
United States	\$51.3	\$42.4	\$20.4	21.0	%	107.8	%
Europe	21.6	14.6	6.3	47.9	%	131.7	%
Asia Pacific	3.7	2.7	1.3	37.0	%	107.7	%
Rest of World	15.4	5.9	1.1	**		**	
	\$92.0	\$65.6	\$29.1	40.2	%	125.4	%
Total Net Product Sales	\$4,130.1	\$3,549.5	\$3,081.7	16.4	%	15.2	%

** 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 the increase in net product sales for December 31, 2018 as compared to 2017 are as follows:

The increase in net product sales for fiscal year 2018, as compared to fiscal year 2017, was primarily due to an increase in unit volumes of 20.1%. This increase in unit volumes is primarily due to increased global demand for SOLIRIS therapy, including sales to patients with gMG, which received regulatory approval in the second half of 2017. Additional unit volume increases were due to increased sales of STRENSIQ and KANUMA during 2018 as a result of our continuing efforts to identify and reach more patients with HPP and LAL-D globally.

The increase in net product sales for fiscal year 2018, as compared to fiscal year 2017, was partially offset by price decreases of 3.9% due, in part, to a price change in Turkey resulting from a formalized reimbursement agreement, subsequent to marketing authorization, in the third quarter of 2018. In addition, rebates in the U.S. and reimbursement agreements outside the U.S. for our metabolic products also contributed to this decrease in net product sales.

The components of the increase in revenues for the year ended December 31, 2017 as compared to the same period in 2016 are as follows:

The increase in net product sales for fiscal year 2017 as compared to fiscal year 2016 was primarily due to an increase in unit volumes of 16.8% due to increased demand globally for SOLIRIS therapy for patients with PNH and aHUS and increased sales of STRENSIQ and KANUMA during 2017.

Cost of Sales

Cost of sales includes manufacturing costs, actual and estimated royalty expenses associated with sales of our products, and amortization of licensing rights.

The following table summarizes cost of sales for the years ended December 31, 2018, 2017 and 2016:

Cost of Sales

Cost of sales as a percentage of net product sales

Cost of sales for the year ended December 31, 2018 and December 31, 2017 included asset related charges of \$5.8 and \$152.1, respectively, associated with the closure of the ARIMF facility announced in the third quarter of 2017 (this facility was sold in 2018). These charges primarily relate to accelerated depreciation and the impairment of manufacturing assets.

Exclusive of the items mentioned above, cost of sales as a percentage of net product sales were 8.9%, 8.5% and 8.4% for the years ended December 31, 2018, 2017 and 2016, respectively.

Research and Development Expense

Research and Development Expense (R&D)

R&D as a % of net product sales

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. 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.

R&D expenses are comprised of costs paid for clinical development, product development and discovery research, as well as costs associated with certain 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, milestone expenses related to our licensing agreements and collaborations 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 and milestone expenses related to our licensing agreements and collaborations in the discovery stage. Upfront payments include upfront payments related to licenses and collaborations. Clinical development costs have been accumulated and allocated to each of our programs, while product development and discovery research costs have not been allocated.

Facilities and 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:

Clinical Development Discovery
Product Development Payroll and Benefits
Upfront Payments Facilities and Other

During the year ended December 31, 2018, we incurred R&D expenses of \$730.4, a decrease of \$148.0, or 16.8%, versus the \$878.4 incurred during the year ended December 31, 2017. The decrease was primarily related to the following:

- Decrease of \$70.9 in direct clinical development expenses related primarily to decreases in various eculizumab clinical studies, offset by expansion of studies for ALXN1210.
- Increase of \$13.0 in direct product development expenses related primarily to an increase in costs associated with the manufacturing of material for ALXN1210 offset by a decrease in ALXN6000 clinical research activities (the ALXN6000 program has been discontinued).
- Decrease of \$22.2 in upfront payments due to the nature and timing of licensing and collaborations agreements executed in 2018 compared to 2017.
- Decrease of \$12.9 in discovery primarily related to de-prioritized preclinical arrangements with Moderna Therapeutics and Blueprint Medicines. We no longer conduct development efforts with these entities.
- Decrease of \$26.0 in payroll and benefits primarily related to headcount reductions resulting from restructuring activities initiated in 2017.
- Decrease of \$29.0 in facilities and other related expenses primarily related to decreased

facilities expenses primarily resulting from the impact of the 2017 restructuring.

During the year ended December 31, 2017, we incurred research and development 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 related primarily to an expansion of ALXN 1210 studies.
- Increase of \$36.2 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 \$48.9 in 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.

The following graph summarizes expenses related to our clinical development programs:
2018 2017 2016

The following graph summarizes accumulated direct expenses related to our clinical development programs from January 1, 2006 to December 31, 2018:

(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 any of our product development 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 remain consistent as a percentage of sales in 2019 as compared to 2018.

Selling, General and Administrative Expense

Selling General and Administrative Expense (SG&A)

SG&A as a % of net product sales

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, 2018, we incurred selling, general and administrative expenses of \$1,111.8, an increase of \$17.4, or 1.6%, versus the \$1,094.4 incurred during the year ended December 31, 2017. The increase was primarily related to the following:

Increase in external selling, general and administrative expenses of \$20.2. The increase was primarily due to an increase in professional services and asset related charges associated with previously announced restructuring programs. These increases were partially offset by decreased distribution expenses as compared to the same period in 2017.

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.

We expect our selling, general and administrative expenses to decrease as a percentage of sales in 2019 as compared to 2018.

Acquired In-Process Research and Development

For the year ended December 31, 2018 we recorded acquired in-process research and development (IPR&D) expense of \$1,183.0. The increase in acquired IPR&D for the year ended December 31, 2018, as compared to 2017 and 2016, is due to the Wilson Therapeutics acquisition completed in the second quarter of 2018 and the Syntimmune acquisition

completed in the fourth quarter of 2018. The IPR&D assets associated with each of these acquisitions, which were the principal assets acquired in each transaction, had not reached technological feasibility and had no alternative future use as of the acquisition date and were therefore expensed in 2018.

Amortization of Purchased Intangible Assets

Amortization expense associated with purchased intangible assets was \$320.1, \$320.1 and \$322.2 for the years ended December 31, 2018, 2017 and 2016, respectively. Amortization expense is primarily associated with intangible assets related to STRENSIQ and KANUMA.

Change in Fair Value of Contingent Consideration

For the years ended December 31, 2018, 2017 and 2016, the change in fair value of contingent consideration expense associated with our prior business combinations was \$116.5, \$41.0 and \$35.7, 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 in connection with previous acquisitions.

In September 2018, we amended the terms of certain contingent milestone payments due under our prior merger agreement with Enobia Pharma Corp. (Enobia), dated December 28, 2011. The agreement removed our obligations with respect to a regulatory milestone and redistributed the contingent payment associated with this milestone to various sales

milestones. As a result of this agreement and the probability of achieving the various sales milestones, our contingent consideration liability increased by \$48.7 in the third quarter 2018.

For the year ended December 31, 2018, changes in the fair value of contingent consideration expense primarily reflect the impact of the agreement with Enobia to amend milestones and 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.

Restructuring Expenses

For the years ended December 31, 2018 and 2017, we recorded \$25.5 and \$104.6, respectively, in restructuring expenses. The charges for the year ended 2018 were mainly attributable to the relocation of our corporate headquarters from New Haven, Connecticut to Boston, Massachusetts and other related costs and the charges for the year ended 2017 were mainly attributable to employee separation costs in connection with the 2017 restructuring (as described below).

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 focused investments in priority growth areas to maximize leadership in complement and grow the rare disease business. The re-alignment also included the relocation of the Company's headquarters to Boston, Massachusetts in 2018. Our New Haven, Connecticut site continues 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 2017 restructuring plan reduced the Company's global workforce by approximately 20.0%. The restructuring achieved 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.

In the first quarter 2019, we have undertaken corporate restructuring activities to re-align our global organization with our re-focused strategy, reduce costs, and realize operational efficiencies. We expect to incur estimated expenses up to \$25.0 associated with this recent restructuring by the end of 2019. For additional information on this 2019 corporate restructuring activity, see Item 1. "Business - Sales and Marketing" elsewhere in this Annual Report on Form 10-K.

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, 2018, 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, 2018 is \$3,252.6.

Other Income and (Expense)

The following table provides information regarding other income and expense:

Investment Income

Interest Expense

Other Income (expense)

For the year ended December 31, 2018, we experienced an increase in investment income primarily due to the recognition of unrealized gains of \$44.4 on our Moderna Therapeutics equity investment.

Income Taxes
 Tax Expense
 Effective Tax Rate

The income tax expense for the years ended December 31, 2018, 2017 and 2016 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. During the year ended December 31, 2018, we recorded an income tax expense of \$164.6 and an effective tax rate of 68.0%, compared to an income tax expense of \$104.5 and \$176.8 and an effective tax rate of 19.1% and 30.7% for the years ended December 31, 2017 and 2016, respectively. The increase in the effective tax rate during 2018, from 19.1% for the year ended December 31, 2017 to 68.0% for the year ended December 31, 2018 was primarily attributable to the acquisitions of Syntimmune and Wilson Therapeutics. Absent successful clinical results and regulatory approval, there is no alternative future use for the in-process research assets we acquired in these acquisitions. Accordingly, the value of the assets acquired of \$1,183.0 were expensed as acquired in-process research and development, for which no tax benefit has been recognized. The Syntimmune and Wilson Therapeutics acquisitions resulted in an increase in the effective tax rate of approximately 102.6%. This increase was partially offset by the decrease to the U.S. statutory rate and other related adjustments as a result of the Tax Act. These items resulted in a decrease of approximately 45.7%.

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 incorporated the impact of the Tax Act in our results of operations or calculated provisional amounts for the tax effects of the Tax Act that could be reasonably estimated for the year ended December 31, 2017. We recorded adjustments to this provisional accounting during 2018, which

resulted in a decrease to tax expense of \$56.5. We completed our accounting for the Tax Act in the fourth quarter 2018.

The Tax Act resulted in an increase to tax expense for the year ended December 31, 2017 of \$45.8. This increase included 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 included \$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 included 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 was 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 of earnings 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.

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, 2018 and 2017:

	December 31, December 31,	
	2018	2017
Cash and cash equivalents	\$ 1,365.5	\$ 584.4
Marketable securities	198.3	889.7
Long-term debt (includes current portion & revolving credit facility)	2,862.5	2,906.3
Current assets	\$ 3,385.0	\$ 2,953.9

Current liabilities	1,174.0	952.5
Working capital	\$ 2,211.0	\$ 2,001.4

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The aggregate increase in cash and cash equivalents and marketable securities of \$89.7 at December 31, 2018 as compared to December 31, 2017 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 (in connection with entering into our Amended and Restated Credit Agreement in June 2018), and purchases of property, plant, and equipment. Excluding the impact of any future asset acquisitions, we expect our annual operating expenses to decrease as a percentage of sales in 2019 as compared to 2018. We also expect reduced capital investment in 2019 as compared to 2018. We anticipate that cash generated from operations and our existing available cash, cash equivalents and marketable securities should provide us adequate resources to fund our operations as currently planned for at least the next twelve months.

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 Amended and Restated Credit Agreement 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. New sources of financing through equity and/or debt financing(s) may not always be available on acceptable terms, or at all, and we may be required to obtain certain consents in connection with completing such financings.

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 debt 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, 2018, three customers accounted for 48.7% of the accounts receivable balance, with these individual customers accounting for 14.0% to 19.1% of the accounts

receivable balance. 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.

For the year ended December 31, 2018, four customers accounted for 50.3% of our product sales, with these individual customers ranging from 10.0% to 16.4% of product sales. 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.

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, 2018, we had foreign exchange forward contracts with notional amounts totaling \$2,523.0. These outstanding foreign exchange forward contracts had a net fair value liability of \$18.9, of which \$40.8 is included in other current assets and noncurrent assets and \$21.9 is included in other current liabilities and noncurrent liabilities. As of December 31, 2018, we had interest rate swap contracts with notional amounts totaling \$3,881.3. These outstanding interest rate swap contracts had a net fair value of \$2.0, of which \$20.1

is included in other current assets and \$18.1 is included in other current liabilities and noncurrent liabilities. 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, 2018, 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, for substantially the full term of the financial instrument. Our Level 2 assets consist primarily of money market funds, commercial paper, municipal bonds, reverse repurchase agreements, U.S. and foreign government-related debt, corporate debt securities, certificates of deposit, equity securities subject to holding period restrictions 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

At December 31, 2018, the purchase agreements for our business combinations include contingent payments totaling up to \$702.0 that will become payable if and when certain development and commercial milestones are achieved. Of these milestone amounts, \$367.0 and \$335.0 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 expect to make milestone payments of approximately \$100.0 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 the sale of equity securities or debt.

Asset Acquisitions and License Agreements

In the fourth quarter 2018, Alexion acquired Syntimmune, a clinical-stage biotechnology company developing an antibody therapy targeting the neonatal Fc receptor (FcRn), for an upfront payment of \$400.0. Under the terms of the agreement, we could also be required to pay up to \$800.0 upon the achievement of specified research, development, regulatory and commercial milestones.

In October 2018, we entered into a collaboration agreement with Dicerna Pharmaceuticals, Inc. (Dicerna) that provides us with exclusive worldwide licenses and development and commercial rights for two preclinical RNA interference (RNAi) subcutaneously delivered molecules for complement-mediated diseases, as well as an exclusive option for other preclinical RNAi molecules for two additional targets within the complement pathway. In addition to the collaboration agreement, we made an equity investment in Dicerna. Under the terms of the agreements, we made an upfront

payment of \$37.0 for the exclusive licenses and the equity investment. The market value of the equity investment was \$10.3 as of the date of acquisition, which we recorded in other assets in our consolidated balance sheets. Due to the early stage of the assets we are licensing, we recorded expense for the upfront license payment of \$26.7 during the fourth quarter 2018. In addition, as of December 31, 2018, we could also be required to pay up to approximately \$625.0 for option exercise fees and amounts due upon the achievement of specified research, development, regulatory and commercial milestones, as well as royalties on commercial sales.

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, 2018, 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 addition, we have entered into other license agreements under which we may be required to pay up to an additional \$137.2 if certain development, regulatory and commercial milestones are met.

We do not expect the payments associated with milestones under our asset acquisitions and licensing agreements to have a significant impact on our liquidity in the near-term. During the next 12 months, we may make milestone payments related to these arrangements of approximately \$255.0.

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 \$13.3, \$14.2, and \$14.0 for the years ended December 31, 2018, 2017, and 2016, respectively. As of December 31, 2018 and 2017, our total facility lease

obligation was \$133.5 and \$134.6, respectively, recorded within other current liabilities and facility lease obligation in 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. We expect the completion of the facility, including obtaining regulatory approval, to be in 2019. As of December 31, 2018 and 2017, we recorded a construction-in-process asset of \$203.9 and \$180.6, respectively, and an offsetting facility lease obligation of \$155.1 and \$159.1, respectively, within other current liabilities and facility lease obligation in our consolidated balance sheets.

In September 2017, we entered into a lease agreement for approximately 150,000 square feet of office space to be constructed in Boston, Massachusetts. Construction of the facility was completed and the building was placed into service in the second quarter 2018. The term of the lease commenced upon the landlord's substantial completion of the facility during the second quarter of 2018 and will expire on the thirteenth anniversary of commencement, with an option to renew for up to an additional 10 years. Although we do 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. Interest expense recognized during 2018 was not material. As of December 31, 2018 and 2017, our total facility lease obligation was \$83.6 and \$59.6, respectively, recorded within facility lease obligation in our consolidated balance sheets.

Our facility lease obligations will be derecognized in 2019 upon adoption of the new lease accounting standard and will be replaced by ROU liabilities going forward. See Note 1 Business Overview and Summary of Significant Accounting Policies to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for more information.

Long-term Debt

On June 7, 2018, Alexion entered into an Amended and Restated Credit Agreement (the Credit Agreement) with Bank of America N.A. as administrative agent. The Credit Agreement amends and restates our credit agreement dated as of June 22, 2015 (the Prior Credit Agreement). The Credit Agreement provides for a \$2,612.5 term loan facility and a \$1,000.0 revolving facility. Borrowings can be used for working capital requirements, acquisitions and other general corporate purposes. Beginning with the quarter ending June 30, 2019, we are required to make amortization payments of 5.00% of the aggregate principal amount of the term loan facility annually, payable in equal quarterly installments. As of December 31, 2018, we had \$2,612.5 outstanding on the term loan and \$250.0 of borrowings outstanding under the revolving credit facility. The \$250.0 of proceeds on the revolving credit facility was used to refinance amounts outstanding under the Prior Credit Agreement. As of December 31, 2018, we had open letters of credit of \$1.7 that offset our borrowing availability on the revolving facility. In January 2019 we paid the outstanding revolving credit facility of \$250.0 in full.

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 and the progress of our clinical development programs.

We have various agreements with Lonza, with remaining total non-cancellable commitments of approximately \$1,084.6 through 2029. 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 that was manufactured at ARIMF prior to its sale and a payment with respect to sales of SOLIRIS manufactured at Lonza facilities.

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In addition to Lonza, we have non-cancellable commitments of approximately \$104.1 through 2020 with other third party manufacturers.

Taxes

We have recorded tax on the undistributed earnings of our controlled foreign corporation (CFC) subsidiaries. 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 withholding, foreign local, and U.S. state income taxes.

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 increased the amount that we are authorized to expend on future repurchases to \$1,000 under the repurchase program, which superseded all prior repurchase programs. Under the program, we repurchased 0.7 and 4.0 shares of our common stock at a cost of \$85.0 and \$463.6 during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, there is a total of \$451.5 remaining for repurchases under the program.

Cash Flows

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

	Year Ended December 31,		
	2018	2017	\$ Change
Net cash provided by operating activities	\$ 426.0	\$ 1,115.6	\$(689.6)
Net cash provided by (used in) investing activities	470.5	(918.3)	1,388.8
Net cash used in financing activities	(102.4)	(596.6)	494.2
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(11.2)	17.7	(28.9)
Net change in cash and cash equivalents	\$ 782.9	\$ (381.6)	\$ 1,164.5

Operating Activities

Cash flows provided by operations in 2018 were \$426.0 compared to \$1,115.6 in 2017. The decrease in cash provided by operating activities was primarily due to the acquisition of Wilson Therapeutics and Syntimmune and higher cash payments for restructuring and incentive compensation, as well as the impact of the timing of cash receipts and other payments for the year ended 2018 as compared to the same period in the prior year. This decrease was partially offset by an increase in operating income, excluding the impact of the IPR&D charge associated with the Wilson Therapeutics and Syntimmune acquisitions.

Investing Activities

Cash provided by (used in) investing activities in 2018 was \$470.5 compared to \$(918.3) in 2017. The increase in cash provided by investing activities was primarily attributable to proceeds and maturities of available-for-sale marketable securities, which resulted

in a net cash inflows of \$690.8 in 2018 compared to a net cash outflows of \$(558.9) in 2017.

During 2018, we also had lower cash outlays associated with the purchase of property, plant and equipment of \$213.0 as compared to \$357.3 in 2017. The significant spending on property, plant and equipment in 2017 related primarily to the construction of our new biologics manufacturing facilities in Ireland.

Financing Activities

Cash flows used in financing activities in 2018 were \$102.4 compared to \$596.6 in 2017. The decrease in cash used for financing activities was primarily due to repurchasing \$378.6 less of our common stock in 2018 than 2017.

Additionally, cash used for financing activities decreased as a result of reduced net payments on our outstanding credit facility of \$43.8 in 2018, compared to \$175.0 in 2017.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2018 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 at December 31, 2018, 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 ⁽¹⁾	\$2,862.5	\$ 348.0	\$ 261.2	\$2,253.3	\$ —
Interest expense ⁽²⁾	407.2	81.8	194.7	130.7	—
Facility lease obligations ⁽³⁾	197.6	13.7	31.1	32.2	120.6
Operating leases	48.0	14.1	14.9	7.4	11.6
Total contractual obligations	\$3,515.3	\$ 457.6	\$ 501.9	\$2,423.6	\$ 132.2
Commercial commitments:					
Clinical and manufacturing development ⁽⁴⁾	\$1,188.7	\$ 271.8	\$ 317.5	\$ 227.4	\$ 372.0
Total commercial commitments	\$1,188.7	\$ 271.8	\$ 317.5	\$ 227.4	\$ 372.0

⁽¹⁾ Includes our term loan and the \$250.0 revolving credit facility balance. Our revolving credit facility is classified as a current liability and has been included in payments to be made within one year. In January 2019, we paid the revolving credit facility of \$250.0 in full.

⁽²⁾ Interest on variable rate debt is calculated based on interest rates at December 31, 2018. Interest that is fixed, associated to our interest rate swaps, is calculated based on the fixed interest swap rate at December 31, 2018.

⁽³⁾ 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. In the fourth quarter of 2018 we amended the New Haven lease agreement significantly reducing our leased square footage in the building beginning in 2019 through the expiration of the lease (in connection with this amendment, in the fourth quarter of 2018, we made a payment of \$53.0 to a third party as an incentive to lease the released square footage). 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.

⁽⁴⁾ Clinical and manufacturing development commitments include only non-cancellable commitments, including all Lonza agreements, at December 31, 2018.

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 11 "Commitments and Contingencies" to the Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

The liability for unrecognized tax benefits related to various federal, state and foreign income tax matters of \$92.7 at December 31, 2018 was not included within the table above. The timing of the settlement of these amounts was not reasonably estimable at December 31, 2018. We do not expect payment of amounts related to the unrecognized tax benefits within the next twelve months.

Contingent payments related to business acquisitions, asset acquisitions or license agreements

are not included within the table above, as the satisfaction of the contingent consideration obligations is uncertain at December 31, 2018 and, if satisfied, the timing of payment for these amounts was not reasonably estimable at December 31, 2018. Contingent payments associated with these business combinations total up to \$702.0 which will become payable if and when certain development and commercial milestones are achieved. During the next 12 months, we expect to make milestone payments of approximately \$100.0 associated with our prior business combinations. Commitments related to asset acquisitions and license agreements include contingent payments that will become payable if and when certain development, regulatory and commercial milestones are achieved. During the next 12 months, we may make milestone payments related to our asset acquisitions and license agreements of approximately \$255.0.

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, 2018. The total unfunded obligation on our defined benefit plans as of December 31, 2018 was \$17.6. Our unfunded obligation can be impacted by changes in the laws and regulations, interest rates, investment returns, and other variables.

Credit Facilities

On June 7, 2018, we entered into an Amended and Restated Credit Agreement (the Credit Agreement), with Bank of America N.A. as administrative agent. The Credit Agreement amends and restates our agreement dated as of June 22, 2015 (the Prior Agreement).

The Credit Agreement provides for a \$1,000.0 revolving credit facility and a \$2,612.5 term loan facility. The revolving credit facility and term loan facility mature on June 7, 2023. Beginning with the quarter ending June 30, 2019, we are required to make amortization payments of 5.00% of the aggregate principal amount of the term loan facility annually, payable in equal quarterly installments.

Loans under the Credit Agreement bear interest, at our option, at either the base rate or a Eurodollar rate, in each case plus an applicable margin. Under the Credit Agreement, 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 based on our consolidated net leverage ratio (as calculated in accordance with the Credit Agreement). Our obligations under the Credit Agreement are guaranteed by certain of our foreign and domestic subsidiaries and secured by liens on certain of our subsidiaries' equity interests, subject to certain exceptions. Under the terms of the Credit Agreement, we must maintain a ratio of total net debt to EBITDA of 3.50 to 1.00 (subject to certain limited adjustments) and EBITDA to cash interest expense ratio of at least 3.50 to 1.00, in each case as calculated in accordance with the Credit Agreement. The Credit Agreement contains certain representations and warranties, affirmative and negative covenants and events of default. The negative covenants in the Credit Agreement restrict Alexion's and its subsidiaries' ability, subject to certain baskets and exceptions, to (among other things) incur liens or indebtedness, make investments, enter into mergers and other fundamental changes, make dispositions or pay dividends. The restriction on dividend payments includes an exception that permits us to pay dividends and make other restricted payments regardless of dollar amount so long as, after giving pro forma effect thereto, we have consolidated net leverage ratio, as defined in the Credit Agreement, within predefined ranges, subject

to certain increases following designated material acquisitions.

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.

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 agreements with Lonza described above. Our commitments with Lonza do not include amounts for estimated consumer price index, or CPI, adjustments which we are obligated to pay to Lonza.

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

(amounts in millions, except percentages)

Interest Rate Risk

As of December 31, 2018, 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 debt 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 \$(0.5) and \$0.5, respectively.

On June 7, 2018, we entered into an Amended and Restated Credit Agreement (the Credit Agreement), with Bank of America N.A. as administrative agent. The Credit Agreement amends and restates our agreement dated as of June 22, 2015 (the Prior Agreement). Loans under the Credit Agreement bear interest, at our option, at either the base rate or a Eurodollar rate, in each case plus an applicable margin. Under the Credit Agreement, 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 based on 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. As of December 31, 2018, we had cash flow hedges with aggregate amounts of approximately 87.0% 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 \$3.0, based on the unhedged portion of our outstanding term loan as of December 31, 2018.

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 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 products.

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 2018, 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 by 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, 2018 and 2017, we held foreign exchange forward contracts with notional amounts totaling \$2,523.0 and \$2,708.1, respectively. As of December 31, 2018 and 2017, our outstanding foreign exchange forward contracts had a net fair value of \$18.9 and \$(47.5), 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, 2018, 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 \$101.5 at December 31, 2018. 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, 2018. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of December 31, 2018, 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, 2018 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, 2018.

The effectiveness of our internal control over financial reporting as of December 31, 2018 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2018 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.

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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 Ethics and Business 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.alexion.com/index.php/corporate-governance>). 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 BI 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, dated as of September 7, 2018, by and between Alexion Pharma Holding Unlimited Company, Shareholder Representative Services LLC, Fonds de Solidarité des Travailleurs du Québec F.T.Q., Capital Régional e Coopératif Desjardins, CTI Life Sciences Fund, L.P., OrbiMed Private Investments III, LP and OrbiMed Associates III, LP (in connection with the Agreement and Plan of Merger, dated December 28, 2011 pursuant to which Alexion acquired Enobia Pharma Corp.)(4)

2.5 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. (5)

2.6 Agreement and Plan of Merger, dated as of September 25, 2018, by and among Alexion Pharmaceuticals, Inc., Syracuse Merger Sub, Inc., Syntimmune, Inc. and Shareholder Representative Services LLC,(4)+

3.1 Certificate of Incorporation, as amended.(6)

3.2 Certificate of Amendment of the Certificate of Incorporation.(7)

3.3 Bylaws, as amended.(8)

4.1 Specimen Common Stock Certificate.(9)

10.1 Employment Agreement, dated as of March 27, 2017, by and between Ludwig N. Hantson and Alexion Pharmaceuticals, Inc. (23)**

10.2

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Employment Agreement, dated as of June 11, 2017, by and between Paul J. Clancy and Alexion Pharmaceuticals, Inc. (24)**

10.3 Employment Agreement, dated as of June 1, 2017, by and between Brian Goff and Alexion Pharmaceuticals, Inc. (26)**

10.4 Form of Employment Agreement (Senior Vice Presidents).(10)**

10.5 Form of Amendment No. 1 to Employment Agreements (Senior Vice Presidents). (11)**

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

10.7 Alexion's 2000 Stock Option Plan, as amended.(13)**

10.8 Alexion's 1992 Outside Directors Stock Option Plan, as amended.(14)**

10.9 Alexion's Amended and Restated 2004 Incentive Plan.(15)**

10.10 License Agreement dated March 27, 1996 between Alexion and Medical Research Council.(16)+

Master Manufacturing and Supply Agreement, dated December 16, 2014 between Alexion Pharma International
10.11 Trading, Alexion Pharmaceuticals, Inc., Lonza Group AG, Lonza Biologics Tuas PTE LTD and Lonza Sales
AG. (22)+

10.12 Form of 2004 Incentive Plan Stock Option Agreement for Directors.(18)**

10.13 Form of 2004 Incentive Plan Stock Option Agreement for Executive Officers (Form A).(19)**

10.14 Form of 2004 Incentive Plan Stock Option Agreement for Executive Officers (Form B).(19)**

10.15 Form of 2004 Incentive Plan Restricted Stock Award Agreement for Executive Officers (Form A).(20)**

10.16 Form of 2004 Incentive Plan Stock Option Agreement (Incentive Stock Options).(17)

10.17 Form of 2004 Incentive Plan Stock Option Agreement (Nonqualified Stock Options).(17)

10.18 Form of 2004 Incentive Plan Restricted Stock Award Agreement.(17)

10.19 Form of 2004 Incentive Plan Restricted Stock Unit Award Agreement.(21)

10.20 Form of 2004 Incentive Plan Stock Option Agreement for Participants in France.(17)**

10.21 Form of 2004 Incentive Plan Restricted Stock Unit Agreement for Participants in France.(17)**

Amended and Restated Credit Agreement, dated as of June 7, 2018, by and among Alexion Pharmaceuticals,
10.22 Inc., as administrative borrower, the subsidiary borrowers party thereto, the lenders and other financial
institutions party thereto and Bank of America, N.A., as administrative agent.(27)

10.23 Alexion Pharmaceuticals, Inc. 2017 Incentive Plan (25)**

10.24 Form of 2017 Incentive Plan Restricted Stock Unit Agreement.(26)**

10.25 Form of 2017 Incentive Plan Nonqualified Stock Option Agreement.(26)**

10.26 Form of 2017 Incentive Plan Performance Stock Unit Agreement (TSR).(26)**

10.27 Form of 2017 Incentive Plan Performance Stock Unit Agreement (R&D Units).(26)**

10.28 Alexion Pharmaceuticals, Inc. 2017 Incentive Plan Rules for Awards Granted to Participants in France.(26)**

10.29 Form of 2017 Incentive Plan Restricted Stock Unit Agreement for French Participants.(26)**

10.30 Form of 2017 Incentive Plan Global Stock Option Agreement.(26)**

10.31 Alexion Pharmaceuticals, Inc. Amended and Restated 2015 Employee Stock Purchase Plan.(4)**

10.32 Form of 2017 Incentive Plan Restricted Stock Unit Agreement for Non-U.S. Participants.(26)**

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.

The following materials from the Alexion Pharmaceuticals, Inc. Annual Report on Form 10-K for the year ended December 31, 2018 formatted in eXtensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Operations, (ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Changes in Stockholders' Equity, (v) the Consolidated Statements of Cash Flows and (vi) related notes, tagged as blocks of text.

(1) Incorporated by reference to our Report on Form 8-K, filed on February 3, 2011.

(2) Incorporated by reference to our Report on Form 8-K, filed on January 4, 2012.

(3) Incorporated by reference to our Report on Form 8-K, filed on February 7, 2012.

- (4) Incorporated by reference to our Quarterly Report on Form 10-Q, for the quarter ended September 30, 2018.
- (5) Incorporated by reference to our Report on Form 8-K, filed on May 6, 2015.
- (6) Incorporated by reference to our Registration Statement on Form S-3 (Reg. No. 333-128085), filed on September 2, 2005.
- (7) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.
- (8) Incorporated by reference to our Report on Form 8-K, filed on January 8, 2016.
- (9) Incorporated by reference to our Registration Statement on Form S-1 (Reg. No. 333-00202).
- (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 Quarterly Report on Form 10-Q for the quarter ended January 31, 2004.
- (14) Incorporated by reference to our Registration Statement on Form S-8 (Reg. No. 333-71879) filed on February 5, 1999.
- (15) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2013.
- (16) Incorporated by reference to our Annual Report on Form 10-K/A for the fiscal year ended July 31, 1996.
- (17) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.
- (18) Incorporated by reference to our Report on Form 8-K, filed on December 16, 2004.
- (19) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2005.
- (20) Incorporated by reference to our Report on Form 8-K, filed on March 14, 2005.
- (21) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2010.
- (22) Incorporated by reference to our Report on Form 10-K for the fiscal year ended December 31, 2014.
- (23) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017.
- (24) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.
- (25) Incorporated by reference to our Registration Statement on Form S-8 (Reg. No. 333-217905) filed on May 5, 2017.
- (26) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.
- (27) Incorporated by reference to our Report on Form 8-K, filed on June 13, 2018.

+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 6, 2019 Chief Executive Officer

(principal executive officer)

By: /s/ Paul J. Clancy

Paul J. Clancy

Date: February 6, 2019 Executive Vice President and Chief Financial Officer

(principal financial officer)

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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 6, 2019
/s/ Paul J. Clancy Paul J. Clancy	Executive Vice President and Chief Financial Officer (principal financial officer)	February 6, 2019
/s/ Daniel A. Bazarko Daniel A. Bazarko, C.P.A.	Senior Vice President and Chief Accounting Officer (principal accounting officer)	February 6, 2019
/s/ David R. Brennan David R. Brennan	Chairman	February 6, 2019
/s/ Felix J. Baker Felix J. Baker, Ph.D.	Director	February 6, 2019
/s/ Christopher J. Coughlin Christopher J. Coughlin	Director	February 6, 2019
/s/ Deborah Dunsire Deborah Dunsire, M.D.	Director	February 6, 2019
/s/ Paul A. Friedman Paul A. Friedman, M.D.	Director	February 6, 2019
/s/ John T. Mollen John T. Mollen	Director	February 6, 2019
/s/ Francois Nader Francois Nader, M.D.	Director	February 6, 2019
/s/ Judith A. Reinsdorf Judith A. Reinsdorf, J.D.	Director	February 6, 2019
/s/ Andreas Rummelt Andreas Rummelt, Ph.D.	Director	February 6, 2019

Alexion Pharmaceuticals, Inc.

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