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, 2020

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:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock $0.0001 par value	**ALXN**	**NASDAQ Stock Market LLC**

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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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.

Large accelerated filer ☒ Smaller reporting company ☐

Accelerated filer ☐ Emerging growth company ☐

Non-accelerated filer ☐

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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 30, 2020, was $23,569,192,552.(1)

Common Stock $0.0001 par value	219,711,754
Class	**Outstanding as of February 4, 2021**

(1) Excludes 9,150,840 shares of common stock held by directors, executive officers and their respective affiliates at June 30, 2020. 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.

DOCUMENTS INCORPORATED BY REFERENCE

The contents of the amendment to this Annual Report on Form 10-K, which will be filed with the Commission within 120 days of the end of the fiscal year ended December 31, 2020, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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,” "potentially," “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 and business, management's beliefs, and certain assumptions made by our management, and may include, but are not limited to, statements regarding:

- the proposed transaction with AstraZeneca PLC;
- the potential benefits and commercial potential of ULTOMIRIS®, SOLIRIS®, STRENSIQ®, KANUMA® and ANDEXXA® 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 our products or for additional indications or in additional territories;
- plans for clinical trials (and proof of concept trials and exploratory clinical studies), 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 and potential to improve treatment in a number of IgG-mediated and neurological diseases;
- 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 and transition to third parties in certain jurisdictions to perform sales, marketing and distribution functions;
- future governmental and regulatory decisions that directly or indirectly impact drug pricing (and discounts) and the adoption, implementation and interpretation of healthcare laws and regulations (and the impact on our business);
- plans, prospects and expected timing 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 for at least the next 12 months, ability to make payment on our credit facility and make contingent payment obligations, the sufficiency of our existing capital resources and projected cash needs, price approval and funding processes in various countries;
- the sources of expected increases in cash flow from operations, if any;
- anticipated impact of interest rate changes on financial statements;

- anticipated future milestone, contingent and royalty payments and lease payments (and, in each case, expected impact on liquidity);
- anticipated impact of the COVID-19 pandemic on our business;
- timing and anticipated amounts of future tax payments and benefits (including the potential recognition of unrecognized tax benefits), as well as timing of conclusion of tax audits;
- collection of accounts receivable and impact of any delay in the future in collecting accounts receivable on financial condition and operations, as well as the ability of counterparties to our derivatives to perform their obligations;
- 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, anticipated regulatory approval of acquisitions and anticipated closing of acquisitions;
- 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, the possibility that our sale to AstraZeneca does not close on the anticipated timeline or at all, the impact of the COVID-19 pandemic on our business (including our financial results and clinical trials), increased competition, actions by regulatory agencies, product candidates not receiving regulatory approvals, the possibility that expected tax benefits will not be realized, changes in healthcare and tax laws and regulations following the U.S. 2020 presidential and congressional elections, 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 and assessments, pending securities class action litigations, the investigation of our Brazilian operations by Brazilian authorities, the tax assessment by the Brazilian Federal Revenue Service and potential future tax assessments or liabilities by other revenue or tax regulators, risks related to the short and long-term effects of other government healthcare measures, intellectual property lawsuits, 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 worldwide that we believe are important to our business, including but not limited to: ALEXION, the Alexion logo, ULTOMIRIS, SOLIRIS, STRENSIQ, KANUMA, ANDEXXA and ONDEXXYA. 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 and devastating conditions through the discovery, development and commercialization of life-changing medicines.

As a leader in rare diseases for more than 25 years, Alexion has developed and commercializes two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), as well as the first and only approved complement inhibitor to treat anti-acetylcholine receptor (AChR) antibody-positive generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive. Alexion also has two highly innovative enzyme replacement therapies and the first and only approved therapies for patients with life-threatening and ultra-rare metabolic disorders, hypophosphatasia (HPP) and lysosomal acid lipase deficiency (LAL-D). With the acquisition of Portola Pharmaceuticals, Inc. (Portola) in July 2020, we added the first and only approved Factor Xa inhibitor reversal agent for patients treated with rivaroxaban or apixaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

In addition to our marketed therapies, we have a diverse pipeline resulting from internal innovation and business development. Alexion focuses its research efforts on novel molecules and targets in the complement cascade and development efforts on the core therapeutic areas of hematology, nephrology, neurology, metabolic disorders, cardiology, ophthalmology and acute care. We were incorporated in 1992 under the laws of the State of Delaware.

On December 12, 2020, we entered into a definitive agreement with AstraZeneca PLC (AstraZeneca) for AstraZeneca to acquire Alexion. If completed, Alexion stockholders will receive $60.00 in cash and 2.1243 AstraZeneca American Depositary Shares (ADSs) for each Alexion share (each ADS representing one-half of one (1/2) ordinary share of AstraZeneca, as evidenced by American Depositary Receipts (ADRs)). Based on AstraZeneca's reference average ADR price of $54.14, this implies total consideration to Alexion stockholders of $39,000.0 or $175.00 per share. Subject to receipt of regulatory clearances and approval by stockholders of both companies, the acquisition is expected to close during the third quarter of 2021, and upon completion, Alexion stockholders would own approximately 15.0% of the combined company. Refer to Part I, Item 1A, “Risk Factors,” Part II, Item 7, “Management's Discussion and Analysis of Financial Condition and Results of Operations,” and Note 1 of the Notes to Consolidated Financial Statements included in this report for additional information regarding the transaction.

Products and Development Programs

We focus our product development programs on life-transforming therapeutics for rare diseases and devastating conditions for which current treatments are either non-existent or inadequate. We have developed or are developing innovative products for, among others, the following indications:

Paroxysmal Nocturnal Hemoglobinuria (PNH)	PNH is a chronic, progressive, debilitating and life-threatening ultra-rare blood disorder characterized by intravascular hemolysis (destruction of red blood cells) that is mediated by an uncontrolled activation of the complement system, a part of the immune system. PNH red blood cells are exquisitely vulnerable to activated complement, resulting in chronic intravascular hemolysis (IVH). Chronic IVH 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). A small sub-set of PNH patients on C5-inhibitor treatment may experience clinically evident extravascular hemolysis (PNH-EVH).
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.
Neuromyelitis Optica Spectrum Disorder (NMOSD)	NMOSD is a severe and ultra-rare autoimmune disease of the central nervous system (CNS) that primarily affects the optic nerves and the spinal cord. Each relapse of the disorder results in a stepwise accumulation of disability, including blindness and paralysis, and sometimes premature death. Complement activation due to anti-AQP4 antibodies is one of the primary underlying causes of the destruction of vital cells in the central nervous system in patients with NMOSD.
Anticoagulant Effects of Factor Xa Inhibitors	Factor Xa Inhibitors (i.e. apixaban, rivaroxaban and edoxaban), may rarely cause patients to be hospitalized with life-threatening or uncontrolled bleeding. Potential events include intracranial hemorrhage; intraocular, pericardial, intraspinal, intraarticular bleeding at critical sites; major gastrointestinal, retroperitoneal, or genitourinary bleeding; and bleeding associated with major blunt or penetrating injury.
Wilson Disease	Wilson disease is a rare disorder, characterized by excess copper stored in various body tissues, 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.
Warm Autoimmune Hemolytic Anemia (WAIHA)	WAIHA is a rare autoimmune disorder caused by pathogenic Immunoglobulin G (IgG) antibodies that react with and cause the premature destruction of red blood cells at normal body temperature. The disease is often characterized by profound, and potentially life-threatening anemia and other 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).
Amyotrophic Lateral Sclerosis (ALS)	ALS is a progressive neurodegenerative disease of the CNS characterized by the loss of upper (brain) and lower (spinal cord) motor neurons. Ongoing loss of motor neurons and muscle strength leads to loss of independence, paralysis and death, typically due to respiratory insufficiency.
C3 Glomerulopathy (C3G)	C3G is a rare, chronic disease affecting the kidneys in which the alternative pathway of the complement system is dysregulated due to genetic mutations or autoantibodies affecting the regulation of the alternative pathway. This lack of regulation results in the alternative pathway overactivation and the excessive deposition of C3 protein fragments in the glomeruli, a key filtration component of the kidney, often leading to serious kidney damage.
Relapsed/refractory B-and T-cell malignancies	The B cell non-Hodgkin lymphomas (NHLs) are a diverse group of disorders of proliferating malignant B cells. Collectively, NHL is the eighth leading type of cancer in the U.S., with B-cell lymphomas diagnosed in approximately 85% to 90% of patients. The T cell lymphomas are represented by diverse histologies depending on the malignant cell of origin. T-cell NHL comprises approximately 10% to 15% of the total cases of NHL. Patients present with fever, night sweats, and unintentional weight loss. With progressive disease, the malignant cells metastasize from lymph nodes and bone marrow to other organs, ultimately resulting in organ failure. Front-line therapy consists of combination chemotherapy with rituximab. Experimental agents are in development to address patients who relapse or are refractory to front-line therapy. There are no curative therapies in the relapsed/refractory setting.
Transthyretin Amyloidosis (ATTR)	Transthyretin (TTR) amyloidosis (ATTR) is a systemic, progressive, life-threatening disease wherein misfolded TTR protein forms fibrils that deposit in organs and tissues, disrupting normal organ function and tissue structure. ATTR is segmented into mutant/hereditary (ATTRm) caused by mutations in the TTR gene and wild type (ATTRwt)/non-hereditary with no mutations in the TTR gene. Phenotypically, ATTR amyloidosis is heterogeneous: • ATTR cardiomyopathy (ATTR-CM), caused by the accumulation of misfolded TTR amyloid in the heart, leading to heart failure • ATTR polyneuropathy (ATTR-PN), caused by the accumulation of misfolded TTR amyloid in the peripheral and/or autonomic-nervous system. These deposits can damage patients' sensory-motor ability, while also impairing normal cardiovascular and digestive function • While ATTRwt is, by definition, a cardiac disease, ATTRm is more heterogeneous, and can present with various degrees of cardiac and neurological manifestations
Hematopoietic Stem Cell Transplantation Associated Thrombotic Microangiopathy (HSCT-TMA)	Thrombotic microangiopathy (TMA) is a disorder that may occur following hematopoietic stem cell transplant (HSCT), often presenting in the setting of multiple triggers, including endothelial insult, immune dysregulation, and uncontrolled complement activation. The TMA has a significant impact to multiple organs, typically resulting in severe organ dysfunction and long-term morbidity. Mortality in patients with HSCT-TMA is approximately 60% with severe TMA approaching 90%.

COVID-19	Coronaviruses are a family of viruses that can cause illnesses such as the common cold, severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). In 2019, a new coronavirus was identified that is now known as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the disease it causes is called coronavirus disease 2019 (COVID-19). In March 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic. Signs and symptoms of COVID-19 may appear two to 14 days after exposure and can include fever, cough, shortness of breath or difficulty breathing. The severity of COVID-19 symptoms can range from very mild to very severe. Some people may have no symptoms at all. People who are older or who have pre-existing diagnosed or undiagnosed medical conditions, such as heart disease, lung disease and/or diabetes, or who have a compromised or overreacting immune system may be at higher risk of serious illness or complications and may require assisted ventilation as well as urgent critical care.

Marketed Products

Our marketed products include the following:

Product	Therapeutic Area	Approved Indication
ULTOMIRIS® (ravulizumab-cwvz) injection for intravenous use	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)
	Hematology/Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)
SOLIRIS® (eculizumab) Injection for Intravenous Use	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)
	Hematology/Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)
	Neurology	Generalized Myasthenia Gravis (gMG)
	Neurology	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Strensiq® (asfotase alfa) for injection	Metabolic Disorders	Hypophosphatasia (HPP)
Kanuma® sebelipase alfa intravenous infusion	Metabolic Disorders	Lysosomal Acid Lipase Deficiency (LAL-D)
Andexxa® Coagulation Factor Xa (Recombinant), inactivated - zhzo	Acute Care	Reversal of anticoagulation in patients treated with Factor Xa inhibitors when experiencing life-threatening or uncontrolled bleeding.

ULTOMIRIS (ALXN1210/ravulizumab-cwvz)

ULTOMIRIS 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, ULTOMIRIS demonstrated rapid, complete, and sustained reduction of free C5 levels.

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

ULTOMIRIS was approved as a new treatment option for adult patients with PNH by Japan's Ministry of Health, Labour, and Welfare (MHLW) in June 2019. ULTOMIRIS was approved by the European Commission (EC) in July 2019 as a treatment for adult patients with PNH with hemolysis with clinical symptoms indicative of high disease activity, and also for adult patients who are clinically stable after having been treated with SOLIRIS for at least the past six months.

In October 2019, the FDA approved the use of ULTOMIRIS as a treatment for adult and pediatric (one

month of age or older) patients with aHUS to inhibit complement-mediated TMA.

In June 2020, the EC approved ULTOMIRIS for the treatment of adults and children with a body weight of 10kg or above with aHUS who are complement inhibitor treatment-naïve or have received SOLIRIS (eculizumab) for at least three months and have evidence of response to eculizumab.

In September 2020, ULTOMIRIS was approved by Japan's MHLW as a new treatment option for adult and pediatric patients with aHUS.

In October 2020, ULTOMIRIS 100 mg/mL formulation was approved by the FDA for the treatment of adult patients with PNH and for adults and pediatric (one month of age or older) patients with aHUS to inhibit complement-mediated TMA. In November 2020, ULTOMIRIS 100 mg/mL formulation was approved by the EC for treatment of PNH and aHUS. The 100 mg/mL formulation is a higher concentration formulation of ULTOMIRIS than the formulation initially approved in December 2018. ULTOMIRIS 100 mg/mL reduces average annual infusion times by approximately 60 percent compared to ULTOMIRIS 10 mg/mL while delivering safety and efficacy consistent with the ULTOMIRIS 10 mg/mL formulation.

SOLIRIS (eculizumab)

SOLIRIS is an innovative C5 inhibitor discovered and developed by Alexion that works by inhibiting the C5 protein in the terminal complement cascade. 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 and aHUS in pediatric and adult patients in the U.S., Europe, Japan and in several other countries. Alexion is sponsoring multinational registries to gather information regarding the natural history of patients with PNH and aHUS and the longer-term outcomes during anti-C5 treatment.

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

In June 2019, SOLIRIS became the first FDA-approved treatment option for adult patients with NMOSD who are AQP4 auto antibody positive. In August 2019, the EC approved SOLIRIS as the first treatment in Europe for NMOSD in adults who are AQP4 antibody-positive with a relapsing course of the disease. In November 2019, the Japanese MHLW approved SOLIRIS as a treatment for the prevention of relapse in patients with AQP4 antibody-positive NMOSD, including Neuromyelitis Optica.

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, in Europe for the treatment of patients with pediatric-onset HPP, and in Japan for the treatment of patients with HPP. Alexion is 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, in Europe for long-term enzyme replacement therapy in patients with LAL-D, and in Japan for the treatment of patients with LAL-D. Alexion is sponsoring a multinational registry to gather information regarding the natural history of patients with LAL-D and the longer-term outcomes during KANUMA treatment.

ANDEXXA (coagulation factor Xa - [recombinant] inactivated-zhzo)

ANDEXXA is approved by the FDA as a reversal agent for patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. ANDEXXA was approved under the FDA's Accelerated Approval Pathway, and received conditional marketing authorization in the EU based on the change from baseline in anti-Factor Xa activity in healthy volunteers and in patients through the ANNEXXA-4 trial demonstrating hemostatic efficacy. Continued approval for this indication is contingent upon post-marketing study results that verify that clinical benefit is conferred to patients.

Clinical Development Programs

Our ongoing clinical development programs include the following:

Product	Mechanism of Action	Development Area	Indication	Phase I	Phase II	Phase III	Phase IV	Filed
ULTOMIRIS (ALXN1210/ravulizumab-cwvz) (Intravenous)	Anti-C5	Neurology Pulmonology	gMG/NMOSD/ALS/COVID-19/HSCT-TMA			I		
ULTOMIRIS (ALXN1210/ravulizumab-cwvz) (Subcutaneous)	Anti-C5	Hematology/Nephrology	PNH/aHUS			I		
ALXN1720 (Subcutaneous)	Anti-C5	Next Generation Subcutaneous Complement Inhibitor		I				
ALXN1820 (Subcutaneous)	Anti-Properdin	Subcutaneous Complement Inhibitor		I				
ALXN1830 (SYNT001) (Subcutaneous)	Anti-FcRN	FcRN		I				
ALXN1840 (WTX101)	High-affinity, specific Cu binder	Metabolic Disorders	Wilson disease			I		
ALXN2040 (ACH-4471/ danicopan)	Factor D Inhibitor	Hematology/Nephrology	PNH-EVH			I		
ALXN2050 (ACH-5228)	Factor D Inhibitor	Hematology/Nephrology	PNH		I			
ALXN2060 (AG10)	TTR Stabilizer	Metabolic Disorders	ATTR-CM			I		
ALXN2070 (ANDEXXA)	Anti-Factor Xa Reversal	Acute Care	Reversal of anticoagulation in patients treated with Factor Xa inhibitors when experiencing life-threatening or uncontrolled bleeding.				I	
ALXN2075 (Cerdulatinib)	Dual spleen tyrosine kinase and janus kinase (SYK/JAK) inhibitor	Oncology	Relapsed/refractory chronic lymphocytic leukemia or B-cell or T-cell NHL		I			

In addition to our ongoing development programs, Alexion holds a minority interest in and an option to acquire Caelum Biosciences (Caelum), a biotechnology company that is developing CAEL-101 for light chain (AL) amyloidosis. CAEL-101 is a first-in-class chimeric monoclonal antibody (mAb) designed to improve organ function by reducing or eliminating amyloid deposits in the tissues and organs of patients with AL amyloidosis, a rare systemic disorder caused by an abnormality of plasma cells in the bone marrow. A Phase Ia/Ib study for CAEL-101 has been completed. Following discussions with the FDA, a Phase II trial for CAEL-101 commenced during the first quarter of 2020. The trial met its primary objectives, supporting the safety and tolerability of CAEL-101 and confirmed the dose and regimen to be adopted for the Phase III studies. In September 2020, Alexion and Caelum announced the initiation of the Cardiac Amyloid Reaching for Extended Survival (CARES) program. This includes two parallel Phase III trials to evaluate the survival benefits of CAEL-101. Dosing is underway in the two parallel Phase 3 studies; one in patients with Mayo stage IIIa disease and one in patients with Mayo stage IIIb disease.

ULTOMIRIS (ALXN1210/ravulizumab-cwvz)

ULTOMIRIS 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.

Intravenous (IV)

In January 2019, Alexion announced that the Phase III, global, single arm, multicenter study evaluating the safety and efficacy of ALXN1210 administered by IV infusion every 8 weeks to adult patients with aHUS who had never been treated with a complement inhibitor (inhibitor-naïve patients) met its primary objective. In the study's initial 26-week treatment period, 53.6 percent of patients demonstrated complete 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 inhibitor-naïve pediatric patients (including adolescents) with aHUS is ongoing.

In March 2019, Alexion initiated a Phase III double-blind, placebo-controlled, multicenter study to evaluate the safety and efficacy of ALXN1210 in adult patients for the treatment of gMG. Additionally, in December 2019, Alexion initiated a Phase III, single arm, open-label, multicenter study to evaluate the safety and efficacy of ALXN1210 in adult patients with NMOSD.

In March 2020, Alexion initiated a Phase III, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of ALXN1210 in patients with ALS.

In May 2020, following the FDA's acceptance of Alexion's IND application, Alexion initiated a Phase III open-label, randomized, controlled clinical trial of ALXN1210 in adult patients with COVID-19, who are hospitalized with severe COVID-19 requiring mechanical ventilation. The trial is investigating the role of terminal complement inhibition in managing patients with severe COVID-19. In January 2021, we paused further enrollment in this study due to lack of efficacy, pending further analysis of the data. This decision was made based on the recommendation of an independent data monitoring committee (IDMC), following their review of data from a pre-specified interim analysis.

In August 2020, Alexion submitted an application to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) to register the ULTOMIRIS 100mg/ml formulation. The 100 mg/mL formulation is a higher concentration formulation of ULTOMIRIS than the formulation initially approved in December 2018. ULTOMIRIS 100 mg/mL reduces average annual infusion times by approximately 60 percent compared to ULTOMIRIS 10 mg/mL while delivering safety and efficacy consistent with the ULTOMIRIS 10 mg/mL formulation.

In December 2020, Alexion initiated a Phase III, multicenter study to evaluate the safety and efficacy of ALXN1210 in HSCT-TMA.

In addition to aHUS, NMOSD, gMG, ALS, COVID-19 and HSCT-TMA, Alexion plans to initiate: (i) a Phase III study of ALXN1210 in complement mediated thrombotic microangiopathy (CM-TMA), (ii) a proof of concept basket study in renal indications, including Lupus Nephritis (LN) and Immunoglobulin A Nephropathy (IgAN) and (iii) a Phase II/III study in dermatomyositis (DM), a rare autoimmune inflammatory myopathy characterized by chronic inflammation and degeneration of muscle and skin.

Subcutaneous (SC) Delivery

In March 2019, Alexion initiated a 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 June 2020, Alexion announced that the ongoing study met its primary objective of pharmacokinetic-based non-inferiority of ULTOMIRIS SC versus intravenous (IV) ULTOMIRIS at Day 71. Pending completion of the study and collection of required 12-month safety data, Alexion expects to file for approval in the U.S. and E.U. for the SC formulation and device combination in PNH and aHUS in the third quarter of 2021.

ALXN1720

ALXN1720 is a novel humanized bi-specific minibody that binds selectively and with high affinity to C5 and to albumin. ALXN1720 is designed for subcutaneous administration as a concentrated formulation for the treatment of disease states involving dysregulated terminal complement activity. In September 2019, Alexion initiated a Phase I healthy volunteer study of ALXN1720 to assess its safety and tolerability. This trial was paused due to the COVID-19 pandemic, but was re-initiated in August 2020. This trial was paused again in fourth quarter 2020 due to a second wave of COVID-19 and we expect to re-initiate it in the second quarter of 2021. Additionally, pending successful completion of the Phase I healthy volunteer study, we plan to initiate ALXN1720 trials in gMG and DM.

ALXN1820

ALXN1820 is a bispecific minibody binding to properdin and albumin and is a first-in-class therapeutic antagonist of properdin, with potent, selective activity, attractive PK-PD, subcutaneous bioavailability and safety. In December 2020, Alexion submitted a Clinical Trial Application to Human Research Ethics Committees (HREC) in Australia.

Approval was received and notification was sent to Australia's Therapeutic Goods Administration for ALXN1820 in December 2020. In the first quarter of 2021, we initiated a healthy volunteers Phase I study. Early preclinical data for ALXN1820 indicate the potential for convenient, weekly, self-administered subcutaneous dosing. There are multiple potential indications for ALXN1820 across a number of therapeutic areas, including hematology, pulmonology, nephrology and dermatology, where properdin is believed to play an important role.

ALXN1830 (SYNT001)

ALXN1830 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. Alexion initiated a Phase I study of a SC formulation of ALXN1830 in healthy volunteers in December 2019. Alexion re-initiated a Phase II trial of the IV formulation in WAIHA in early 2020. Due to the COVID-19 pandemic, Alexion discontinued the Phase II trial in WAIHA and the Phase I healthy volunteer study. A new Phase I healthy volunteer study is planned to be initiated in the first quarter of 2021, while the Phase II studies in WAIHA and gMG exclusively with the SC formulation are planned to start in the second half of 2021.

ALXN1840 (WTX101)

ALXN1840, 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 the ability to access and mobilize copper from tissue.

In February 2020, Alexion completed enrollment in a Phase III study of ALXN1840 for the treatment of Wilson disease. We expect top-line results from this Phase III study in the first half of 2021.

ALXN1850

ALXN1850 is an Enzyme Replacement Therapy replacing deficient alkaline phosphatase (ALP) activity and targets ALP substrates to improve bone mineralization and ameliorate systemic manifestations of the disease. It is a next generation HPP therapy that is designed to be provide higher activity, higher bioavailability, and longer half-life than STRENSIQ (asfotase alfa). These improvements may result in significant benefit for HPP patients, including potentially lower, less frequent doses, improved efficacy and lower injection volumes when compared to STRENSIQ. In November 2020, Alexion submitted an IND for ALXN1850 to the FDA and received approval to proceed with a Phase I study in HPP patients. We plan to initiate the Phase I study in the second quarter of 2021. ALXN1850 is designed for subcutaneous administration.

ALXN2040 (danicopan/ACH-4771)

ALXN2040 is an oral Factor D inhibitor designed to treat diseases associated with dysregulation of the complement alternative pathway. ALXN2040 as an add on therapy to anti-C5 for PNH patients with clinically evident extravascular hemolysis (EVH) has received orphan drug and breakthrough therapy designation by the FDA and both orphan and PRIME designation by EMA. Two Phase II studies of ALXN2040 as an oral add-on therapy for PNH-EVH are ongoing, and a Phase III trial for PNH-EVH was initiated, with dosing of the first patient in the first quarter of 2021. Two Phase II studies previously initiated evaluating the safety, efficacy, pharmacokinetics, and pharmaco-dynamics of ALXN2040 in patients with C3G have been discontinued and we are no longer pursuing ALXN2040 as a treatment for C3G. Alexion plans to develop ALXN2050 in a variety of orphan renal indications including C3G.

We plan to initiate a Phase II study of ALXN2040 in Geographic Atrophy, a chronic and progressive degeneration of the portion of the retina responsible for central and color vision and leading to permanent loss of visual acuity, in the second half of 2021.

ALXN2040 was added to the pipeline as a result of the Achillion acquisition.

ALXN2050 (ACH-5228)

ALXN2050 is an oral Factor D inhibitor designed to treat diseases associated with dysregulation of the complement alternative pathway. ALXN2050 is in a Phase II trial as a potential monotherapy treatment for PNH and is being evaluated for development in other alternative pathway-mediated rare diseases. We have paused additional enrollment in the Phase II study of ALXN2050 monotherapy that is underway in PNH patients, pending the receipt of further Phase I data (expected in the second quarter of 2021) that will allow for dose escalation in the Phase II study. Additionally, Alexion plans to initiate proof-of-concept trials of ALXN2050 in patients with various renal diseases in the first half of 2021.

ALXN2050 was added to the pipeline as a result of the Achillion acquisition.

ALXN2060 (AG10)

In September 2019, Alexion entered into an agreement with Eidos Therapeutics, Inc. (Eidos), through which Alexion obtained an exclusive license to develop and commercialize AG10 in Japan for transthyretin amyloidosis (ATTR). AG10 is an orally administered small molecule in development designed to target the root cause of ATTR by stabilizing transthyretin (TTR) in the blood. Eidos is currently studying AG10 in a Phase III clinical trial in patients with ATTR cardiomyopathy (ATTR-CM) and a Phase III

clinical trial in patients with ATTR polyneuropathy (ATTR-PN), excluding Japan. In the fourth quarter 2020, Alexion initiated a single arm AG10 Phase III study in ATTR-CM in Japan. The Japan Phase III study data for ATTR-CM is expected to bridge to the global randomized controlled Phase III study being conducted by Eidos, and serve as the basis for seeking regulatory approval to commercialize AG10 in Japan.

ALXN2070 (ANDEXXA)

The acquisition of Portola added Portola's commercialized medicine, ANDEXXA, for which additional clinical trials are currently being conducted to obtain full regulatory approvals and to expand the approved indications. As noted above, ANDEXXA has obtained accelerated approval in the US and conditional marketing authorization in the EU based on the change from baseline in anti-Factor Xa activity in healthy volunteers, and in patients through the ANNEXA-4 trial. Full approval in the US and EU for current indications requires completion of ANNEXA-I, a Phase IV randomized controlled clinical trial currently underway evaluating the safety and efficacy of ANDEXXA versus standard of care in patients presenting with acute intracranial hemorrhage while taking an oral Factor Xa inhibitor. A Japan J-NDA filing is planned for the first quarter 2021. A US supplemental Biologics License Application (sBLA) submission for a label expansion for the reversal of edoxaban and enoxaparin associated bleeds occurred in the fourth quarter of 2020.

Additionally, we plan to initiate a Phase II study in 2021 for the reversal of anticoagulation in patients taking apixaban, rivaroxaban, edoxaban, or enoxaparin who require urgent surgery.

ALXN2075 (Cerdulatinib)

ALXN2075 (Cerdulatinib) is a small molecule SYK/JAK inhibitor in development for treatment of hematological malignancies. We are reviewing preliminary clinical data and considering Follicular Lymphoma as a next step in the program. A Phase I/IIa study is ongoing for the treatment of hematological malignancies. ALXN2075 was added to the pipeline portfolio as a result of the acquisition of Portola.

SOLIRIS (eculizumab)

SOLIRIS is an innovative C5 inhibitor discovered and developed by Alexion that works by inhibiting the C5 protein in the terminal complement cascade. SOLIRIS is a humanized monoclonal antibody that effectively blocks terminal complement activity at the doses currently prescribed.

In June 2020, Japan's MHLW granted SAKIGAKE designation for SOLIRIS in Guillain-Barré syndrome (GBS). Results from the Japanese eculizumab trial for GBS (JET-GBS study) suggested the potential efficacy and safety of SOLIRIS as a treatment for GBS. Complement activation may play a role in the pathophysiology of GBS. Alexion plans to initiate a Phase III study of SOLIRIS in GBS in Japan in the first half of 2021.

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 a KANUMA production facility in Georgia. Third party contract manufacturers, including Lonza Group AG and its affiliates (Lonza), provide cell bank services, bulk drug substance, drug product and finished product, as well as other manufacturing services like purification, product filling, finishing, packaging, and labeling.

We have various agreements with Lonza to provide cell bank and drug substance through 2030, with remaining total non-cancellable commitments of approximately $1,137.8. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangements. Under an existing arrangement with Lonza, we pay Lonza a royalty on the sales of SOLIRIS and ULTOMIRIS manufactured at Lonza facilities. In the fourth quarter 2020, Lonza received FDA approval for a new manufacturing facility in New Hampshire that will manufacture STRENSIQ for commercial use. Commitments entered into under this arrangement are included in the non-cancellable commitments previously noted.

In addition, we have non-cancellable commitments of approximately $175.6 through 2023 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. We have also completed construction of a new biologics manufacturing facility at this site and we are currently pursuing regulatory approval.

In May 2015, we announced plans to construct a new biologics manufacturing facility on our existing property in Dublin, Ireland. Construction of this facility has been completed. In January 2021, the European Medicines Agency (EMA) approved the facility as a manufacturer of Drug Substance for SOLIRIS and we are currently pursuing regulatory approval by the FDA.

While we continue to actively engage with regulators, the timing of regulatory approvals for each of these facilities may be delayed as a result of the COVID-19 pandemic.

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. Given our focus in rare diseases and devastating conditions, we have a relatively small sales force; however, we believe that the size of our sales force is appropriate to effectively market our products due to the incidence and prevalence of rare diseases and devastating conditions. 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, in selected geographies within our international commercial organization, we have transitioned from a direct sales model to an indirect sales model that relies to a greater extent or entirely on third-parties to promote, distribute and sell our products. We have also reallocated resources necessary to align our organization with our diversifying portfolio of new products and strategic objectives. We are making investments in digital capabilities, technologies and solutions to support a more virtual and digital customer experience, tailored to the markets in which we operate.

Customers

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

Our net product sales to three customers, AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc., each accounted for more than 10.0% of total revenues for the year ended December 31, 2020 and on a combined basis, accounted for approximately 47.4%. Our net product sales to four customers, AmerisourceBergen Corporation, McKesson Corporation, Cardinal Health, Inc. and PANTHERx Rare Pharmacy, each accounted for more than 10.0% of our total revenues for the years ended December 31, 2019 and 2018 and on a combined basis, accounted for approximately 56.4% and 50.3%, respectively.

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 for SOLIRIS, ULTOMIRIS, STRENSIQ AND KANUMA, customers often carry limited inventory. ANDEXXA is administered almost exclusively in the hospital and urgent care setting. While ANDEXXA inventory on hand is also limited, there may be a longer period from product sale to patient use and a greater risk of return for product expiry.

Please also refer to *Management's Discussion and Analysis – Net Product Sales*, and Note 18, *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

We rely on intellectual property rights to protect our investment in discovering, developing and marketing our marketed products, product candidates and investigational compounds. Accordingly, we own or license rights to many patents in the U.S. and foreign countries that cover our marketed products, product candidates 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, we believe, material value and we undertake reasonable measures to protect those rights.

Patent rights and regulatory protections are key factors 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, including the U.S., provide compensatory mechanisms to extend patent terms for biopharmaceutical products.

Regulatory protections are another source of exclusive rights that contribute toward market exclusivity for our products. Many developed countries provide such non-patent incentives to develop medicines. For example, countries provide data protection for a period of time after the approval of a

new drug, during which regulatory agencies may not rely on the innovator's data to approve a biosimilar or generic copy. Some countries provide additional incentives to develop medicines for rare diseases, or orphan drugs, and medicines for pediatric patients. Regulatory protections can work in conjunction with patents to strengthen market exclusivity, and in countries where patent protection has expired or does not exist, regulatory protections can be the basis 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*.

Intellectual property rights in our industry are often disputed. For information regarding legal actions that pertain to ULTOMIRIS and SOLIRIS intellectual property rights, refer to 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 also benefits from orphan drug exclusivity for treating gMG until 2024 and for treating NMOSD until 2026 (orphan drug exclusivity for SOLIRIS for treating PNH and aHUS in the U.S. previously expired). In Europe, SOLIRIS is protected by orphan drug exclusivity through late 2023 for aHUS, until 2027 for gMG and until 2029 for NMOSD (orphan drug exclusivity for SOLIRIS for treating PNH in Europe previously expired). In Japan, we own an issued patent that covers the eculizumab composition of matter and will expire in 2027. SOLIRIS is also protected in Japan by orphan drug exclusivity until 2027 for gMG and until 2029 for NMOSD (orphan drug exclusivity for SOLIRIS for treating PNH in Japan previously expired). 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.

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. This decision is currently under appeal.

While we have the patent rights to SOLIRIS as detailed above, on August 30, 2019, the U.S. Patent and Trademark Office instituted inter partes review (IPR) of three of our patents that relate to SOLIRIS. In May 2020, we entered into a Confidential Settlement and License Agreement with Amgen to settle the three IPRs (Settlement Agreement). Pursuant to the Settlement Agreement, Alexion and Amgen have terminated each of the pending IPRs and, effective March 1, 2025 (or an earlier date in certain circumstances), Alexion grants to Amgen (and its affiliates and certain partners) a non-exclusive, royalty-free, license under U.S. patents and patent applications related to eculizumab and various aspects of the eculizumab product that Alexion currently markets and sells under the tradename SOLIRIS.

ULTOMIRIS Exclusivity

With respect to ULTOMIRIS, we own issued U.S., European and Japanese patents that cover the composition of matter, use and formulation of ravulizumab that will expire in 2035. ULTOMIRIS is also protected by orphan drug exclusivity for treating PNH in the U.S. until 2025 and in Japan until 2029. ULTOMIRIS is also protected in Japan by orphan drug exclusivity for treating PNH until 2029. In addition to the foregoing patent and regulatory protections, we own other patents and pending patent applications that are directed to various aspects of ULTOMIRIS 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 2029, including patent term restoration. STRENSIQ is also protected in the U.S. by orphan drug exclusivity until 2022. In Europe, we own two issued patents that cover the asfotase alfa composition of matter and these will expire in 2025 and 2028. Additionally, we have received supplementary protection certificates that extend the patent protection until 2030 in many European countries. STRENSIQ is also protected in Europe by orphan drug exclusivity until 2027. In Japan, STRENSIQ is protected by an issued patent that covers the asfotase alfa composition of matter until 2028 and by orphan drug exclusivity until 2025. In addition to the foregoing patent and regulatory protections, we own other patents and pending patent applications that are directed to various aspects of STRENSIQ and which may provide additional protection for STRENSIQ in the U.S., Europe, Japan and other countries.

KANUMA Exclusivity

With respect to KANUMA, we own issued patents in the U.S., Europe and Japan that cover the composition of matter and/or methods of using the product to treat LAL-D that 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 that has been extended to 2026 via supplementary protection certificates further protects KANUMA in certain European countries. KANUMA also is protected by orphan drug exclusivity until 2022, 2027 and 2026 in the U.S., Europe and Japan, respectively.

ANDEXXA/ONDEXXYA Exclusivity

With respect to ANDEXXA, we own an issued U.S. patent that covers the andexanet alfa composition of matter and has an expiration in 2030. A pending application for patent term extension could extend the expiration to 2032. ANDEXXA is also protected in the U.S. by orphan drug exclusivity until 2025. In Europe, we own two issued patents that cover the andexanet alfa composition of matter and have expirations in 2028. Additionally, we have applied for supplementary protection certificates that could extend the patent protection until 2033 in many European countries. In Japan, we own an issued patent that covers the andexanet alfa composition of matter and has an expiration in 2028. In addition to the foregoing patent and regulatory protections, we own other patents and pending patent applications that are directed to various aspects of ANDEXXA/ONDEXXYA and which may provide additional protection for ANDEXXA/ONDEXXYA in the U.S., Europe, Japan and other countries.

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.

Asset Acquisition and In-License Agreements

From time to time, we enter into arrangements with third parties, including asset purchase agreements, licensing arrangements, and option agreements in order to advance and obtain technologies and services related to our business. 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 us to pay an initial fee and certain agreements call for future payments upon the attainment of agreed upon development, regulatory and/or commercial milestones. These agreements may also require minimum royalty payments based on sales of products developed from the applicable technologies, if any.

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.

Government Regulation

Drug Development and Approval in the United States

The preclinical studies and clinical testing, manufacture, labeling, storage, record keeping, advertising, promotion, regulatory approval pharmacovigilance reporting, export, and marketing, among other things, of our products and product candidates, including ULTOMIRIS, SOLIRIS, STRENSIQ, KANUMA and ANDEXXA, 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 (FDCA) and other laws, including, in the case of biologics, the Public Health Service Act. Our five 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. We also have product candidates, including our Factor D pipeline assets ALXN2040 and ALXN2050, and

ALXN1840 that are small molecule compounds and, if we complete trials and request approval to market these products, these small molecules require the submission of a New Drug Application (NDA) to the FDA. Failure to comply with FDA, state and foreign regulatory requirements, both before and after product approval, may subject us and/or our partners, distributors, 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 or small molecule 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 pharmaceutical 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 in the case of a biologic or an NDA or supplemental NDA in the case of a small molecule compound;

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

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

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 or an NDA 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 product labeling. Phase III trials evaluate clinical efficacy of a specific endpoint(s) 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. For example, we paused enrollment for our Phase III trial of ULTOMIRIS in adults with COVID-19, who are hospitalized with severe COVID-19 requiring mechanical ventilation because of lack of efficacy following the recommendation of an IDMC.

In certain circumstances, regulatory authorities, including the FDA, can require a product undergo a Phase IV trial. Phase IV trials are post-marketing studies, which are conducted after a product is approved for use by the regulatory authority, in order to provide additional information including the product's risks, benefits, and best use. While the requirement for Phase IV is not a regulatory requirement for approval for every product, it is imposed at the discretion of the regulatory authority. For example, the accelerated approval of ANDEXXA in the U.S. and the granting of a Conditional Marketing Authorization in the EU for current indications required completion of ANNEXA-I, a Phase IV randomized controlled multicenter clinical trial, which is currently underway and designed to evaluate the safety and efficacy of ANDEXXA versus standard of care in patients presenting with acute intracranial hemorrhage while taking an oral Factor Xa inhibitor.

We must register each controlled clinical trial, other than Phase I trials, on a website administered by the National Institutes of Health (NIH) (http://clinicaltrials.gov). Registration must occur no 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, NDA, NDA 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 or NDA 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 or NDA, as well as annual fees for commercial manufacturing establishments and for approved products, can be substantial. The review fee alone can exceed $2.0 subject to certain limited deferrals, waivers and reductions that may be available. Each BLA and NDA 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 submission sufficiently complete, the FDA will "file" the application, thus triggering a full review of the application. The FDA may refuse to file any BLA or NDA that it deems incomplete or not properly reviewable at the time of submission. The 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 or NDA to an advisory committee composed of outside experts for evaluation and a recommendation as to whether the application should be approved.

Further, the outcome of the FDA 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 application, 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 application 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 or NDA, 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 Manufacturing Practice (cGMP) requirements. The FDA may deny approval of an application if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information. FDA approval of any BLA or NDA 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 (as is the case with ANDEXXA, where the FDA's continued approval is contingent upon post-marketing study results that verify clinical benefit is conferred to patients). The 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 beyond those in the product label, or to make certain manufacturing or other changes, requires FDA review and approval of a BLA supplement or new BLA (or NDA or NDA supplement in the case of a small molecule compound) 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.

The 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, considerations in demonstrating interchangeability with a reference product, including a biologic, and questions and answers on issues involving biosimilar development. FDA has also issued a draft guidance for biologics and interchangeable biosimilars regarding the licensure for fewer than all conditions of use for which the reference product has been licensed.

The FDA approved the first biosimilar product under the BPCIA in 2015 and, as of December 2020, twenty nine (29) 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. Also, in 2019, the CREATES Act was signed, which requires that product manufacturers timely sell comparator trial supply at a commercially reasonable price (no more than the manufacturers wholesale acquisition cost) to biosimilar developers. 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, may be priced significantly lower than our products, and result in a reduction in the pricing and reimbursement of our products.

Both before and after the FDA approves a product, the manufacturer and the holder or holders of the BLA or NDA, 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, supplemental BLA, NDA or supplemental NDA. 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 U.S. federal 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. and Japan, and for the subcutaneous treatment of patients with aHUS in the U.S. SOLIRIS has received orphan drug designation for (a) aHUS in 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; and (d) 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., the EU and Japan. Finally, ANDEXXA has received orphan drug designation in the U.S. as a reversal agent for patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. Certain products in our pipeline, including ALXN2040, have received the orphan drug designation. 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; for KANUMA in the treatment of LAL-D presenting in infants and for ANDEXXA for patients treated with direct FXa inhibitors when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. 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 provisions 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 authorized $1,800.0 in funding for the "Cancer Moonshot" initiative (the Initiative) over a seven-year period to be run by the National Cancer Institute under 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 continue to monitor these developments but cannot currently assess how the Initiative may impact our business.

Right to Try Act

The Right to Try Act was signed into law on May 30, 2018. The law provides an access pathway for eligible patients (as defined under the law) who have been diagnosed with life-threatening diseases or conditions and have tried all approved treatment options and are unable to participate in a clinical trial to obtain certain investigational or unapproved treatments, each as defined under the law.

As a clinical trial sponsor, when requested, Alexion is required to provide eligible patients or their providers with information about whether our products are considered an eligible investigational drug under Right to Try and if we would provide products under the Right to Try Act.

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 drug development, pre-clinical trials, human clinical trials, marketing approval, manufacturing, pharmacovigilance 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 the approval process 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 process and 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 Committee for Medicinal Products for Human Use (CHMP) 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 (EEA) states and such marketing authorization applications may be eligible for accelerated assessment if the CHMP decides the product is of major interest for the public health and therapeutic innovations. 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.

Similar 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 have in the past, and expect that they will continue to, 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, marketers 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.

In April 2014, the EU adopted a new Clinical Trials Regulation, (EU) No 536/2014, which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the EU, the new EU clinical trials legislation was passed as a regulation that is directly applicable in all EU Member States without the need for implementation into the Member States' national laws. All clinical trials performed in the EU are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable. According to the current plans of the EMA, the new Clinical Trials Regulation will become applicable in late 2021 or early 2022. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for old regulatory framework.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the EU portal; a single set of documents to be prepared and submitted for the application, as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states; and harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts.

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 take additional actions as well, including restricting 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 in connection with the 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 or there may be no coverage at all. Certain payers have in the past, and may in the future, remove our products from their existing formularies and, as a result, beneficiaries no longer have access to our products. These measures can lower the demand for our products, including 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, individuals with end-stage renal disease and ALS. Our products when used by Medicare beneficiaries 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. In addition, ANDEXXA, which is used in the urgent care setting in order to reverse the effects of certain anticoagulant medications for patients suffering sever bleeds, is covered by Medicare Part A, which covers, among other things, in-patient care in a hospital.

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 plus 6.0% for most Part B-covered drugs and biologics. 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 certain 340B covered entities at ASP minus 22.5% (or 77.5% of ASP) for separately payable Part-B covered drugs and biologics that were purchased under the 340B Program in a hospital outpatient setting, as discussed further below. In addition, the sequester that is currently in place through 2030 (which Congress temporarily suspended from May 1, 2020 through March 31 2021 due to the COVID-19 pandemic) reduces the portion of the payment paid by Medicare by 2.0%, which results in a net payment rate equivalent to ASP plus 4.3%. The sequester affects other Medicare payments, and the overall 2.0% sequester rate is 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, as discussed below). Medicare Part A generally covers inpatient hospital benefits and other inpatient facility stays. 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 and other applicable inpatient facilities generally do not receive separate payment for drugs and biologics administered to patients during an inpatient hospital stay. As a result, hospitals and other inpatient facilities 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 plans, Medicare Advantage organization plans negotiate discounts with

health care providers and implement utilization controls, including, most notably, step therapy for Part B drugs, which became effective January 1, 2019. This means that Medicare Advantage plans can now require beneficiaries to use a more cost-effective drug therapy first and only progress to a more costly therapy if and when determined necessary after medical review. This method of utilization management can lower the demand for therapies subject to step therapy, including expensive therapies.

The Budget Control Act of 2011, 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 2030 (except for the period from May 1, 2020 through March 31, 2021 during which Congress temporarily suspended the sequester due to the COVID-19 pandemic). This 2.0% reduction in Medicare payments affects all Parts of the Medicare program and could impact sales of our products. Additional sequestration orders under the statutory Pay-As-You-Go Act of 2010 could also be triggered, potentially resulting in up to a 4.0% reduction in Medicare payments. These potential future reductions to Medicare Part B reimbursement to physicians could potentially negatively impact our business as well, including our C5 inhibitors which are administered in the inpatient setting.

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 single source and innovator multiple source products, the best price for each drug. As further described below under "U.S. Healthcare Reform and Other U.S. and International 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. Additionally, the Right Rebate Act became effective April 2019, which primarily imposes new penalties on drug manufacturers that knowingly misclassify a covered outpatient drug under the Medicaid Drug Rebate Program.

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, certain rural referral centers and certain sole community hospitals, each as defined by PPACA. However, "orphan drugs" i.e., those designated under section 526 of the FDCA, such as certain of our products that have received market authorization (as identified above), are exempted from the ceiling price requirements for these eligible entities added by PPACA (except for certain children's hospitals). 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 pricing-related matters: the President, HHS officials (including CMS and the FDA), and lawmakers and regulators (at both the federal and state level) 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. Members of Congress, for example, have launched investigations into the pricing practices of the prescription drug industry, have held hearings to investigate increases in drug prices, and continue to consider and pass legislation to address high drug prices and increase drug price transparency. This includes a coronavirus relief and government appropriations bill passed in December 2020 containing several important new drug price reporting and transparency measures that could result in additional pricing transparency, including requirements for certain Medicare plans to implement tools to display Medicare Part D prescription drug benefit information in real time and for group and health insurance issuers to report information on certain pharmacy benefit and drug costs to the Secretaries of HHS, Labor, and the Treasury.

In addition, on November 20, 2020, CMS issued an interim final rule with comment period (IFC) to implement a Most Favored Nation (MFN) Model for certain included drugs and biological products payable under Medicare Part B. Throughout its seven-year performance period, the MFN Model would gradually reduce Medicare Part B reimbursement for included products to their respective MFN price, which generally reflects the lowest price for a pharmaceutical product sold in certain economically-comparable member countries of the Organisation for Economic Co-operation and Development. The IFC identified our product, SOLIRIS (eculizumab injection), as one of 50 drugs and biological products included in the first performance year of the MFN Model. The MFN Model was scheduled to commence on January 1, 2021; however, litigation challenging the MFN Model has delayed its implementation, and the outcome of the litigation is unclear. It is also unclear whether the change in the U.S. presidential Administration in January 2021 will result in changes to the MFN model or other federal drug pricing measures. As discussed in “Government Regulation – U.S. Healthcare Reform and Other U.S. and International Healthcare Laws” included in Part I, Item 1 of this Annual Report on Form 10-K, the incoming Biden Administration issued a memorandum “freezing” certain regulations and guidance documents issued by the Trump Administration that had not become effective as of President Biden’s inauguration on January 20, 2021. Changes in the U.S. presidential Administration and the Congress following the 2020 elections could also potentially result in further legislative and regulatory changes, continued Congressional and Executive Branch scrutiny, and negative attention with respect to drug pricing and related matters.

State governments have also been pursuing legislative and regulatory changes to address drug prices. For example, the state of California passed legislation that requires drug manufacturers to notify the state at least 60 days of instituting price increases and Maryland passed legislation to create a drug pricing review commission that will evaluate drug cost and recommend setting an upper limit or cap for therapies deemed too expensive. We cannot predict what other reforms may ultimately be implemented at the federal or state level or the effect of any future legislation or regulation and, accordingly, face uncertainties that may result from additional reforms and their 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 examples of which include France, Italy, Germany, Netherlands, Poland, Spain 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 structure, function, remit, and approaches of these HTA bodies vary according to the different health systems and political structures they operate in.

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 without limitation, 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. On November 20, 2020, OIG issued two final regulations implementing significant modifications to regulatory safe harbors to the federal Anti-Kickback Statute. The first rule finalized new safe harbors and modified existing safe harbors to promote certain value-based and coordinated care arrangements and reduce regulatory burden, which are scheduled to become effective January 19, 2021. However, the Government Accountability Office has determined that this effective date was premature in light of certain Congressional Review Act restrictions. This rule is likely subject to the regulatory "freeze" memorandum issued by the Biden Administration, as discussed in "Government Regulation – U.S. Healthcare Reform and Other U.S. and International Healthcare Laws" included in Part I, Item 1 of this Annual Report on Form 10-K. " included in Part I, Item 1 of this Annual Report on Form 10-K. The second rule (the Rebate Rule) created new safe harbor protection, which was scheduled to become effective January 29, 2021, for certain (i) point-of-sale discounts from pharmaceutical manufacturers to Medicare Part D plans, Medicaid managed care organizations, and their contracted pharmacy benefit managers (PBMs), and (ii) fees for certain services that PBMs provide to pharmaceutical manufacturers. The Government Accountability Office found this effective date to be premature in light of Congressional Review Act requirements, and OIG subsequently delayed the effective date of these provisions to March 22, 2021, in order to further review the rule in accordance with the regulatory "freeze" memorandum issued by the Biden Administration. In addition, the Rebate Rule revised the discount safe harbor to exclude from protection price reductions (e.g., rebates) for pharmaceutical products from manufacturers to Part D plans when made directly or indirectly through a PBM. This change was originally scheduled to become effective January 1, 2022, but the Rebate Rule has been subject to litigation, and the effective date for this change was subsequently delayed to January 1, 2023 in accordance with an order from the U.S. District Court for the District of Columbia. The Rebate Rule is intended to create incentives for manufacturers, covered plans, and PBMs to shift from retrospective rebates to point-of-sale discounts, potentially lowering list prices of, and reducing consumers' out-of-pocket costs for, prescription drugs. Implementation of these rules is uncertain and could trigger further regulatory action by coordinating agencies within HHS. We cannot predict the full impact of these rules and any subsequent related regulatory actions on our operations.

- 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 between eleven thousand six hundred sixty five dollars and twenty three thousand three hundred thirty one dollars per false claim or statement for penalties assessed after June 19, 2020, with respect to violations occurring after November 2, 2015 (and penalties of between five thousand five hundred and eleven thousand dollars per false claim 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, patient support programs, certain financial arrangements with healthcare providers, misstated government drug 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, 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 other regulated parties, 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 assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. Accordingly, applicable manufacturers are required to track certain payments and other transfers of value made to these additional covered recipients during calendar year 2021. 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 to 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’ speaker programs, product and patient assistance programs, including manufacturer reimbursement support services, relationships with specialty pharmacies, and grants to independent charitable foundations. There was, for example, a recent enforcement action in August 2020 against a pharmaceutical company for violations of the FCA and Anti-Kickback Statute that resulted in payments of hundreds of millions of dollars to the government and

imposition of an extensive corporate integrity agreement. 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 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. In April 2019, we entered into a civil settlement agreement with the U.S. Department of Justice (DOJ) and OIG to resolve this matter. As part of the settlement agreement, Alexion paid $13.1 to the DOJ and OIG. 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. 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. See Other Regulations below for additional information on such regulations outside the U.S.

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

In the U.S., there have been, and we expect there will continue to be, a number of legislative and regulatory changes to healthcare systems. In the U.S., the pharmaceutical industry has been a particular focus of healthcare reform efforts and has been significantly affected by the PPACA, which was adopted in March 2010. This law substantially changed 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 impacted 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.

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 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. In December 2020, CMS issued another final regulation implementing further changes to the Medicaid Drug Rebate Program, including updates to align existing regulations with certain statutory amendments enacted subsequent to PPACA. Among other provisions, the rule affects price reporting related to manufacturer-sponsored patient assistance programs subject to PBM accumulator programs, certain value-based purchasing arrangements, line extensions, and authorized generics. As with other Trump Administration regulations not made effective as of President-elect Biden's inauguration on January 20, 2021, certain aspects of this rule may potentially be subject to the regulatory "freeze" memorandum expected to be issued by the incoming Biden Administration. Ultimately, issuance of these regulations, as well as 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 certain Medicaid Drug Rebate Program requirements

Additional provisions of PPACA may negatively affect manufacturers' revenues. For example, PPACA required 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). Due to successful FDA approval of indications other than an orphan indication and based on sales projections, we anticipate that one of our products, ULTOMIRIS, may be subject to the branded prescription drug fee beginning in 2022.

In addition, as part of PPACA's provisions closing the coverage gap 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, including certain of our products, from the ceiling pricing requirements for these eligible covered entities added by PPACA (except for certain children's hospitals).

The framework of the PPACA continues to evolve as a result of executive, legislative, regulatory, and administrative developments that have challenged the law during 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," which became effective 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. In December 2019, the Fifth Circuit Court of Appeals agreed that the individual mandate was unconstitutional, but remanded the case back to the district court for further analysis of whether the mandate could be severed from PPACA. The U.S. Supreme Court granted certiorari on March 2, 2020, and conducted oral argument in November 2020. The case is expected to be decided in 2021. Further legislative changes to and regulatory changes under PPACA remain possible. We expect to continue to see legislative, regulatory, and litigation changes involving the PPACA that may impact the PPACA and, potentially, coverage and reimbursement of our products.

In addition, as described in "Government Regulation – Pharmaceutical Pricing and Reimbursement" and "Government Regulation – Fraud and Abuse" included in Part I, Item 1, the Trump Administration recently promulgated regulations that, if implemented, could potentially have a significant impact on the pharmaceutical and broader healthcare industries. However, recent changes in the U.S. presidential Administration following the 2020 elections could affect certain Trump Administration regulatory actions. This includes a memorandum issued by the Biden Administration "freezing" certain regulations and guidance documents issued by the Trump Administration that had not become effective as of President Biden's inauguration on January 20, 2021. This memorandum, like similar memoranda issued by prior incoming Administrations, directs federal agencies to take steps to halt, delay, or conduct further review of certain regulatory actions taken by the Trump Administration, including by postponing the effective dates for rules that had not taken effect by January 20, 2021 for the purpose of reviewing any questions of fact, law, and policy raised by such rules. The Biden Administration has also undertaken other actions—and will likely continue to do so—signaling a change in policy from the prior Administration. Such activities include Executive Order 13992 revoking several Trump Administration orders that had certain deregulatory effects, and a letter to the United Nations retracting the United States' intent to withdraw from the World Health Organization. Other actions by the Biden Administration and/or legislation passed by the new Congress could further impact the pharmaceutical and broader healthcare industries in ways that are difficult to predict but that could also materially impact our operations. We cannot predict what other healthcare reforms will ultimately be implemented at the federal or state level or the effect of any future legislation, executive action or regulation and, accordingly, face uncertainties that might result from additional reforms.

Privacy, Data Protection and Information Security

Numerous international, federal, and state laws, including state privacy laws (such as the California Consumer Privacy Act, or CCPA), state and city security breach notification and information security 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 penalties and sanctions, including criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information (protected 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 protected 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. The GDPR introduced comprehensive data protection requirements in the EU and substantial fines for breaches of the data protection rules. EU regulators also have issued guidance regarding the handling and protection of EU personal data with respect to the transfer of personal data from the EU to the U.S. and other issues relevant to our operations. The GDPR and associated guidance from EU regulators increased our responsibility and liability in relation to EU personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with evolving EU data protection requirements, in particular relating to international transfers of 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. For example, the Brazilian General Data Protection Law (LGPD), which went into effect in 2020, may impact our collection and use of personal information related to this jurisdiction.

Moreover, we rely on our internal 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 (or may not be covered at all by any of our insurance policies depending on the circumstances). 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 Securities Exchange Commission 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. The investigations focused on operations in various countries, including Brazil, Colombia, Japan, Russia and Turkey, and Alexion's compliance with the FCPA and other applicable laws. In May 2020, DOJ informed us that it has closed its inquiry into these matters. On July 2, 2020, we reached a civil settlement with the SEC fully resolving the SEC's investigation into possible violations of the FCPA. Alexion neither admitted nor denied any wrongdoing in connection with the settlement and paid $21.5 to the SEC, consisting of amounts attributable to disgorgement, civil penalties, and pre-judgment interest. 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 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 existing EU legislation and the new Clinical Trial Regulation there is an obligation to publish clinical trial results within a certain timeframe. A breach of this obligation would constitute non-compliance with EU legislation 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. For example, in October 2018, the Japanese MHLW conducted an administrative inspection of Alexion's Japanese operations. The MHLW inquiry primarily focused on our communication efforts regarding the proper use of SOLIRIS in Japan for aHUS, among other matters. We have cooperated with the inquiries and the investigation, and in March 2019, the MHLW indicated that it has completed its investigation.

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 and aHUS (although several companies are currently evaluating other complement inhibitors for the treatment of PNH and aHUS in clinical trials). SOLIRIS is currently the only approved complement inhibitor therapy for the treatment of AChR antibody-positive gMG (although several companies are currently evaluating complement inhibitors, such as C3 and C5 inhibitors, and other mechanisms of action, including Factor B and Factor D inhibitors, for the treatment of PNH, aHUS and gMG in clinical trials).

SOLIRIS is also approved as a therapy for patients with NMOSD who are AQP4 auto antibody-positive. During 2020, two therapies were approved by the FDA (and certain other regulatory authorities) as treatments for NMOSD. The first, Uplizna (inebilizumab-cdon), a Viela Bio product, is also an intravenous infusion treatment for NMOSD for adult patients who are AQP4 auto antibody-positive. UPLIZNA is a CD19-directed cytolytic antibody and was approved by the FDA in June 2020. The second, Enspryng (satralizumab-mwge), a Roche group product, is a subcutaneously delivered treatment for NMOSD for adults who are AQP4 auto antibody-positive. Enspryng is designed to target and inhibit interleukin-6 (IL-6) receptor activity and was approved by the FDA in August 2020. Both of these NMOSD indicated-therapies, which rely on mechanisms of action that are different from C5 inhibitors, are new entrants to the market and, therefore, it is difficult at this time to determine the impact of these products on the trends in market demand and competitive conditions in the NMOSD market In addition, while the label for rituximab, a monoclonal anti-CD20 antibody that is delivered by intravenous infusions, does not carry indications for NMOSD, we are aware that rituximab is commonly prescribed by physicians for the treatment of NMOSD in the U.S. and outside the U.S. Rituximab is currently co-marketed by Biogen and Genentech in the U.S., by Hoffmann-La Roche in Canada, the European Union (EU) and Chugai Pharmaceuticals Zenyaku Kogyo in Japan. Clinical trials have not been conducted to compare the safety and efficacy of SOLIRIS and rituximab, Uplizna or Enspryng in NMOSD.

We are also evaluating ULTOMIRIS and SOLIRIS in clinical studies 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, KANUMA is the only product approved for the treatment of LAL-D and ANDEXXA is the only product approved as a reversal agent for patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. Many pharmaceutical and biotech companies have publicly announced intention to establish or develop rare disease programs that may be competitive with ours, including competing products to our C5 inhibitors, STRENSIQ, KANUMA and ANDEXXA. 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 and resources in preclinical testing, human clinical trials, product process development and 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 biologics and with specialized biotechnology firms in the U.S., 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, gMG and NMOSD (in additional to those products already approved by regulatory authorities), and we are aware of companies that have initiated or are planning to initiate studies for diseases we are also targeting (in some cases, these companies have clinical trial programs that are more advanced than our clinical trial programs for these diseases). In addition, in 2019 a SOLIRIS biosimilar was introduced in Russia (which was sold by Generium) and we experienced a significant decrease in sales of SOLIRIS following the introduction of Generium's biosimilar. We are aware that other 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.

Brexit

In June 2016, the U.K. electorate voted in a referendum to voluntarily depart from the E.U., known as Brexit. Following the formation of a majority Conservative government in December 2019, the U.K. approved the Withdrawal Agreement and left the European Union (Brexit) on January 31, 2020. The U.K. and the E.U., however, agreed to keep many things the same until December 31, 2020, to allow enough time to agree to the terms of a new trade deal, which was finalized on December 24, 2020.

The potential impact on our results of operations and liquidity resulting from Brexit still remains unclear. The actual effects of Brexit will depend upon many factors and significant uncertainty remains with respect to the implementation of the final terms of the new trade agreement. The final terms of the implementation of the trade pact may impact certain of our commercial and general business operations in the U.K. and the E.U., including the approval and supply of our products. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations, including with respect to pharmaceuticals and biologics (as well as tax and free trade agreements, intellectual property rights, supply chain logistics, environmental, health and safety laws and regulations and employment laws), as the U.K. determines which E.U. laws to replace or replicate.

Compliance with any resulting regulatory mandates may prove challenging and the macroeconomic impact on our sales and consolidated results of operations from these developments remains unknown. We do not, however, expect Brexit to have a material impact on our consolidated results of operations as the U.K. does not account for a material component of our annual revenues.

We cannot predict the direction Brexit-related developments will take nor the impact of those developments on our European operations and the economies of the markets where we operate.

Human Capital

Alexion's employees are guided by our mission to transform the lives of people affected by rare diseases and devastating conditions by continuously innovating and creating meaningful value in all that we do. Our employees are further guided by our code of conduct and our culture values to serve patients, act with integrity, empower people, and innovate for solutions.

Employees:

As of December 31, 2020, we had 3,837 full-time, world-wide employees, of which 1,687 were engaged in research, product development, manufacturing and clinical development, 1,502 in sales and marketing, and 648 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.

Talent Acquisition and Development:

Alexion's talent acquisition goal is to attract, retain, and develop the highest quality talent. Alexion employees provide diverse backgrounds and ideas, are trained to operate and act in their work capacity at the highest standards of ethics and integrity, and are dedicated to achieve the highest level of medical innovation and to redefine what it means to live with a rare disease or devastating condition. To support our talent acquisition, our human resources programs are designed to develop talent to prepare them for leadership positions in the future; reward employees through an industry leading benefits program, including competitive pay, incentive compensation, and an equity program; enhance our culture through efforts aimed at making the workplace more engaging and inclusive; and retain and develop talent that embody our culture values.

Diversity, Inclusion, and Belonging:

Diversity, inclusion, and belonging (DI&B) is a key strategic priority for Alexion. At Alexion, we believe that diversity is fact, inclusion is an act, and belonging is a pact. Our DI&B vision does not stop with diversity and inclusion. We strive to foster a true sense of belonging, which is designed to ensure that every person feels included. During 2020, Alexion established a Chief Diversity Officer role reporting into the CEO and a DI&B function as an important next step in our continued efforts to cultivate diversity, inclusion and a unique sense of belonging. The newly

established function defines and drives our DI&B strategy that is designed to accelerate Alexion's efforts to embed diversity across the company, spanning employee programs, external partnerships, corporate social responsibility initiatives, culture efforts and patient programs.

COVID-19 Pandemic:

We are operating at a unique time, as we face a serious public safety crisis as a result of the COVID-19 virus. We remain focused on continuing to serve the patients who rely on us, as well as protecting the health and safety of our employees and the communities in which we live and work. In early March 2020, we activated a task force designed to assess, mitigate and manage the risks related to COVID-19 to avoid or minimize business disruption, including safeguarding of our facilities, and to ensure the safety and sense of security for our staff. In early March 2020, Alexion closed all sites to non-essential employees and the Company has suspended all travel indefinitely. In early June 2020, Alexion gradually allowed re-entry to certain sites in some geographies through a pilot program, including Switzerland, Germany, Australia, and Japan in accordance with local government laws, regulations and restrictions and our own safety procedures and checklists. In September 2020, we extended our global guidance to employees to strongly encourage working remotely until at least July 2021, while offering limited access to physical sites through pilot programs. Office sites are being reconfigured to maintain physical distancing and we expect to adopt and implement additional precautions commensurate with any expansion of employees returning to worksites. To date, our remote working arrangements have not significantly affected our ability to maintain critical business operations.

Information about our Executive Officers

The executive officers of the Company and their respective ages and positions as of February 8, 2021 are as follows:

Name	Position with Alexion	Age
Ludwig Hantson, Ph.D.	Chief Executive Officer	58
Aradhana Sarin, M.D.	Executive Vice President, Chief Financial Officer	46
Tanisha Carino, Ph.D.	Executive Vice President, Chief Corporate Affairs Officer	46
Ellen Chiniara, J.D.	Executive Vice President, Chief Legal Officer and Corporate Secretary	62
Indrani Franchini, J.D.	Executive Vice President, Chief Compliance Officer	49
Brian Goff	Executive Vice President, Chief Commercial and Global Operations Officer	51
John Orloff, M.D.	Executive Vice President, Head of Research and Development	63

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

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

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

Aradhana Sarin, M.D., is Executive Vice President, Chief Financial Officer of Alexion. In this role, she is responsible for overseeing global financial management, treasury, internal audit, corporate strategy, business development, investor relations, security activities, and business operations, including corporate planning, at Alexion.

Dr. Sarin joined Alexion in November 2017 to drive strategy and business development, and she served as Alexion's Chief Business and Strategy Officer prior to becoming the Chief Financial Officer in October 2019. She brings to Alexion more than 20 years of professional experience at global financial institutions. Dr. Sarin has extensive knowledge of global healthcare systems, and has closed more than 100 transactions across M&A, equity and debt financing transactions. Prior to joining Alexion, Dr. Sarin was Managing Director of Healthcare Corporate & Investment Banking at Citi Global Banking (which she joined in 2010), focusing on clients in the life sciences and biopharmaceutical sectors. Before this, she served as Managing Director of Healthcare Investment Banking at UBS, and worked at JP Morgan in the M&A Advisory and Healthcare groups focusing on transaction execution. Before her banking career, Dr. Sarin trained as a medical doctor in India and spent two years practicing in both India and Africa.

Dr. Sarin completed her medical training at the University of Delhi and received her MBA from Stanford Business School.

Tanisha Carino, Ph.D., is Executive Vice President, Chief Corporate Affairs Officer of Alexion. In this role, Dr. Carino is responsible for global government relations, policy and communications.

Prior to joining Alexion, Dr. Carino served as Executive Director of FasterCures, a Center of the Milken Institute, a nonpartisan think tank whose mission is working with global government, philanthropic, and business leaders to accelerate treatments to patients. Prior to leading FasterCures, Dr. Carino was an executive at GlaxoSmithKline where she led the United States policy function, and spent over a decade with Avalere Health, a strategic advisory services organization, where she worked with senior leaders of life sciences companies to maximize opportunities and mitigate challenges related to biomedical research and patient access. Dr. Carino also worked in the U.S. Medicare program to improve access for its beneficiaries and support the development of real-world evidence.

Dr. Carino is a Fulbright Fellow, earned her Ph.D. in health policy from Johns Hopkins University, and is associate faculty at the Johns Hopkins Bloomberg School of Public Health. Dr. Carino also serves on the Governing Board of the Patient-Centered Outcomes Research Institute (PCORI) and the Board of Directors of the National Health Council.

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

Ms. Chiniara previously served as Executive Vice President, General Counsel of Alexion until September 2019. 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 Graduate School in Fukuoka, Japan.

Brian Goff is Executive Vice President, Chief Commercial and Global Operations Officer of Alexion. Mr. Goff leads the global commercial and operations teams, which includes 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 30-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 an MBA from the Wharton School at the University of Pennsylvania and a Bachelor of Arts from Skidmore College.

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.

Risk Factors Summary:

The following is a summary of the principal risks that could adversely affect our business, operations and financial results.

Risks Related to our Proposed Acquisition by AstraZeneca

- Our proposed acquisition by AstraZeneca is subject to various closing conditions and there can be no assurances as to whether and when it may be completed.
- Failure to complete the merger could negatively impact our stock price and future business and financial results.
- If the merger agreement is terminated, we may be obligated to pay a termination fee to AstraZeneca.
- Because the exchange ratio is fixed and the market price of shares of AstraZeneca stock fluctuates our stockholders cannot be sure of the value of the merger consideration they will receive in the merger.
- While the merger is pending, we are subject to business uncertainties and contractual restrictions that could materially adversely affect our operating results or result in a loss of employees, customers, collaborators or suppliers.
- Lawsuits may be filed against us and/or AstraZeneca challenging the merger. An adverse ruling in any such lawsuit may delay or prevent the proposed acquisition from being completed.
- We may have difficulty attracting, motivating and retaining executives and other key employees in light of the merger.

Risks Related to Revenue Concentration and Conversion

- If we are unable to continue to increase revenues from sales of our C5 complement inhibitors, our business would be materially harmed.
- If we are unable to achieve our conversion objectives of patients from SOLIRIS to ULTOMIRIS, our business may be harmed. In addition, even if we are successful, due to the pricing of ULTOMIRIS, our revenues may decrease unless we are able to increase the number of patients using our C5 inhibitors.

Risks Related to the COVID-19 Pandemic

- Our business may be adversely affected by the ongoing COVID-19 pandemic.

Risks Related to Pricing and Reimbursement

- Sales of our products depend on reimbursement by payers and these payers are subject to pressures to contain costs.

Risks Related to Intellectual Property

- If we cannot obtain new patents, maintain our existing patents and protect our trade secrets and other intellectual property, our business and competitive position may be harmed.
- If we are found to be infringing third party patents, we may be forced to pay damages and/or obtain a license. If we cannot obtain a license, we may be prevented from the manufacture, sale or development of our products or product candidates.
- It is possible that we could lose market exclusivity for a product earlier than expected.

Risks Related to Our Products and Product Candidates

- Our future commercial success depends on gaining regulatory approval for new products and obtaining approvals for existing products for new indications.
- Our products and product candidates target diseases with small patient populations and we may not be effective at identifying patients.
- We may not be able to gain or maintain market acceptance of our products among the medical community, patients or payers.
- If our products harm patients, or are perceived to harm patients, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

- We anticipate that we will face increased competition from companies that will enter into the markets we currently serve and as we enter new markets.

Risks Related to Business Operations

- We rely on a limited number of facilities to produce our products and manufacturing issues at these facilities could cause product shortages, interrupt commercialization of our products, disrupt or delay our clinical trials or regulatory approvals, and adversely affect our business.
- We rely on a limited number of providers for our raw materials and supply chain services.
- Counterfeit versions of our products could result in significant harm to patients, reduced sales of our products and harm to our reputation.
- If we are unable to establish and maintain effective sales, marketing and distribution capabilities, we may be unable to successfully commercialize our products.
- Our efforts to expand our business and product offerings through acquisitions may not be successful.
- The acquired business of Portola may underperform relative to our expectations, and we may not be able to integrate the business and achieve anticipated synergies.
- In order to support potential growth of the business, we will be required to make significant investments in our business operations.
- Completion of preclinical studies or clinical trials does not guarantee advancement of development, regulatory approval or successful commercialization.
- Our clinical studies may be costly and lengthy, and there are many reasons why drug testing could be delayed or terminated.
- We expect our operating results to fluctuate.
- We cannot guarantee that we will achieve our financial goals, including our ability to maintain profitability in the future.
- 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.
- We may not achieve the expected benefits of our current and future restructuring plans and restructurings may adversely affect our business.
- If we fail to satisfy our debt service obligations or our contingent obligations, we may be unable to commercialize our products or continue or complete our product development.
- We may not be able to access the capital and credit markets on terms that are favorable to us or at all
- We have incurred significant impairment charges, and may continue to incur such charges in the future and such amounts may be material.
- 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 financial results and position.
- Our sales and operations are subject to risks relating to our international business.
- Our business involves environmental risks and potential exposure to environmental liabilities.
- Currency fluctuations and changes in exchange rates could adversely affect our revenue, increase our costs and negatively affect our profitability.

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 could lose our approvals to market our products.
- Our product candidates require extensive clinical testing and failure to satisfy regulatory requirements may prevent us from being able to market our products and limit our ability to grow our business and diversify our revenue.
- If we fail to comply with applicable healthcare laws and regulations we may be subject to investigations and civil or criminal penalties and our business could be adversely affected.
- Our business could be adversely affected by litigation, regulatory enforcement actions and government investigations.
- Changes in healthcare laws and regulations, as well as changes in healthcare policy, may affect coverage and reimbursement of our products and these changes could adversely affect our business and financial condition.
- If we fail to comply with our reporting and payment obligations under governmental

pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines.

- 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.
- We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.
- Security breaches, cyber-attacks or other disruptions could expose us to liability and affect our business and reputation.
- Negative public opinion of recombinant and transgenic products, genetically modified products and animals may damage public perception of our KANUMA product.

Risks Related to Our Common Stock

- Our stock price is volatile.
- 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 our current management.
- The exclusive forum provision in our bylaws could limit our stockholders' ability to obtain an alternate judicial forum for disputes with us.

Risk Factors:

Risks Related to our Proposed Acquisition by AstraZeneca

Our proposed acquisition by AstraZeneca is subject to various closing conditions, including regulatory and stockholder approvals as well as other uncertainties, and there can be no assurances as to whether and when it may be completed.

On December 12, 2020, we entered into an Agreement and Plan of Merger (Merger Agreement), with AstraZeneca, Delta Omega Sub Holdings Inc., a Delaware corporation and a wholly owned subsidiary of AstraZeneca (Bidco), Delta Omega Sub Holdings Inc. 1, a Delaware corporation and a direct wholly owned subsidiary of Bidco (Merger Sub I) and Delta Omega Sub Holdings LLC 2, a Delaware limited liability company and a direct wholly owned subsidiary of Bidco (Merger Sub II). Under the terms and subject to the conditions set forth in the Merger Agreement, Merger Sub I will merge with and into Alexion (the First Merger) with Alexion surviving the First Merger as a wholly-owned subsidiary of Bidco and, immediately following the effective time of the First Merger (the Effective Time), Alexion will merge with and into Merger Sub II (the Second Merger and, together with the First Merger, the "Mergers"), with Merger Sub II surviving the Second Merger as a wholly owned subsidiary of Bidco and an indirect wholly owned subsidiary of AstraZeneca. Upon completion of the Mergers, each outstanding share of Alexion common stock, other than certain excluded shares (as described forth in the Merger Agreement) and shares held by stockholders who properly exercise their appraisal rights under Delaware law, will automatically be canceled and converted into the right to receive (1) 2.1243 American depositary shares of AstraZeneca (or, at the election of the holder thereof, a number of ordinary shares of AstraZeneca equal to the number of underlying ordinary shares represented by such American depositary shares) and (2) $60.00 in cash, without interest (the Merger Consideration).

Completion of the Mergers is subject to customary closing conditions, and it is possible that such conditions may prevent, delay or otherwise materially adversely affect the completion of the Mergers. These conditions include, among other things: (1) the adoption of the Merger Agreement by Alexion's stockholders (2) approval of the transactions contemplated by the Merger Agreement by AstraZeneca's shareholders; (3) the absence of any law or order prohibiting the consummation of the Mergers; (4) AstraZeneca's registration statement on Form F-4 having been declared effective by the Securities and Exchange Commission; (5) AstraZeneca's shareholder circular (or, if required, prospectus) having been approved by the U.K. Financial Conduct Authority; (6) the American depository shares of AstraZeneca issuable in the Mergers (and the ordinary shares of AstraZeneca represented thereby) having been approved for listing on the Nasdaq; (7) the expiration or early termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ("HSR Act"), as amended, and the approval of the Mergers under the antitrust and foreign investment laws of other specified jurisdictions; (8) accuracy of the other party's representations and warranties, subject to certain materiality standards set forth in the Merger Agreement and (9) compliance by the other party in all material respects with such other party's obligations under the Merger Agreement.

The governmental authorities from which authorizations under antitrust and foreign investment laws, including the HSR Act, are required have broad discretion in administering the governing laws and regulations, and may take into account various facts and circumstances in their consideration of the Mergers, including other potential transactions in the pharmaceutical industry or other industries. These governmental authorities may initiate proceedings

seeking to prevent, or otherwise seek to prevent, the Mergers. As a condition to authorization of the Mergers or related transactions, these governmental authorities also may impose requirements, limitations or costs, require divestitures or place restrictions on the conduct of AstraZeneca's business after completion of the Mergers. Under the terms of the Merger Agreement, the parties have agreed to use their respective reasonable best efforts to complete the Mergers as promptly as reasonably practicable, including in obtaining each third party consent or regulatory approval necessary, proper or advisable to complete the Mergers, and AstraZeneca has agreed to (1) propose, negotiate, commit to, or effect any divestiture, (2) terminate, unwind, divest or assign, subcontract or otherwise secure substitute parties for relationships, ventures, and contractual or commercial rights or obligations, and (3) take any such other remedial action, in each case to permit the closing of the Mergers to occur as promptly as reasonably practicable.

We can provide no assurance that all required consents and approvals will be obtained or that all closing conditions will otherwise be satisfied (or waived, if applicable), and, if all required consents and approvals are obtained and all closing conditions are satisfied (or waived, if applicable), we can provide no assurance as to the terms, conditions and timing of such consents and approvals or the timing of the completion of the Mergers. Many of the conditions to completion of the Mergers are not within either our or AstraZeneca's control, and neither company can predict when or if these conditions will be satisfied (or waived, if applicable). Any delay in completing the Mergers could cause us not to realize some or all of the benefits that we expect to achieve if the Mergers are successfully completed within its expected timeframe.

Failure to complete the Mergers could negatively impact our stock price and future business and financial results.

If the Mergers are not completed for any reason, including as a result of our stockholders failing to adopt the Merger Agreement or AstraZeneca shareholders failing to approve the transactions contemplated by the Merger Agreement, we will remain an independent public company. Our ongoing business may be materially and adversely affected and we would be subject to a number of risks, including the following:

- we may experience negative reactions from the financial markets, including negative impacts on trading prices of our common stock, and from our customers, collaborators, suppliers, regulators and employees;
- we may be required to pay AstraZeneca a termination fee of $1,180.0 if the Merger Agreement is terminated under certain circumstances, including in the event Alexion's board of directors changes its recommendation in favor of the Mergers or if Alexion terminates the Merger Agreement in order to enter into an agreement providing for a superior proposal, and $270.0 if the Merger Agreement is terminated because the Mergers are not adopted by Alexion stockholders;
- the Merger Agreement places certain restrictions on the conduct of our business prior to completion of the Mergers, and such restrictions, the waiver of which is subject to the consent of AstraZeneca, may prevent us from making certain acquisitions, entering into or amending certain contracts, taking certain other specified actions or otherwise pursuing business opportunities during the pendency of the Mergers that we would have made, taken or pursued if these restrictions were not in place; and
- matters relating to the Mergers (including integration planning) will require substantial commitments of time and resources by our management and the expenditure of significant funds in the form of fees and expenses, which would otherwise have been devoted to day-to-day operations and other opportunities that may have been beneficial to us as an independent company.

In addition, we could be subject to litigation related to any failure to complete the Mergers or related to any proceeding to specifically enforce our performance obligations under the Merger Agreement.

If any of these risks materialize, they may materially and adversely affect our business, financial condition, financial results and stock prices.

If the Merger Agreement is terminated, we may, under certain circumstances, be obligated to pay a termination fee to AstraZeneca.

If the Merger Agreement is terminated, in certain circumstances, including in the event Alexion's board of directors changes its recommendation in favor of the Mergers or if Alexion terminates the Merger Agreement in order to enter into an agreement providing for a superior proposal, we would be required to pay a termination fee of $1,180.0 to AstraZeneca. In addition, we would be required to pay a termination fee of $270.0 if the Merger Agreement is terminated because the Mergers are not adopted by Alexion stockholders. If the Merger Agreement is terminated under such circumstances, the termination fee we may be required to pay under the Merger Agreement may require us to use available cash that would have otherwise been available for general

corporate purposes and other uses. For these and other reasons, termination of the Merger Agreement could materially adversely affect our business operations and financial results, which in turn would materially and adversely affect the price of our common stock.

Because the exchange ratio is fixed and the market price of shares of AstraZeneca stock has fluctuated and will continue to fluctuate, our stockholders cannot be sure of the value of the Merger Consideration they will receive in the Mergers.

Upon completion of the Mergers, each share of our common stock outstanding immediately prior to the effective time of the Merger will be converted into the right to receive $60.00 in cash without interest thereon and 2.1243 American depositary shares of AstraZeneca (or, at the election of the holder thereof, a number of ordinary shares of AstraZeneca equal to the number of underlying ordinary shares represented by such American depositary shares). Because the exchange ratio of 2.1243 American depositary shares of AstraZeneca is fixed, the value of the share consideration will depend on the market price of shares of American depository shares of AstraZeneca at the time the Mergers are completed. The market price of American depositary shares of AstraZeneca has fluctuated since the date of the announcement of the Mergers and will continue to fluctuate from the date of this Annual Report on Form 10-K until the date the Mergers are completed, which could occur a considerable amount of time after the date hereof. AstraZeneca's American depository share price changes may result from a variety of factors, including, among others, general market and economic conditions, changes in AstraZeneca's and Alexion's respective businesses, operations and prospects, risks inherent in their respective businesses, changes in market assessments of the likelihood that the Mergers will be completed and/or the value that may be generated by the Mergers, and changes with respect to expectations regarding the timing of the Mergers and regulatory considerations. Many of these factors are beyond our control.

While the Mergers are pending, we are subject to business uncertainties and contractual restrictions that could materially adversely affect our operating results, financial position and/or cash flows or result in a loss of employees, customers, collaborators or suppliers.

The Merger Agreement includes restrictions on the conduct of our business prior to the earlier of the completion of the Mergers or termination of the Merger Agreement, generally requiring us to use commercially reasonable efforts to conduct our business in all material respects in the ordinary course. Without limiting the generality of the foregoing, we are subject to a variety of specified restrictions. Unless we obtain AstraZeneca's prior written consent (which consent may not be unreasonably withheld, conditioned or delayed) and except (i) as required or expressly contemplated by the Merger Agreement, (ii) as prohibited or required by applicable law or (iii) as set forth in the confidential disclosure schedule delivered by Alexion to AstraZeneca, we may not, among other things and subject to certain exceptions and aggregate limitations, incur additional indebtedness, issue additional shares of our common stock outside of our equity incentive plans, repurchase our common stock, pay dividends, acquire assets, securities or property, dispose of businesses or assets, enter into material contracts or make certain additional capital expenditures. We may find that these and other contractual restrictions in the Merger Agreement delay or prevent us from responding, or limit our ability to respond, effectively to competitive pressures, industry developments and future business opportunities that may arise during such period, even if our management believes they may be advisable. The pendency of the Mergers may also divert management's attention and our resources from ongoing business and operations.

Our employees, customers, collaborators and suppliers may experience uncertainties about the effects of the Mergers. It is possible that some customers, collaborators, suppliers and other parties with whom we have a business relationship may delay or defer certain business decisions or might decide to seek to terminate, change or renegotiate their relationship with us as a result of the Mergers. Similarly, current and prospective employees may experience uncertainty about their future roles with us following completion of the Mergers, which may materially adversely affect our ability to attract and retain key employees. If any of these effects were to occur, it could materially and adversely impact our operating results, financial position and/or cash flows and/or our stock price.

Lawsuits may be filed against us and/or AstraZeneca challenging the transactions contemplated by the Merger Agreement. An adverse ruling in any such lawsuit may delay or prevent the proposed acquisition from being completed.

Lawsuits arising out of or relating to the Merger Agreement, AstraZeneca's registration statement on Form F-4 (which will include a document that serves as a prospectus of AstraZeneca and a proxy statement of Alexion) and/or the proposed acquisition of us by AstraZeneca may be filed in the future. One of the conditions to completion of the Mergers is the absence of any injunction or other order being in effect that prohibits completion of the Mergers. Accordingly, if a plaintiff is successful in obtaining an injunction, then such order may prevent the proposed acquisition from being completed, or from being completed within the expected timeframe.

We may have difficulty attracting, motivating and retaining executives and other key employees in light of the Mergers.

Uncertainty about the effect of the Mergers on our employees may have an adverse effect on our business. This uncertainty may impair our ability to attract, retain and motivate key personnel. Employee retention may be particularly challenging during the pendency of the Mergers, as our employees may experience uncertainty about their future roles in the combined business. No assurance can be given that we will be able to attract or retain key employees to the same extent that we have been able to attract or retain employees in the past.

Risks Related to Revenue Concentration and Conversion

We depend on revenue from sales of our C5 complement inhibitors and, if we are unable to continue to increase revenues from sales of our C5 complement inhibitors, our business would be materially harmed and our future operating results may be adversely impacted.

Since 2007, our revenue has depended primarily on the sales of SOLIRIS, a C5 complement inhibitor with a 2-week dosing schedule. In December 2018, we obtained our first regulatory approval in the U.S. to sell ULTOMIRIS, a long-acting C5 complement inhibitor, with an 8-week dosing schedule (and in 2020 we obtained approval in the U.S. and Europe for a 100mg/mL formulation of ULTOMIRIS). Our C5 complement inhibitors accounted for 84.7% of our total revenues for the fiscal year ended December 31, 2020. Unless we are able to develop or acquire and commercialize new products beyond these C5 complement inhibitors, and/or materially increase sales of STRENSIQ, KANUMA and ANDEXXA® (our other approved products), we will remain dependent on sales of SOLIRIS and ULTOMIRIS as a source of our revenue. We expect our revenues for 2021 will continue to depend on our ability to sell our C5 complement inhibitors.

The commercial success of our C5 complement inhibitors and our ability to generate revenue depends on several factors, including: the safety and efficacy of our C5 complement inhibitors; coverage or reimbursement by government or third-party payers for our C5 complement inhibitors; pricing for our complement inhibitors; the analysis by doctors, payers and patients of the cost of our C5 complement inhibitors relative to the perceived benefits; manufacturing and uninterrupted supply; the introduction and success of competing products (including novel products and biosimilars to SOLIRIS); the size of patient populations and the number of patients diagnosed who may be treated with our C5 complement inhibitors; the impact of legal, administrative, regulatory or legislative developments that impact the price or use of C5 complement inhibitors; and our ability to develop, obtain regulatory approval for and commercialize our C5 complement inhibitors for new indications. Any of these or other factors may cause revenues from sales of our C5 complement inhibitors to decrease, which would harm our business results.

While SOLIRIS and ULTOMIRIS are studied for indications beyond those currently approved by regulatory authorities and ULTOMIRIS is being studied for subcutaneous administration, there is no guarantee that we can obtain regulatory approval or achieve any commercial sales of SOLIRIS or ULTOMIRIS for such other indications or for subcutaneous administration of ULTOMIRIS. Nor can we guarantee that, even if regulatory approval is obtained for such additional indications and routes of administration, physicians and patients will accept SOLIRIS or ULTOMIRIS as a treatment for such indications or means of administration, or that payers will pay for or reimburse the costs of these therapies.

If we are not able to maintain revenues from sales of SOLIRIS and ULTOMIRIS, or such revenues decrease, our operating results would be negatively impacted and our ability to fund research and development, commercialize or acquire new products would be harmed, which would limit our ability to diversify our revenue base and our stock price could be adversely affected. In addition, as a result of having our revenue concentrated in SOLIRIS and ULTOMIRIS, our future revenues and results of operations can be significantly harmed by, among other factors, the introduction of one or more biosimilar products or other competitive products that treat the same indications, adverse developments in the commercialization and sale of our C5 inhibitors or a change in reimbursement policies by payers for the C5 complement inhibitors. For example, a biosimilar has been introduced in Russia and a CD19-directed cytolytic antibody treatment and an IL-6R antibody, were both recently approved for NMOSD patients in the U.S. and certain other jurisdictions.

We aim to facilitate the conversion of patients from SOLIRIS to ULTOMIRIS. If we are unable to achieve our conversion objectives, our business may be harmed. In addition, even if we are successful, due to the pricing of ULTOMIRIS, our revenues may decrease unless we are able to increase the number of patients using our C5 inhibitors.

ULTOMIRIS has been approved for patients with PNH and aHUS in certain jurisdictions, including in the U.S., Europe and Japan.

One of our principal business objectives is to facilitate the conversion of PNH and aHUS patients from SOLIRIS to ULTOMIRIS. While clinical trials in PNH patients demonstrated that ULTOMIRIS is non-inferior to SOLIRIS at an 8 week dosing interval

(compared to a 2 week dosing interval for SOLIRIS), existing patients taking SOLIRIS for PNH or aHUS and their physicians may decline to switch to ULTOMIRIS. If we are unable to facilitate conversion to ULTOMIRIS prior to the loss of intellectual property or regulatory exclusivities for SOLIRIS, our future revenues could be adversely impacted if we were to face biosimilar competition for SOLIRIS. If ULTOMIRIS is approved as an indication for NMOSD and gMG, we will commence efforts to facilitate conversion of those SOLIRIS patients to ULTOMIRIS upon approval.

We have established what we believe is a globally sustainable and durable pricing strategy for ULTOMIRIS that is intended to facilitate such patient conversions (for example, in the U.S. the cost of current labeled maintenance therapy for ULTOMIRIS for adult PNH patients of average weight, represents on an annual basis an approximate 10% decrease relative to the cost of SOLIRIS). However, in the first year of PNH conversion to ULTOMIRIS, due to the loading doses required, there is an approximate 10% premium to the cost of SOLIRIS. We have also priced ULTOMIRIS for patients with aHUS in the U.S. at a cost relative to the cost of SOLIRIS for patients with aHUS in the U.S. that is approximately 30% less on an annual basis for an average adult patient on maintenance therapy (unlike PNH, the cost in the first year of aHUS conversion to ULTOMIRIS is approximately 20% less than the cost of SOLIRIS). If we achieve our goal of facilitating the conversion of patients from SOLIRIS (which accounted for approximately $4,064.2, or 67.0%, of our revenues in 2020) to ULTOMIRIS, due to the reduction in annual cost we anticipate that U.S. revenue attributable to each patient that converts from SOLIRIS to ULTOMIRIS will decrease on an annual basis. In addition, as a result of the decreased cost for ULTOMIRIS relative to SOLIRIS on a per patient basis, in order to maintain or increase C5 complement inhibitor revenues in the future as we succeed in converting patients from SOLIRIS to ULTOMIRIS, we must increase the total number of patients utilizing SOLIRIS, including gMG and NMOSD patients, and ULTOMIRIS.

Finally, as a result of patient conversion from SOLIRIS to ULTOMIRIS, we expect variability in our revenues in future quarters due to the extended ULTOMIRIS dosing interval and infusion timing which may result in either one or two infusions in a quarter.

Due to the decision to price ULTOMIRIS lower than SOLIRIS on an annual basis, we anticipate U.S. revenues will be unfavorably impacted by the lower annual cost per patient in maintenance years, with the impact more pronounced for aHUS due to the greater decrease in vials for aHUS ULTOMIRIS patients.

Risks Related to the COVID-19 Pandemic

Our business may be adversely affected by the ongoing COVID-19 pandemic.

Our business could be adversely affected by health epidemics in regions where we have operations, sales or other business activities, including regions where we have offices, manufacturing facilities, clinical trial sites and where our third party manufacturers, vendors and suppliers operate and where patients and potential patients are located. The outbreak of a novel strain of virus, which causes the disease called COVID-19, has evolved into a global pandemic. The ultimate impact of the COVID-19 pandemic on our business operations and financial results is highly uncertain and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, the ultimate geographic spread of the disease, future spikes in cases, additional or modified government actions, new information that will emerge concerning the severity and impact of the coronavirus and the actions taken to address its impact, among others.

In May 2020, we initiated a global Phase III study to investigate ULTOMIRIS in a subset of adults with COVID-19, who are hospitalized with severe COVID-19 requiring mechanical ventilation. In January 2021, we paused further enrollment in this study based on the recommendation of an independent data monitoring committee (IDMC), following review of data from a pre-specified interim analysis. The IDMC recommended that additional enrollment be paused, pending further analysis of the data, due to lack of efficacy when ULTOMIRIS was added to best supportive care, compared to best supportive care alone. At this time, we cannot guarantee that the further analysis of study data would cause us to commence additional enrollment in the trial.

As a result of the COVID-19 pandemic, we expect that we may experience disruptions that could severely impact our business and results of operations, including:

- Government and healthcare policies and federal, state, local or foreign regulations to address the COVID-19 pandemic may adversely affect our sales and revenue. Due to quarantines, travel restrictions, hospital policies and patient concerns regarding exposure to COVID-19, we have observed fewer patient/doctor interactions, we have also noted that the new patient productivity and initiation queue has decreased since the COVID-19 outbreak (particularly in our neurological indications) and our representatives are having fewer in-person visits with health care providers, including for infusion of our products which has adversely impacted our revenue growth in the current

year and may continue to affect our revenue growth in the future. A decrease in the demand of our products could cause our cost of goods sold to increase due to expiration of inventory on hand, an increase in manufacturing overhead allocated to inventory sold and other factors. Our net product sales could also be adversely impacted by the negative effects the COVID-19 pandemic has had on the global economy, which could result in (i) an increased number of patients utilizing our patient access programs to receive free drug due to loss of employer-based health insurance, or other factors impacting their ability to afford our medicines; and (ii) patients increasingly seeking Medicaid coverage for our products, which would lead to higher gross-to-net revenue reductions compared to commercial insurance providers. We are monitoring the impacts on our business of the growth in unemployment and loss of commercial insurance coverage and/or growth in Medicaid with higher discounts.

- Due to financial demands in addressing the COVID-19 pandemic, payors have requested and may continue to request extended credit terms, may extend payment dates beyond those experienced in the past, or may not be able to timely reimburse us for our products or at all, and such actions could have a material adverse impact on our cashflow from operations. Additionally, federal and state governments and foreign jurisdictions where we operate could increase tax rates to offset the economic impact and cost of addressing the COVID-19 pandemic. Any increase in such tax rates could have an adverse impact on our business and results of operations.
- We believe that the COVID-19 pandemic has had, and will likely continue to have, an impact on various aspects of our clinical programs and trials. For example, our Phase I trial for ALXN1720 are currently paused (for the second time) due to COVID-19. Patient dosing and study monitoring in other trials may be paused, delayed or temporarily halted (and clinical trial re-start schedules may be delayed beyond the dates we anticipated) due to changes in policies at various clinical sites and federal, state, local or foreign laws, rules and regulations, including quarantines or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of our clinical trials, or other reasons related to the COVID-19 pandemic. If the COVID-19 pandemic continues for an extended period of time, other aspects of our clinical trials may be adversely affected, delayed or interrupted, including, for example, site initiation, patient recruitment and enrollment, availability of clinical trial materials, and data analysis. Some patients and clinical investigators may not be able to comply with clinical trial protocols and patients may choose to withdraw from our studies, or we may choose to or be required to pause enrollment and/or patient dosing in our ongoing clinical trials in order to preserve health resources and protect trial participants. Any such disruption could negatively impact the results generated in the trial, the development of our pipeline programs and the timing and probability of paying milestones associated with prior acquisitions and active license agreements (which may lead to litigation over milestone payments).
- We currently utilize third parties to, among other things, manufacture our products and product candidates, supply raw materials and consumables, perform quality testing and provide supply chain services. We also manufacture certain of our products and product candidates and perform various services at our manufacturing facilities. If any of these processes or services are adversely impacted by the COVID-19 outbreak, our ability to manufacture and supply our products to patients or manufacture product candidates for our clinical trials and conduct our research and development operations may be materially affected. For example, if the U.S. government invokes the Defense Production Act, including as part of Operation Warp Speed, to redirect capacity at our third-party suppliers toward COVID-19 vaccine production or other pandemic relief efforts, it could delay manufacturing services by our suppliers and delay manufacture of our products and product candidates, negatively impact our ability to conduct clinical trials and maintain inventories of our products, any of which could have a material negative impact on our business and results of operations.
- The potential economic and financial impacts of the pandemic, including a deterioration in economic conditions that may negatively impact revenue and our liquidity, increase expenses and result in market capitalization declines, and disruption to our business, may result in the impairment of our long-lived and other assets, including goodwill, intangible assets and equity investments without readily

determinable fair values. The impairment of significant assets could have a material impact on our deferred tax assets and liabilities. In addition, any impairment charge would have a negative impact on our financial results in the quarter that the charge is taken, and such charge may be material in amount.

- In accordance with business continuity plans and for the safety of our employees, we have directed most of our personnel to work remotely and we have generally restricted on-site staff to only those personnel and contractors who perform essential activities that must be completed on-site. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber-security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations.
- While our essential R&D employees have been able to access our laboratory space, if employees and contractors conducting such activities were exposed to or contracted COVID-19, we may be required to restrict access to our laboratory space for an extended period of time as a result. Governmental authorities may also impose restrictions limiting access to our lab space. As a result, this could delay timely completion of preclinical and other R&D activities.
- Health regulatory agencies globally may experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and other foreign regulatory agencies may have slower response times or be under-resourced to continue to authorize and monitor our clinical trials or review regulatory submissions (or authorize the use of facilities for manufacturing and related services) and, as a result, review, inspection, and other timelines may be materially delayed.
- In addition, a recession or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business, the value of our common shares and the availability of credit to operate our business and execute business development transactions. As a result, we may face difficulties raising capital (if needed) through sales of our common shares, accessing credit to support our business development activities or other capital initiatives or such sales of common stock or credit may only be available on unfavorable terms.
- The trading prices for our common shares and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic and we expect this volatility may continue.

COVID-19, and the volatile regional and global economic conditions stemming from the pandemic, could also precipitate or aggravate the other risk factors discussed in this Annual Report on Form 10-K, which could materially adversely affect our business, financial condition, results of operations, liquidity, and stock price.

Risks Related to Pricing and Reimbursement

Sales of our products depend on reimbursement by payers and these payers are subject to pressures to contain costs.

Our commercial success depends on setting a price for our products that will enable us to obtain reimbursement at anticipated levels. Our products are significantly more expensive than traditional drug treatments and almost all patients require governmental payers and/or private third-party payers to pay all or a portion of the cost of our products. There is a significant trend in the health care industry by public and private payers to contain or reduce their costs, including by taking the following steps, among others: decreasing the portion of costs payers will cover, ceasing to provide adequate payment for certain products or not covering certain products at all. If payers implement any of the foregoing with respect to our products, it would have an adverse impact on our revenue and results of operations. We have, for example, recently experienced non-governmental payers removing our products from their formulary and, therefore, it was not available to certain beneficiaries.

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 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 health technology assessments (HTAs), which assess, among other things, how well a prescription drug works in relation

to its cost. Additionally, U.S. payers are increasingly considering new metrics, including HTAs, as the basis for reimbursement rates. If our products do not meet or surpass these metrics, these payers may not reimburse the use of our products or may reduce the rate of reimbursement for our products and as a result, revenue from such products may decrease. We have voluntarily elected to reduce prices or establish price caps with payers for certain products, which we believe provides value in the long term (but decreases revenue per patient).

In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement governmental controls on pharmaceutical pricing. Both the executive and legislative branches of the U.S. government have recently unveiled proposals to implement such controls. In late-2020, CMS issued an interim final rule to implement a Most Favored Nation (MFN) Model for certain included drugs and biological products payable under Medicare Part B. The MFN Model would gradually reduce Medicare Part B reimbursement for included products to their respective MFN price, which generally reflects the lowest price for a pharmaceutical product sold in certain economically-comparable member countries of the Organisation for Economic Co-operation and Development. SOLIRIS is one of 50 drugs and biological products included in the first performance year of the MFN Model. The MFN Model implementation was delayed as a result of certain litigation, but could have an impact on SOLIRIS revenue if implemented (for additional information on the MFN Model, see “Government Regulation – Pharmaceutical Pricing and Reimbursement” included in Part I, Item 1 of this Annual Report on Form 10-K). Among some of the additional proposals from the executive and legislative branches are: to allow Medicare to negotiate certain drug prices (and such prices would apply to the private market as well) (this measure was passed in the U.S. House of Representatives in late-2019), to move to a reimbursement regime that would establish pharmaceutical pricing by reference to a target price derived from the international price index, and to permit importation of medicines from other countries that have lower prices. Certain states have also proposed measures that are designed to control the costs of pharmaceuticals that they reimburse. If the U.S. (through the federal or state governments) were to move to a pricing system based on negotiated prices or to an international price index, such as the MFN Model (or similar model) that were to apply to our products, we expect that our revenues for sales in the U.S. would be lower, and potentially materially lower than if the current pricing program remained in place.

Other countries, including many European countries and Canada, have established pricing and reimbursement policies that contain costs by referencing the price of the same or similar products in other countries. In these instances, if coverage or the level of reimbursement is reduced, limited or eliminated in one or more countries, we may be unable to obtain or maintain anticipated pricing or reimbursement in other countries or in new markets. This may create the opportunity for third-party cross-border trade or influence our decision whether to sell a product, thus adversely affecting our geographic expansion plans and revenues. See Note 11, *Commitments and Contingencies* to the consolidated financial statements for information about our lawsuit against the Patented Medicine Prices Review Board (PMPRB) to establish that Alexion did not excessively price SOLIRIS in Canada, which uses reference pricing.

Due to the cost of our therapies, any potential increase in the number of patients receiving our products 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 (which may exclude one or more of our products);
- 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 treatment.

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 imposition or 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 treatments, consistent with applicable laws, regulations, and government guidance. Such organizations assist patients whose insurance coverage imposes high 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 or limited insurance coverage for drugs through related charitable purposes, consistent with applicable laws, regulations, and government guidance. 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.

In 2020, three customers accounted for 47.4% of our total revenues. If any one or more of these customers were to require significant discounts or rebates, or were to discontinue purchasing our products (due to cost or otherwise), our results of operations may be materially and adversely impacted.

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 and to prevent third parties from infringing on our rights.

We have procured patent rights, through both ownership and license, that cover our products and investigational compounds, and will likely apply for additional patent protections in the future. However, our patent applications may not result in the issuance 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, the European Patent Office in September 2019 rejected a patent application relating to the composition of matter for SOLIRIS; related patents were granted in the U.S. and Japan.

Even if a patent is issued, that is not conclusive as to its inventorship, scope, validity or enforceability and therefore that patent may not afford adequate (or any) protection for our products. On the basis of such inconclusiveness, third parties may challenge our patents, have done so 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 one of our European patents that relates to the formulation of SOLIRIS. Further, on August 30, 2019, the U.S. Patent and Trademark Office instituted inter partes review (IPR) of three of our patents that relate to SOLIRIS. In May 2020, we entered into a Confidential Settlement and License Agreement with Amgen to settle the three IPRs (Settlement Agreement). Pursuant to the Settlement Agreement, Alexion and Amgen have terminated each of the pending IPRs and, effective March 1, 2025 (or an earlier date in certain circumstances), Alexion grants to Amgen (and its affiliates and certain partners) a non-exclusive, royalty-free, license under U.S. patents and patent applications related to eculizumab and various aspects of the eculizumab product that Alexion currently markets and sells under the tradename SOLIRIS. We may enter into similar agreements in the future to grant or clarify certain rights of third-parties in connection with our intellectual property rights in SOLIRIS or other products or product candidates. In addition, under the settlement agreement with Amgen, if certain circumstances are satisfied, Amgen may have the right to market and sell an eculizumab product in the U.S. prior to March 2025.

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. 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. In addition, we may in the future enter into agreements similar to the agreement with Amgen that provides certain intellectual property rights to our marketed products or products in our pipeline.

We may finance or collaborate in research and development projects conducted by third parties, including government organizations, hospitals, universities or other educational or research institutions, or other for-profit companies. Such third parties may be unwilling to grant us certain rights to technology or products developed through such projects. Disputes may also arise as to the rights to technology or products developed in collaboration with such third parties.

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.

Some of the sensitive technology, techniques and proprietary compounds used in our business are protected as trade secrets. However, we may also rely on collaboration with, or discuss the potential for collaboration with, suppliers, outside scientists and other biopharmaceutical companies. Collaboration and discussion of potential collaboration or inadvertent disclosure of a trade secret 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 or developed in collaboration with third parties, 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. Chugai Pharmaceutical Co., Ltd. filed suits in the U.S. and Japan alleging that ULTOMIRIS infringes patents held by Chugai. See Note 11, *Commitments and Contingencies* to the footnotes to the consolidated financial statements. 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 we have invalidated the patents, obtained licenses, or expect to obtain licenses. However, with regard to others 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, which may be material in amount, and seek to prevent us from manufacturing, selling or developing our products (and we may be, in certain cases, prevented from initiating product launches in certain jurisdictions or required to withdraw the product from the market after it has been launched). Intellectual property disputes, such as those initiated by Chugai, can be costly and time consuming to defend and there is no guarantee that we would prevail in such lawsuit. If we cannot successfully defend against any infringement claims, we may seek to invalidate the patent or seek a license to the technology prior to or during legal actions in order to reduce the risks in connection with the product launches (or at a later time after product introduction) 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 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 it will decide any 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.

Market exclusivity for our products depends in large part on patent rights and certain regulatory forms of protection. As noted above, patent protection can be uncertain as to the validity, scope and enforceability of many issued patents. Absent relevant patent protection for a product, once regulatory exclusivity periods expire, biosimilar or generic versions of the product can be approved and marketed. For example, in 2019, a SOLIRIS biosimilar was approved in Russia for the treatment of patients with PNH and aHUS. We also believe that the manufacturer of a SOLIRIS biosimilar has commenced the process to obtain regulatory approval to market and sell a SOLIRIS biosimilar in Brazil and Turkey and, if approved, this biosimilar may compete with SOLIRIS in Brazil and Turkey.

The market exclusivity of our products may be impacted by competitive products that are either innovative, biosimilar or generic copies. In our industry, the risk of biosimilar or generic challenges has been increasing. 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 (SOLIRIS, ULTOMIRIS and ANDEXXA are each innovative biologics) on the basis of less extensive data than is required for a full biologic license application (and there are similar pathways for generic copies of small molecule therapies (the Factor D therapies (ALXN2040 and ALXN2050) acquired in connection with the Achillion transaction are, for example, small molecules)). The law provides a mechanism to challenge the patents that protect an innovator's products. 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, would likely result in a decrease in volume of sales of our products, as well as a decrease in prices and lower margins for our products. In addition, approval of a biosimilar that is a substitute 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 2020), it may also have a material impact on ULTOMIRIS revenue and margins and the ability of ULTOMIRIS to gain market acceptance.

Our other products and product candidates in development and trials are also at risk from biosimilars and generic drugs. Other than SOLIRIS for the treatment of gMG and NMOSD and SOLIRIS and ULTOMIRIS as a treatment for PNH and aHUS, 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 or other therapy (such as the two non-C5 therapies approved by certain regulatory authorities, including the FDA, as a treatment for NMOSD), 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 Products and Product Candidates

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

We invest significant amounts in acquiring new products and technologies and advancing our existing product candidates and technologies. Our success and revenue growth and diversification will depend in part on our identification, acquisition (including licenses from or collaborations with 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 is very expensive, takes significant time and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. For example, we recently paused enrollment in our ULTOMIRIS trial for certain COVID-19 patients due to lack of efficacy and in 2020 we terminated our agreement to co-develop ABY-039 with Affibody and determined not to exercise the co-development option agreement with Stealth BioTherapeutics Corp., in each case due to results of clinical trials. In addition, our recent investment and acquisition activities focused on new technologies with which we have limited experience, including a Factor Xa reversal agent and antibody therapeutics

targeting the neonatal Fc receptor, which may make the development, approval and commercialization of such potential products challenging for us.

Our ability to maintain or grow and diversify 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, for new routes of administration (subcutaneous delivery) and in new jurisdictions, obtain marketing approval for STRENSIQ, KANUMA and ANDEXXA in additional territories, obtain approval for different dosing regimens (or expansion of indications included in the product label) or acquire or license products and technologies from third parties.

Even if we are successful in developing new products or addressing new indications, we cannot market any of those products unless and until we obtain all required regulatory approvals in each jurisdiction where we plan to sell these therapies. We must also maintain all such regulatory approvals for the period of time that we sell the product in each such jurisdiction. Our failure to obtain, or a delay in obtaining, approval or if we fail to maintain approvals once obtained, will prevent us from selling products and generating revenues for those products in such jurisdiction where we do not hold such approvals.

Our products and product candidates target diseases and conditions with small patient populations and we may not be effective at identifying patients.

The therapies that we have developed, acquired and that are in our product pipeline and in preclinical development target diseases and conditions that have small patient populations that have not been definitively determined. Further, in many cases there are either no or limited diagnostic tools for the indications we treat or may treat in the future. 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 that will benefit from our therapies, 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, they may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify, all of which may adversely affect our ability to grow and diversify revenue and 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, payers and others. Although we have received regulatory approval for certain of our products in certain territories (and may receive approvals for additional products or in additional jurisdictions), such approvals do not guarantee future revenue. 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, biosimilars and generics;
- perceived safety of our products
- demonstrated clinical safety and efficacy compared to other drugs;
- perceived benefits relative to cost and/ or evaluations in HTAs (or similar assessments);
- 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 and ULTOMIRIS for patients who present in acute treatment settings may depend on how quickly SOLIRIS or ULTOMIRIS can be delivered to the hospital or clinic, and our distribution methods may not be sufficient to satisfy this need. In addition, 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 (and the same may occur in connection with the use of ULTOMIRIS for aHUS). 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 may cause our SOLIRIS or ULTOMIRIS 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 and small molecule therapies 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 generally 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.

Under pharmacovigilance guidelines, we are required to timely report any adverse events that any patient using our products experiences, as well as any clinical evaluations of outcomes in the post-marketing setting. This information is required to be reported to appropriate regulatory agencies in accordance with relevant regulations and, 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 on Alexion by regulators). In the event any new risks or adverse effects are discovered as 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 or require changes to labeling or reformulation of the products (or take other actions that may adversely impact sales of such products).

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of our products, it could significantly reduce demand for the product, harm our reputation, result in product withdrawals, recalls, delays or revocations of regulatory approvals or require us to take actions that could negatively affect sales and operating results, including conducting additional clinical trials and safety studies, making changes in labeling, reformulating our products or making changes and obtaining new approvals for our and our suppliers' manufacturing facilities. 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).

There are also 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, especially for those patients that present in acute treatment settings, 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). In addition, ANDEXXA has been associated with thrombolic risks, ischemic risks, cardiac arrest and sudden death. 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. In addition, many patients who use our products are already very ill and may suffer adverse events, including death, for reasons that may or may not be related to our products. 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 will 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 therapies for certain indications they treat. For example, SOLIRIS and ULTOMIRIS are the only approved treatments for PNH and aHUS in the U.S., Europe and Japan. We expect that SOLIRIS and ULTOMIRIS may compete with new drugs and biosimilars currently in development. Several companies are developing other therapies to treat PNH, aHUS, gMG and NMOSD, and other pharmaceutical companies have publicly stated that they are developing and intend to commercialize a SOLIRIS biosimilar.

In 2020, the FDA and certain other foreign regulatory authorities have approved therapies developed by third parties for the treatment of NMOSD in adult patients who are anti-aquaporin-4 antibody positive. The introduction of these and other competitive products may negatively impact our business, including our revenue and profitability. In addition, following the introduction of a SOLIRIS biosimilar in 2019 in Russia for the treatment of PNH and aHUS, we experienced a decrease in revenue from sales of SOLIRIS and expect that Russia will account for a minor portion, if any, of future SOLIRIS revenue as a result of this competitive product. We also believe that the manufacturer of a SOLIRIS biosimilar has commenced the process to obtain regulatory approval to market and sell a SOLIRIS biosimilar in Brazil and Turkey and, if approved, this biosimilar may compete with SOLIRIS in Brazil and Turkey and, like Russia, have an adverse impact on SOLIRIS revenues in Brazil and Turkey. STRENSIQ, KANUMA and ANDEXXA may also experience competition in the future. We are also aware of companies that have initiated or are planning to initiate studies for diseases and conditions 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 and conditions that we also target with approved therapies.

Some of our competitors and future competitors may have significantly greater financial, technical and marketing resources than us and may commercialize competitive products that are cheaper, more effective, safer, have less frequent dosing schedules, or are easier and quicker 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 (or generics that may be approved that compete with our small molecule therapies), may significantly reduce both the price that we receive for our 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 2020 revenue was attributable to SOLIRIS, one or more competitive novel products or biosimilars 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 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 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 and the production of such 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, product recalls and regulatory actions. 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. These manufacturing challenges are coupled with the fact that we have limited experience manufacturing commercial quantities of certain of our products (so we or our third party manufacturers may have limited previous experience resolving any issues in connection with the manufacture of certain of our products and any issues may take significant time to remediate or we may be unable to solve any manufacturing problems). In addition, with our acquisition of Achillion, we also have small molecules in clinical trials and we are planning future clinical trials in new indications and we expect that manufacture of these therapies and compliance with cGMP will pose similar challenges and we have limited

experience manufacturing small molecules for clinical trials and for commercial sales.

If we and/or our third party manufacturers (including those involved in drug substance, drug product, and finished product) and other suppliers fail to meet the highly technical requirements/specifications of manufacturing our biologic and small molecule 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. For example, we rely on Lonza owned and operated facilities for the production of a significant portion of our products, including ANDEXXA which we recently acquired, and Lonza has undertaken the construction and operation of new facilities to meet demand for certain of our products (including a new facility in New Hampshire that was qualified for manufacturing in 2020) and these facilities must meet our production requirements and new facilities must be qualified by regulatory authorities before product can be sold. Our failure or the failure of our third-party manufacturers (including the Lonza facilities that manufacture certain of our products) to produce sufficient quantities of our products and product candidates or to meet our specifications and quality standards or those standards imposed by regulatory authorities 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, harm to our reputation or could accelerate introduction of competing products to the market. For example, we experienced unexpected chemistry, manufacturing and control (or CMC) issues with our ALXN 1830 program that resulted in a delay in the clinical trial timeline for that program. We may experience similar CMC issues in the future that may impact marketed products or other clinical trials.

If we underestimate demand for ULTOMIRIS, SOLIRIS, ANDEXXA 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, public health crises (such as COVID-19), 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 of the nature identified above) are amplified because we rely on a limited number of facilities to produce our products and product candidates. Further, 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 our complement inhibitors. Although we have business continuity plans, including with respect to inventory, to reduce the potential for manufacturing disruptions or delays and reduce the severity of a disruptive event, there is no guarantee that these plans will be adequate, which could adversely affect our business and operations.

We and our third party suppliers and 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 that 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, in connection with drug substance, drug product, finished product, 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 ongoing 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 risks. We have made significant investments in biologics manufacturing facilities, warehousing, fill-finish and other facilities at our sites in Athlone and Dublin, Ireland and at dedicated sites owned by third parties, including a Lonza facility in New Hampshire. We commenced manufacturing operations at certain of these sites prior to receiving regulatory approval and we have $39.8 of product produced at such sites in inventory as of December 31, 2020. 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 appropriate validation processes or obtain the necessary regulatory approvals for these and other facilities, that we will be able to perform the intended manufacturing and supply chain services at these facilities for commercial or clinical use or that we will be able to use the product manufactured at these

sites. Prior to such time, we may continue to rely on third parties for these services.

If our products are subject to any manufacturing issues or we lose manufacturing slots due to Operation Warp Speed, 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 manufacturing or related 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. Further, transfer of production operations to a new supplier is time-consuming and new manufacturing will take significant time before the product can be sold commercially.

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.

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. If a raw material manufacturer were unable to supply such materials, our business may be impacted because we rely on one or a limited number of such manufacturers for certain materials for our products, including the limited third-parties we rely on to operate our master cell banks. 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, or at all, may impact our ability to produce sufficient quantities of our products for clinical or commercial requirements. A material shortage, delay, 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.

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.

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.

Our 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. 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 raw materials and other drug supply and drug product, as well as the delivery and supply chain operations regarding our products, 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 being 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. If 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. In addition, in order to gain greater efficiencies in our operations, certain portions of our international commercial operations, including sales, distribution, marketing and related efforts in designated countries are conducted by third-parties.

Due to the fact that some of our products are new to the market, we do not have lengthy experience in marketing and selling these products to patients, healthcare providers and payers (for example, we are relatively new to certain therapeutic areas, such as neurology (gMG and NMOSD)). In addition, ANDEXXA is also new to the market, having been authorized by the FDA to be marketed in the US in mid-2018. This challenge is coupled with the fact that many members of our sales and marketing team are new to working with Alexion products (and ANDEXXA) and we rely on third parties to market, distribute and sell our product in certain countries. The success of our re-launch of ANDEXXA will depend on our success in marketing the product and being able to execute on the sales strategy which will focus on issues such as pricing, removing access barriers and dosing to ensure appropriate use (and this launch strategy is different than that adopted by Portola prior to the acquisition). If we and our third parties are unable to successfully market and sell our new products (and expand our sales and commercial operations) and to successfully sell our products in new therapeutic areas, our business and sales may be harmed. We cannot guarantee that we will be able to establish, maintain and expand our own capabilities or maintain any sales, marketing or distribution agreements with third-party providers on acceptable terms, if at all, or that we will be able to continue to manage the transition to third-party sales, marketing and distribution in the relevant jurisdictions that will not cause any interruption or disruption in our business and sales of our products. We will not exercise the same degree of control over such third parties that we do over our direct sales force and the ability to direct the third party and provide incentives for such third party to market and sell our products may not be as strong as in the case of a direct sales force. As we move to new third party sales force, marketers and distributors in certain countries it may also increase the risk of litigation with or liability to third parties that we had previously engaged to perform services for us in jurisdictions where we are implementing these operational changes (and we have been subject to certain such claims in the past).

Even if we hire qualified sales and marketing personnel necessary to support our objectives and

enter into 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, which could result in decreased revenues or margins. In addition, as we launch new products, such as ULTOMIRIS (and re-launch ANDEXXA), and we move into other therapeutic areas (such as neurology and reversal of Factor Xa inhibitors), 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 increase. Our expenses associated with building up and maintaining the sales force and distribution capabilities around the world, and relying on third party sales, marketing and distribution, 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.

Our efforts to expand our business and product offerings through acquisitions of businesses and technologies may not be successful.

Building our product pipeline is a key strategic objective to address revenue concentration risk in C5 complement inhibitors and we may, from time to time, evaluate and, when appropriate and in accordance with our obligations under the Merger Agreement with AstraZeneca, purchase businesses and acquire, co-develop or license technologies and products from third parties in an effort to expand and diversify our pipeline, product offerings, and our technologies. For example, in 2020 we acquired Portola and Achillion. 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 integrating 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 on-going operations;
- the potential loss of our key employees or key employees of the acquired companies;
- risks of entering disease areas and indications or modalities in which we have limited or no direct experience; and
- significant investments in resources and personnel to evaluate, integrate and develop acquisition and in-license programs.

A substantial portion of our strategic efforts are focused on opportunities for rare disorders, but the availability of such opportunities may be 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 (some of which may be larger and may be able to provide more consideration than we can) 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 acceptable terms, or at all. In such event, we may not be able to further rebuild our pipeline and any future revenue may remain largely dependent on our existing products, which are subject to the risks noted above.

In addition, through our business development initiatives we have acquired or obtained rights to new technologies, including a therapy to reverse Factor Xa inhibitors, Factor D small molecules and two FcRN platforms (in February 2020, based on data from our Phase I study, we terminated the agreement to co-develop ABY-039 with Affibody, which was the developer of one such FcRN platform), among others. These technologies are intended to diversify our pipeline and revenue base (if products based on these technologies are, where applicable, approved by regulatory authorities), but we have limited experience with these technologies, including developing these therapies, operating clinical trials with these therapies, obtaining regulatory approval and commercializing these assets. If we are unable to successfully bring these products to market and to increase sales of approved medicines in the case of ANDEXXA, we may not be able to diversify our revenue or generate a return on our investments.

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 or may not result in short-

term or long-term benefits to us (such as our transactions with Affibody and Stealth). A commercial stage product or near-commercial stage product acquired may not result in the revenues that we anticipate or we may be unable to realize expected profits on sales due to expenses related to the manufacturing and/or sales of the commercial product. 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 in preclinical trials or early-stage clinical trials. Any therapies we acquire that are pre-clinical or in clinical trials may not result in a commercialized product and any revenues, if the product is commercialized, may not meet our projections or result in generating an adequate return on our investment.

The acquired business of Portola may underperform relative to our expectations, and we may not achieve anticipated synergies.

We completed the acquisition of Portola on July 2, 2020. Through the acquisition, we acquired ANDEXXA, a commercial-stage product that is intended, in part, to diversify our revenue from reliance on C5 inhibitors. The acquired business of Portola may underperform relative to our expectations, which may cause our financial results to differ from our own or the investment community's expectations, and it may not result in the revenue or generate the operating income in the future that we anticipate. The ultimate success of the acquisition will depend, in part, on Alexion's ability to successfully integrate the Portola business and realize the anticipated benefits, including synergies, innovation opportunities and operational manufacturing and sales efficiencies, from the acquisition and successful execution of our relaunch strategy for ANDEXXA, including expansion into new geographies and label expansion to include new indications. If we are unable to achieve our objectives within the anticipated time frame, or at all, the anticipated benefits may not be realized fully or at all, or may take longer to realize than expected, and the value of Alexion's common stock may decline. In addition, if the results of the Phase IV post-marketing trial required by the FDA does not meet the safety and efficacy requirements of the FDA, ANDEXXA (the product that generated almost all of Portola's revenues) may be withdrawn from the market or otherwise subject to regulatory restrictions which may limit the ability to realize expected value from the transaction. Andexanet alfa also received conditional approval in the EU.

The integration of the two companies may result in material challenges, including, without limitation:

- the diversion of management's attention from ongoing business concerns;
- managing a larger combined business that includes a new therapeutic area for Alexion;
- retaining existing business and operational relationships, including customers, suppliers and employees and other counterparties, and attracting new business and operational relationships; and
- coordinating geographically separate organizations.

The financial results of ANDEXXA, and our ability to generate returns on our investment in Portola, will require that we successfully commercialize this product (which received conditional approval from the FDA in 2018). ANDEXXA utilization will depend, in large part, on access for the therapy at both the institutional level (where adoption will be driven by hospitals and emergency care facilities including ANDEXXA in the approved protocols for care and by ANDEXXA being qualified for adequate reimbursement by payers for use) and at the individual prescriber level (where adoption will be driven by immediate physical access to the product as it will be used in the acute care setting and by acceptance and endorsement of use by individual physicians who will need to be satisfied with, among other things, ANDEXXA's safety and efficacy). In addition, ANDEXXA may not gain expected market acceptance due to, among other reasons: pricing and reimbursement decisions and lower than anticipated usage at facilities and dosing. While we do have experience with obtaining institutional approval for our therapies and promoting acute care products (SOLIRIS and ULTOMIRIS for aHUS) we will need to effectively address the needs of institutions and prescribers, as noted above, in order to increase sales of ANDEXXA.

In order to support potential growth of the business, we will be required to make significant investments in our business operations.

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, clinical trial capabilities, manufacturing and other areas of our operations. Efforts to advance our product pipeline, including the increased number of clinical trials that are under way or will commence in the future, will require significant expense in 2021. 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 through development, trials, regulatory approval and to commercialization. We may not have

the necessary funds for these capital expenditures and expenses or these funds 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 (where permitted under our existing contractual obligations), which could dilute current stockholders' ownership interest in our company, or securities convertible into our capital stock (where permitted under our existing contractual obligations), which could dilute current stockholders' ownership interest in us upon conversion.

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

Conducting clinical trials is a complex, time-consuming and expensive process and there are no guarantees that any trial will meet its endpoints or objectives. 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. Many companies have believed their product candidates performed satisfactorily in clinical trials but nonetheless failed to obtain marketing approval of their drug candidate. If the design or results achieved in our clinical trials are insufficient to proceed to further trials or to sustain regulatory approval of our product candidates, our business could be materially adversely affected. Failure of a clinical trial to achieve its pre-specified primary endpoint or objective generally increases the possibility that additional studies or trials may be required if we even 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(s) or objective(s) 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 and may not result in a product that obtains regulatory approval.

ULTOMIRIS may not be approved as a treatment for additional indications or in other jurisdictions and any clinical trials may not achieve the designated endpoints and prove to be effective for use in patients with these additional indications. For example, we have initiated Phase III clinical trials for ULTOMIRIS as a treatment for: (i) Amyotrophic Lateral Sclerosis (ALS), (ii) patients with COVID-19, who are hospitalized with severe COVID-19 requiring mechanical ventilation and (iii) patients with HSCT TMA, (and we plan to initiate studies of ULTOMIRIS in other indications). There is no guarantee that the Phase III clinical trial for ALS, and HSCT TMA (or the additional studies that we are planning for ULTOMIRIS) will provide sufficient evidence to advance our research beyond these stages. Drug development is very uncertain. We had, for example, conducted an exploratory clinical study in Primary Progressive Multiple Sclerosis (PPMS) that we have decided to no longer pursue based on biomarker analysis. Further, in January 2021, based on the recommendation of the IDMC, we recently paused enrollment in our ULTOMIRIS trial for certain COVID-19 patients due to lack of efficacy.

In addition, we are also conducting clinical trials in therapeutic areas with which we have limited experience (for example, ALXN1840 (WTX101), a therapy for Wilson's disease), Factor D small molecules, and with technology platforms with which we also have limited experience (for example, humanized monoclonal antibody that inhibits the interaction of FcRn with Immunoglobulin G (IgG) and IgG immune complexes). Further, we plan to initiate a Phase II clinical trial for ALXN2040 in Geographic Atrophy (GA), which is our first clinical trial in ophthalmology, an indication with which we have limited experience at Alexion. In addition, we intend to also initiate a proof of concept trial using a Factor D molecule, ALXN2050, in patients with various renal diseases. And we are pursuing trials to expand the label for ANDEXXA to treat additional acute care indications. Each of these clinical trials, and any other trial we commence, require significant financial expenses and operational resources, is subject to the risks highlighted above and the investments we have made in these technologies may not generate the expected returns.

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 generally be tested at various doses and formulations for each clinical indication. Many of our programs focus on diseases and conditions with small patient populations making

patient enrollment difficult and requiring a relatively large number of trial sites to meet enrollment requirements to power our clinical trials to our desired levels for efficacy and, in certain cases, superiority. Additionally, we can have multiple clinical trials running for the same indication, further challenging clinical trial enrollment. 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 (as patients have, and may in the future, suffer injuries during clinical trials). If initial trials do not produce adequate results, 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.

Even if we were to complete clinical trials for one or more of our therapies, we or regulatory authorities may determine that the results are not be sufficient for filing a BLA or NDA or granting approval to market the therapy.

We rely on a small number of clinical research organizations to carry out our clinical trial related activities, and two contract research organizations (CROs) are responsible for many of our studies. We rely on such parties to enroll clinical sites and patients, operate trials and 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 approval or as part of ongoing monitoring, will review a CRO's 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:

- 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;
- 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;
- 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 expect 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, acquisitions and business development transactions and the impact of converting patients from SOLIRIS to ULTOMIRIS (as noted above). We may not be able to sustain or increase profitability on a quarterly or annual basis. Since we have a limited sales and operating history with certain of our products and for new indications of existing products (such as ANDEXXA and the 100mg/mL formulation of ULTOMIRIS), we may not be able to accurately forecast demand for our products or for new indications and formulations. 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. You should not consider our financial performance, including our revenue growth, in recent periods as indicative of our future performance.

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.

In the future, we may not generate sufficient revenues or control expenses to achieve our financial goals. 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 financial guidance and anticipated customers for certain indications for future periods (including neurology patients in the U.S. using our products), and future product launches and if our actual operating results fail to meet or exceed the guidance or forecasts that we have previously provided to our investors, our stock price could drop suddenly and significantly. Financial guidance, anticipated customer levels and product launches are based on certain assumptions about future performance and such guidance and forecasts are not a guarantee that the targets set forth will be achieved. In addition, due to the potential impact of COVID-19 on our business, operations and results of operations (including our revenues), the estimates, judgments and inputs required to generate guidance and customer levels are increasingly uncertain and therefore accurately forecasting performance is even more challenging in light of the current health crisis.

As we attempt to grow and expand our business, we may have substantial expenses as we continue our research and development efforts and our efforts to develop the assets we have acquired through acquisitions, collaborations and in-licenses, continue to undertake additional business development activities, 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 control expenses and/or achieve our financial objectives. Additionally, business development activities may include milestone and royalty obligations and may require substantial investment in research and development to achieve product approval. These expenses may increase and such increases may exceed analyst and investor expectations.

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, governmental regulations and commercial organizations and across the many geographies in which we operate. There is intense competition in the biopharmaceutical industry for these types of personnel.

Our business is specialized and global and we must attract and retain highly qualified individuals across many geographies and areas of expertise. 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.

We may not achieve some or all of the expected benefits of our current and future restructuring plans and restructurings may adversely affect our business.

We initiated our most recent restructuring in the third quarter 2020, which is principally focused within our commercial organization as part of an initiative intended to redefine our operating model and reallocate resources necessary to align our organization with our diversifying portfolio of new products and strategic objectives. We may undertake additional restructurings in the future. Implementation of a restructuring plan may be costly and disruptive to our business, and we may not be able to obtain the estimated cost savings and benefits that were initially anticipated in connection with a restructuring in a timely manner, or at all. Additionally, as a result of any restructuring, we may experience a loss of continuity, loss of accumulated knowledge and/or inefficiency during transitional periods. Reorganization and restructuring can require a significant amount of management and other employees' time and focus, which may divert attention from operating and growing our business. If we fail to achieve some or all of the expected benefits of restructuring, it could have an adverse effect on our business, financial condition, results of operations and cash flows.

If we fail to satisfy our debt service obligations or our contingent obligations, we may be unable to

commercialize our products or continue or complete our product development.

We have significant debt service obligations. In addition to the obligations to make interest and principal payments under our credit 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.

Our 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 (due to, for example, the failure to comply with certain covenants in the Amended and Restated Credit Agreement), 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.

In addition, we have substantial contingent liabilities, including milestone and royalty obligations associated with 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 (we are currently subject to a claim in litigation in connection with the Syntimmune acquisition that we failed to meet our obligations with respect to the contingent consideration and plaintiff has requested payment of the full earn-out amount) . 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 and research and development;
- 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.

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 in accordance with our existing contractual commitments to supplement our existing funds and cash generated from operations for working capital, capital expenditure and debt service requirements, and other business activities (including business and technology acquisitions). 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 and complete new manufacturing facilities or enhance our manufacturing and related 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 or any tax assessment or liability), 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) or business development activities, we may have to delay, scale-back or eliminate certain research, development, manufacturing, acquisition or commercial activities or sell certain assets and technologies.

We have incurred significant impairment charges, and may continue to incur such 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 and may also have an adverse impact on our reputation.

As of December 31, 2020, the net carrying value of our goodwill and other intangible assets, net totaled $8,102.5. As required by GAAP, we evaluate goodwill and intangible assets for impairment on an annual basis, or as facts and circumstances warrant. 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, adverse clinical results, intensified competition, divestitures, market capitalization declines and other factors may impair our goodwill and other intangible assets.

As part of our standard quarterly procedures, we review facts and circumstances regarding our long-lived assets, including the KANUMA asset, to assess for potential indicators of impairment. During the quarter ended June 30, 2020, based on continued challenges expanding patient growth and new alternative commercial opportunities, we revised our strategic view of KANUMA and determined that we have exhausted commercially viable initiatives related to KANUMA and will have difficulty expanding patient growth over the long term as we focus on promoting other commercial programs and growing our pipeline. While management is committed to continued access to KANUMA for existing patients and providing access to future patients diagnosed with LAL-D, as we grow our business and product offerings, including through the recent acquisition of Portola Pharmaceuticals, we will prioritize programs where the opportunity to find patients who can benefit from Alexion therapies is the greatest. Therefore, we no longer expect to increase the number of KANUMA patients at the rate we previously assumed in our cash flow projections for KANUMA. As a result of these developments during the second quarter 2020, management adjusted assumptions in our long term cash flow forecast model for KANUMA and recognized an impairment charge of $2,042.3 related to the associated intangible asset.

Cash flow models used in our assessments of intangible assets are based on the projected commercial sales of the underlying products which considers, where applicable, our commercial experience with the product to date. Cash flow models for products currently in development also include the likelihood of approval. These cash flow models require the use of significant estimates and judgements, which include, but are not limited to, probability of regulatory approval, market access assumptions, long-range pricing expectations and patient-related assumptions, including patient identification, conversion and retention rates. As we continue to develop and sell products that have a related intangible asset associated with it, new data may cause us to adjust the assumptions in our cash flow models. Changes to assumptions used in our net cash flow projections may result in material impairment charges in subsequent periods, similar to the impairment charge recognized in the second quarter 2020 related to KANUMA.

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 (and such tax authorities have disagreed with certain positions we have taken in prior years, and may do so again the future), 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, including potential changes following the U.S. presidential and congressional elections, 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. For example, in August 2020, we received a notice of examination from the Dutch Tax Authorities ("DTA") regarding certain matters relating to our 2014 through 2017 tax years. We entered into an agreement with the DTA in December 2020 and have agreed to pay approximately $73.8 in connection with the settlement, inclusive of the 2018 and 2019 tax years. After taking into account the $56.1 U.S. foreign tax credit claimed on the settlement, the net cash outflow was $17.7, representing a 3.1% net increase to the effective tax rate. 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 or decisions that adversely impact pricing or reimbursement policies in foreign countries;
- 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 or used for clinical trials) and we may be required to pay additional duties or fines and such amounts may be substantial. For example, our offices in Brazil were visited by the Brazilian federal tax authorities and we received a written notice from such authorities requesting information with respect to the importation of SOLIRIS free of charge to patients in Brazil from 2014 to 2019. In connection with this matter, in August 2019, the Brazilian Federal Revenue Service provided a Notice of Tax and Description of the Facts to, among others, two Alexion subsidiaries. This notice focuses on: (i) the identity of the importer and (ii) the importation value of SOLIRIS vials in connection with Alexion's free drug program in Brazil. See Note 11, *Commitments and Contingencies* to the consolidated financial statements for more information on this matter);
- 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 local 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, operations 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 employees, distributors and third party service providers in countries where we operate. We have policies and procedures, and we are committed to continually focusing on our compliance program and we continue to enhance our comprehensive company-wide program and efforts, and these are designed to enhance our business processes, structures, controls, training, talent, and systems across Alexion's global operations and to help us and our representatives, including our employees and our vendors and distributors, comply with such laws. We cannot, however, guarantee that these policies, programs and procedures will protect us against liability under the FCPA or other anti-bribery laws for actions taken by us, our employees 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 commence operations. In addition, as we have moved from a direct sales force to third-party sales force, distributors and marketers in certain countries and regions, we may also have liability under the FCPA and anti-bribery laws and regulations for the actions of these third parties. Although we can impose contractual restrictions on what these third parties 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.

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, local and foreign environmental laws and regulations concerning the handling and disposal of regulated wastes, such as medical and biological wastes, chemical wastes and potential emissions and discharges into the environment (including 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 such property or locations (should a release occur), without regard to whether the owner or operator knew of or caused the contamination. Although our safety procedures for handling and disposing of hazardous materials are designed to comply with the laws and regulations established by state, federal, local and foreign regulators, the risk of loss of, or accidental contamination or injury from, these materials cannot be eliminated. If an incident 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.

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. We cannot predict fluctuations in currency exchange rates and such fluctuations in exchange rates (and inflation) could negatively affect our business, cash flow, results of operations, financial position and prospects. 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. While our hedging agreements may limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks may be costly and not always successful and the results may have a material impact on our 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, including 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 elsewhere in this Annual Report on Form 10-K). If we or a regulatory agency discover new or previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where a 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 applicable product, the manufacturing facility or us. In 2013, we 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 (or other regulatory authority) approval and/or criminal prosecution.

If we or our third-party providers, including our product or raw material manufacturers, product fill-finish providers, packagers and labelers, fail to comply fully with applicable regulations, then we may be required to, among other things, initiate a recall or withdrawal of our products. In addition to our manufacturing operations and those of our 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 that apply to our business, including statutes and regulations, administered by the FDA, the EMA, the competent authorities of the EU Member States, the MHLW or other comparable agencies, could result in:

- a product recall;
- a product withdrawal;
- modification or revision to a product label;
- 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, suspension or termination 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, NDAs or BLA or NDA supplements for our products, or a facility that manufactures our products;
- seizing or detaining product;
- requiring us or third-parties performing services for us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- injunctions; and/or
- criminal prosecution.

In addition, we are subject to antitrust regulations with respect to interactions with other participants in the markets we currently serve or may serve in the future. These antitrust laws are vigorously enforced in the U.S. and in other jurisdictions in which we operate.

Our product candidates require extensive preclinical and clinical testing and regulatory approval and failure to satisfy regulatory requirements relating to 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 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 (or comparable approval), provided adequate patient enrollment rates, timely and appropriately reported any adverse events and serious adverse events to the appropriate authorities and ensured compliance with cGLP and 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 as they relate to our products and operations, 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 and small molecule compounds. Included in the post-approval marketing requirements are, for example, the REMS program for both SOLIRIS and ULTOMIRIS in the U.S., and a REMS program can be updated from time to time by the FDA and such updates can be costly and burdensome to implement. In addition, continued approval for ANDEXXA for its currently approved indication in the US is contingent upon post-marketing study results that verify that clinical benefit is conferred to patients.

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 revised labeling, additional 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, product liability claims 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 pharmacovigilance-related services on our behalf, including clinical trial investigators and distributors, have not complied with the applicable reporting or other pharmacovigilance requirements, we may become subject to additional inspections, clinical holds, 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 we established a PNH Registry and an aHUS Registry to collect additional data on 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. In the case of ANDEXXA, it was approved under the FDA's Accelerated Approval Pathway, and received conditional marketing authorization in the EU based on the change from baseline in anti-Factor Xa activity in healthy volunteers and in patients through the ANNEXA-4 trial demonstrating hemostatic efficacy. Continued approval for this indication is contingent upon post-marketing study results that verify that clinical benefit is conferred to patients. 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 other 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 any of our future products that obtain regulatory approval. 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 False Claims Act (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 (including through the use of speaker programs); 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 employees or third-party distributors or service providers.

There is also enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. In 2019, we settled an investigation by the Department of Justice relating to our support for 501(c)(3) entities. If we, or our vendors or donation recipients, are deemed to fail to comply with relevant laws, regulations or government guidance in the operation of these programs again in the future, we could be subject to significant fines or penalties.

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, the HIPAA criminal federal health care fraud statute, 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 in Part I, Item 1 of 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, 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, and, for reports submitted on or after January 1, 2022, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. 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/or 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, among other regulatory agencies, 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 example. Although we believe that our marketing materials and training programs for physicians do not constitute improper promotion, the FDA, the DOJ, other federal or state government agencies, the EU, EU Member States or the MHLW (or other foreign regulatory agencies) 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 (which occurred in 2019 in Japan) 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.

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, and continue to, take steps that are intended to enhance 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, including Brazil, Colombia, Japan, Russia and Turkey. 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. DOJ informed us that it closed its inquiry into these matters. We settled the investigation with the SEC in July 2020, and made payment of approximately $21.5 in disgorgement, civil penalties, and pre-judgment interest in connection with the settlement. In addition, following the settlement with the SEC in July 2020, the Ministry of Health in Turkey initiated an investigation regarding the matters referenced in the SEC Order as they relate to the Company's operations in Turkey between 2010 and 2015 (for more information, see Note 11, *Commitments and Contingencies* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K). We are cooperating with this investigation.

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. At this time, we are unable to predict the duration, scope or outcome of the open investigations. In addition, even though we have settled the DOJ investigation relating generally to our support of certain 501(c)(3) organizations that was initiated by the U.S. Attorney's Office for the District of Massachusetts in December 2016, the SEC investigation (which was settled in July 2020), the DOJ investigation (that was closed by the DOJ in May 2020) and the MHLW closed its 2018 investigation into our Japanese operations, we may be subject to similar investigations in the future by the same or other regulatory agencies and government authorities and the penalties imposed on us may be materially greater in amount or we may be subject to material limitations on our operations, activities and our business. In addition, any remedial actions that have been or will be taken with the intent to address the matters that were the subject of these or other governmental investigations may not prevent future investigations and potential liability as a result of such further 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 greater or stricter than the amounts or terms that we proposed in discussions (or the amount that we accrued for such matter during negotiations). 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.

Our business could be adversely affected by litigation and regulatory enforcement actions.

We operate in many jurisdictions in a highly regulated industry and we could be subject to litigation, government investigations (as noted above) and enforcement and other legal actions on a variety of matters in the U.S. or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, tax and custom/import duties, 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. We are involved in certain legal proceedings from time to time. See Note 11, *Commitments and Contingencies* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for information on certain of these legal proceedings. In addition, in connection with any acquisitions, we may assume potential liability related to pending legal proceedings of the acquired company. For example, securities class action complaints were filed against Portola and certain officers of Portola alleging violation of the antifraud provisions of the Exchange Act of 1934 and the Securities Act of 1933 due to misrepresentations and omissions in public disclosures concerning sales of andexanet alfa between January 8, 2019 and February 26, 2020. Legal proceedings are inherently unpredictable, and the outcome can result in costly verdicts, fines and penalties, exclusion from federal healthcare programs and/or injunctive relief that affect how we operate our business. Defense of litigation claims can be expensive, time consuming and distracting, and it is possible that we could incur judgments or enter into settlements of claims for monetary damages or change the way we operate our business, which could have a material adverse effect on our product sales, business and results of operations. In addition, product liability is a major risk in testing, selling, using and marketing biotechnology and pharmaceutical products. We may face potential product liability exposure in human clinical trials and for products we sell after regulatory approval. Product liability claims, regardless of their merits, could be costly and divert management's attention and could adversely affect our reputation and the demand for our products and result in significant monetary liability.

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, for example, 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 and generic 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, industry competition, formulary composition, and may result in the development of new programs, including Medicare payment for performance initiatives, health technology assessments 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 and promulgated a final regulation in December 2020 implementing further changes to the program, as described in "Government Regulation - U.S. Healthcare Reform and Other U.S. and International

Healthcare Laws" included in Part I, Item 1. 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 MFN Model may ultimately be implemented or the executive branch may issue similar pricing or discount initiatives that impact SOLIRIS or our other products. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate Program has and may continue to decrease revenues, 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 cost-reduction 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 and regulate the industry 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. In certain cases, governments may challenge the price we charge for our products already delivered to patients under applicable regulations in those countries (and if these governments prevail, we could be required to return amounts to the government or the government may take steps in an attempt to claw-back amounts that were previously paid to us and such amounts may be material).

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 and with respect to the potential implementation of the MFN Model. There is no assurance that the PPACA or MFN Model, 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, state or foreign legislative or administrative changes relating to healthcare reform may affect our business. The recent COVID-19 pandemic may introduce temporary or permanent healthcare reform measures for which we cannot predict the financial implication on our business.

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 pharmaceutical 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 and enforcement 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 revenues or successfully commercialize our product candidates, or could limit or eliminate our future spending on development projects and product candidates. 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 for payment to be available for our products under 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 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. 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 underage in our rebate liability for past quarters, and such amount may be material. 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 and any such actions could negatively impact our business and results of operations.

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 manufacturer 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 "Government Regulation – Pharmaceutical Pricing and Reimbursement" included in Part I, Item 1 of this Annual Report on Form 10-K. 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. 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:

- the method of calculating the 340B ceiling price for our products;
- any expansion of the entities that qualify as covered entities; and
- other programmatic changes

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

Pursuant to a final rule adopted on January 1, 2019, we could be subject to civil monetary penalties if the government finds that we knowingly and intentionally overcharged a 340B covered entity. In addition, the 340B pricing program also 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 (FFS) 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 with respect to our pricing or participation in government health programs, 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 have affected and 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, which 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, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information from a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, numerous proposals regarding privacy and data protection are pending before U.S. and non-U.S. legislative and regulatory bodies. For example, in the U.S., the California Consumer Privacy Act (CCPA) became effective as of January 1, 2020, and the California Attorney General finalized regulations and began enforcement of the CCPA on July 1, 2020. However, obligations under the CCPA also continue to evolve, as the California Attorney General has proposed further modifications to the regulations. Moreover, the CCPA was amended by a ballot initiative, the California Privacy Rights Act (CPRA), which was included on the November 2020 ballot in California and approved by California voters. The majority of CPRA provisions will go into effect on January 1, 2023 and will require additional investment in compliance programs and potential modifications to business processes.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. 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, among other things, our ability to conduct clinical trials that involve EU personal data and engage in other activities that require the processing of EU personal data and in particular international transfers of personal data. These laws are complex, subject to interpretation by local authorities, and any determination that we breached such laws could lead to government enforcement actions, significant penalties and these may adversely impact our operating results.

Privacy and data protection laws, industry standards, regulations and regulatory enforcement in the U.S. and internationally continue to evolve. In May 2018, the EU's GDPR, which applies in all EU Member States, went into effect. The regulation introduced comprehensive data protection requirements in the EU and substantial fines for breaches of the data protection rules. It increased 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 evolving EU data protection rules. The GDPR also includes restrictions on the transfers of personal data from the EU to jurisdictions that have not been deemed to provide essentially equivalent data protection safeguards through national laws outside of certain legal transfer mechanisms. In July 2020, the Court of Justice of the European Union invalidated the EU-U.S. Privacy Shield as one means of transferring data to the United States, and called for additional assessments in the context of reliance upon standard contractual clauses. While Alexion was not Privacy Shield certified, additional compliance efforts may be needed to respond to evolving EU regulatory guidance. Any determination that we are not in compliance with such requirements could lead to government enforcement actions and significant penalties, which may adversely impact our operations.

Security breaches, cyber-attacks, other disruptions to, or vulnerabilities in, our information technology systems and infrastructure, or those of our clients, partners, counterparties, or other third-party service providers on which we rely, 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 designed to protect patients' personal information and other corporate information (including proprietary 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 information technology 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. Our proprietary and confidential information may also be accessed. Any one of these events could cause our business to be materially harmed and our results of operations may be adversely impacted.

Additionally, in response to the ongoing COVID-19 pandemic, we have generally required all employees who are able to work from home to do so until further notice. As a result of these measures, and as our employees continue to work from home and access our systems remotely, we may be subject to heightened information security risks, including the risk of cyber attacks.

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 KANUMA product.

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 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 or our competitors' 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 Chugai lawsuits alleging patent infringement, acquisitions or other strategic transactions, and the perceptions of our investors that we are not performing or meeting expectations. In addition, the sales of our common stock by our officers, directors, or by any entities that an officer or director may be affiliated with, may have caused our stock price to drop in the past and any future sales by such officer, director or affiliate (or the perception that such sales could occur) may have a negative impact on our stock price. 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.

Our amended and restated bylaws designate the courts located in the State of Delaware as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain an alternate judicial forum for disputes with us.

Our amended and restated bylaws designate that, unless we consent in writing to the selection of an alternate forum, the state courts located in the State of Delaware (or if no state court within the State of Delaware has jurisdiction, the federal district court for the State of Delaware) will be the sole and

exclusive forum for (i) any derivative action or proceeding brought on or on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director or officer or other employee of the Company to the Company or the Company's stockholders, (iii) any action asserting a claim against the Company or any director or officer or other employee of the Company arising pursuant to any provision of the Delaware General Company Law or the Company's Certificate of Incorporation or the bylaws (as either may be amended from time to time), or (iv) any action asserting a claim against the Company or any director or officer or other employee of the Company governed by the internal affairs doctrine. This exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or the Securities Act of 1933, as amended. As a stockholder in our Company, you are deemed to have notice of and have consented to the provisions of our amended and restated bylaws related to choice of forum. The choice of forum provision in our amended and restated bylaws may limit your ability to obtain an alternate judicial forum for disputes with us.

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 operations headquarters, global supply chain, distribution, and administration offices	160,000	Owned
Athlone, Ireland	Commercial, research and development manufacturing	80,000	Owned

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. We have completed construction of a new biologics manufacturing facility at this site and we are currently pursuing regulatory approval.

In May 2015, we announced plans to construct a new biologics manufacturing facility on our existing property in Dublin, Ireland. Construction of this facility has been completed. In January 2021, the European Medicines Agency (EMA) approved the facility as a manufacturer of Drug Substance for SOLIRIS and we are currently pursuing regulatory approval by the FDA.

While we continue to actively engage with regulators, the timing of regulatory approvals for each of these facilities may be delayed as a result of the COVID-19 pandemic.

In the fourth quarter 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, 2020, refer to 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 February 4, 2021, we had approximately 81 stockholders of record of our common stock. The closing sale price of our common stock on February 4, 2021 was $155.59 per share.

DIVIDEND POLICY

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

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

The following table summarizes our common stock repurchase activity during the fourth quarter 2020:

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, 2020	0.4	$ 119.92	0.4	$ 2,048.8
November 1-30, 2020	0.2	$ 121.50	0.2	$ 2,024.7
December 1-31, 2020	—	$ —	—	$ 2,024.7
Total	0.6	$ —	0.6	

In November 2012, our Board of Directors authorized a share repurchase program. In February 2017, our Board of Directors increased the amount that we are authorized to expend on future repurchases to $1,000.0 under our repurchase program, which superseded all prior repurchase programs. The entire amount authorized pursuant to this February 2017 Board approval has been utilized. On October 22, 2019, the Board of Directors approved a share repurchase authorization of up to $1,000.0. On July 28, 2020, the Board of Directors approved a new share repurchase authorization of up to an additional $1,500.0. 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 our discretion. As of December 31, 2020, there is a total of $2,024.7 remaining for repurchases under the repurchase program.

EQUITY COMPENSATION PLAN INFORMATION *(amounts in millions except per share amounts)*

The information provided in the following table is as of December 31, 2020.

Plan Category	Number of shares of common stock to be issued upon exercise of outstanding options (1)	Weighted-average exercise price of outstanding options	Weighted-average term to expiration of options outstanding (years)	Number of shares of common stock remaining available for future issuance under equity compensation plans (2)
Equity compensation plans approved by stockholders	2.2	$134.15	3.52	8.9
Equity compensation plans not approved by stockholders	—	$—	—	—

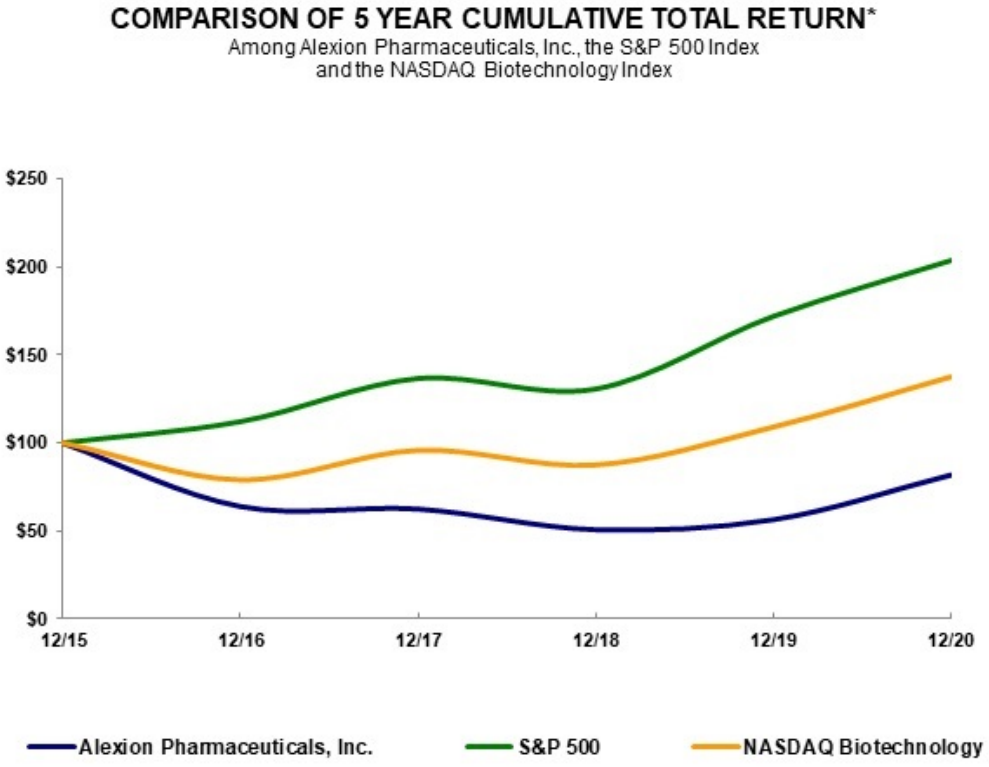
(1) Reflects number of shares of common stock to be issued upon exercise of outstanding options under all our equity compensation plans, including our 2017 Incentive Plan. Does not include 5.4 of outstanding restricted stock units, including performance-based restricted stock units, that were issued under the 2017 Incentive plan and the previous Amended and Restated 2004 Incentive Plan.

(2) Of these shares, 8.6 remain available for future issuance under the 2017 Incentive Plan and 0.3 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.

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 S&P 500 Index, and (ii) the NASDAQ Biotechnology Index. The graph assumes (a) $100 was invested on December 31, 2015 in each of the Company's common stock, the stocks comprising the S&P 500 Index 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.



*$100 invested on 12/31/15 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

CUMULATIVE TOTAL RETURN

	12/15	12/16	12/17	12/18	12/19	12/20
Alexion Pharmaceuticals, Inc.	$100.00	$64.14	$62.69	$51.04	$56.70	$81.91
S&P 500	$100.00	$111.96	$136.40	$130.42	$171.49	$203.04
NASDAQ Biotechnology	$100.00	$78.65	$95.67	$87.19	$109.08	$137.90

This performance graph is furnished and shall not be deemed "filed" with the SEC or subject to Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any of Alexion's filings under the Securities Act of 1933, as amended.

Item 6. SELECTED FINANCIAL DATA.

(amounts in millions, except per share amounts)

The following selected financial data for the years ended December 31, 2020, 2019 and 2018 and as of December 31, 2020 and 2019 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. The selected financial data for the years ended December 31, 2017 and 2016 and as of December 31, 2018, 2017, and 2016 are derived from our audited financial statements not included in this Annual Report on Form 10-K.

Consolidated Statements of Operations Data:

	Year Ended December 31,				
	2020	2019	2018	2017	2016
Net product sales	$ 6,069.1	$ 4,990.0	$ 4,130.1	$ 3,549.5	$ 3,081.7
Other revenue	0.8	1.1	1.1	1.6	2.4
Total revenues	6,069.9	4,991.1	4,131.2	3,551.1	3,084.1
Costs and expenses:					
Cost of sales (exclusive of amortization of purchased intangible assets) [1]	553.5	394.5	374.3	454.2	258.3
Research and development	1,002.9	886.0	730.4	878.4	757.2
Selling, general and administrative	1,399.9	1,261.1	1,111.8	1,094.4	953.0
Acquired in-process research and development [2]	—	(4.1)	1,183.0	—	—
Amortization of purchased intangible assets [4]	253.7	309.6	320.1	320.1	322.2
Change in fair value of contingent consideration	61.2	11.6	116.5	41.0	35.7
Acquisition-related costs [3]	117.6	—	—	—	2.3
Restructuring expenses [1]	10.3	12.0	25.5	104.6	3.0
Impairment of intangible assets [4]	2,053.3	—	—	31.0	85.0
Gain on sale of asset	(14.8)	—	—	—	—
Total costs and expenses	5,437.6	2,870.7	3,861.6	2,923.7	2,416.7
Operating income	632.3	2,120.4	269.6	627.4	667.4
Other income and (expense) [5] [6]	(63.3)	58.4	(27.4)	(79.6)	(91.2)
Income before income taxes	569.0	2,178.8	242.2	547.8	576.2
Income tax (benefit) expense [4] [7] [8] [9]	(34.4)	(225.5)	164.6	104.5	176.8
Net income	$ 603.4	$ 2,404.3	$ 77.6	$ 443.3	$ 399.4
Earnings per common share					
Basic	$ 2.74	$ 10.77	$ 0.35	$ 1.98	$ 1.78
Diluted	$ 2.72	$ 10.70	$ 0.35	$ 1.97	$ 1.76
Shares used in computing earnings per common share					
Basic	220.1	223.2	222.7	223.9	224.3
Diluted	222.0	224.8	224.5	225.4	226.3

Consolidated Balance Sheet Data:

	As of December 31,				
	2020	2019	2018	2017	2016
Cash, cash equivalents and marketable securities	$ 2,999.4	$ 2,749.5	$ 1,563.8	$ 1,474.1	$ 1,293.4
Total assets [4] [7] [10]	18,103.0	17,544.6	13,931.9	13,583.3	13,253.3
Long-term debt (current and noncurrent)	2,562.0	2,501.7	2,595.5	2,888.1	3,055.1
Contingent consideration (current and noncurrent) [11]	414.3	192.4	280.8	168.9	152.9
Financing lease obligations (current and noncurrent) [12]	72.9	78.1	372.2	353.3	243.4
Total liabilities [7] [10]	6,451.8	6,272.8	4,766.6	4,690.2	4,559.5
Total stockholders' equity	11,651.2	11,271.8	9,165.3	8,893.1	8,693.8

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 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 Alexion Rhode Island Manufacturing Facility to cost of sales (the 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.

(2) 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 was 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. In connection with the agreement of the final working capital adjustment for the Syntimmune acquisition, we recognized a benefit of $4.1 associated with previously acquired in-process research and development in the second quarter 2019.

(3) In 2020, we recorded $117.6 of acquisition-related costs primarily in connection with our Achillion and Portola acquisitions.

(4) In the second quarter 2020, we recognized impairment charges of $2,053.3, primarily related to our KANUMA intangible asset. The KANUMA impairment charge resulted in a decrease in amortization of purchased intangible assets during 2020. The recognized impairment charges resulted in a deferred tax benefit of $379.8. Please refer to Note 4, *Intangible Assets & Goodwill* for additional information.

(5) In 2020, 2019 and 2018, we recorded gains of $76.5, $59.7 and $43.0, respectively, on our strategic equity investments.

(6) In 2019, we amended the terms of our agreement with Caelum Biosciences which resulted in the recognition of a $32.0 gain. In 2020, in connection with entering into the Merger Agreement with AstraZeneca, we determined that the fair value of our option to acquire the remaining equity of Caelum decreased as a result of a change to the expected option exercise date. This resulted in a $49.0 impairment charge.

(7) In 2019, we recognized a net tax benefit of $115.8 attributable to the integration of intellectual property of Wilson Therapeutics into the Alexion corporate structure, a $17.0 tax benefit attributable to the completion of a comprehensive analysis of our prior year estimate related to our foreign-derived intangible income (“FDII”), and a $382.2 tax benefit attributable to the completion of an intra-entity asset transfer of certain intellectual property within our captive foreign partnership. The Company recognized deferred tax assets of $2,221.5 and deferred tax liabilities of $1,839.3 in connection with the intra-entity asset transfer.

(8) 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.

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

(10) In 2020, in connection with our Achillion and Portola acquisitions, we recorded net assets acquired of $1,061.2 and $1,621.6, respectively. The acquisitions of Achillion and Portola were accounted for as business combinations. Please refer to Note 2, *Acquisitions* for additional information.

(11) In the first quarter 2020, in connection with our Achillion acquisition, we recorded an initial fair value estimate of contingent consideration in the form of non-tradeable contingent value rights (CVRs) of $160.7. As of December 31, 2020, the fair value of the contingent consideration for the Achillion acquisition was $210.6.

(12) Upon adoption of the new lease standard in 2019, we derecognized $372.2 of facility lease obligations associated with previously existing build to-suit arrangements and capitalized $83.1 of financing lease liabilities. Financing lease liabilities as a result of the new standard are included in other current liabilities and other liabilities.

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 expectations, plans and anticipated 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 forecasted 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 and devastating conditions through the discovery, development and commercialization of life-changing medicines.

As a leader in rare diseases for more than 25 years, Alexion has developed and commercializes two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), as well as the first and only approved complement inhibitor to treat anti-acetylcholine receptor (AChR) antibody-positive generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive. Alexion also has two highly innovative enzyme replacement therapies and the first and only approved therapies for patients with life-threatening and ultra-rare metabolic disorders, hypophosphatasia (HPP) and lysosomal acid lipase deficiency (LAL-D). With the acquisition of Portola Pharmaceuticals, Inc. (Portola) in July 2020, we added the first and only approved Factor Xa inhibitor reversal agent for patients treated with rivaroxaban or apixaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

In addition to our marketed therapies, we have a diverse pipeline resulting from internal innovation and business development. Alexion focuses its research efforts on novel molecules and targets in the complement cascade and development efforts on the core therapeutic areas of hematology, nephrology, neurology, metabolic disorders, cardiology, ophthalmology and acute care.

Merger Agreement with AstraZeneca

On December 12, 2020, we entered into an Agreement and Plan of Merger (the Merger Agreement) with AstraZeneca PLC, a public limited company incorporated under the laws of England and Wales (AstraZeneca), Delta Omega Sub Holdings Inc., a Delaware corporation and a wholly owned subsidiary of AstraZeneca (Bidco), Delta Omega Sub Holdings Inc. 1, a Delaware corporation and a direct, wholly owned subsidiary of Bidco (Merger Sub I) and Delta Omega Sub Holdings LLC 2, a Delaware limited liability company and a direct, wholly owned subsidiary of Bidco (Merger Sub II). The Merger Agreement provides, among other things, that subject to the satisfaction or waiver of the conditions set forth therein (1) Merger Sub I will merge with and into Alexion (the "First Merger"), with Alexion surviving the First Merger as a wholly owned subsidiary of Bidco, and (2) immediately following the effective time of the First Merger (the Effective Time), Alexion will merge with and into Merger Sub II (the Second Merger and, together with the First Merger, the Mergers), with Merger Sub II surviving the Second Merger as a wholly owned subsidiary of Bidco and an indirect wholly owned subsidiary of AstraZeneca.

Under the Merger Agreement, at the Effective Time (as defined in the Merger Agreement), each share of common stock, par value $0.0001 per share, of Alexion issued and outstanding immediately prior to the Effective Time (other than certain excluded shares as described in the Merger Agreement) will be converted into the right to receive (1) 2.1243 American depositary shares of AstraZeneca (or, at the election of the holder thereof, a number of ordinary shares of AstraZeneca equal to the number of underlying ordinary shares represented by such American depositary shares) and (2) $60.00 in cash, without interest (collectively, the "Merger Consideration").

The boards of directors of both companies have unanimously approved the acquisition.

The respective obligations of Alexion and AstraZeneca to consummate the transactions contemplated by the Merger Agreement are subject to the satisfaction or waiver of a number of customary conditions, including: (1) the adoption of the Merger Agreement by Alexion's stockholders; (2) approval of the transactions contemplated by the Merger Agreement by AstraZeneca's shareholders; (3) the absence of any law or order prohibiting consummation of the Mergers; (4) AstraZeneca's registration statement on Form F-4 having been declared effective by the Securities and Exchange Commission; (5) AstraZeneca's shareholder circular (or, if required, prospectus) having been approved by the U.K. Financial

Conduct Authority; (6) the American depository shares of AstraZeneca issuable in the Mergers (and the ordinary shares of AstraZeneca represented thereby) having been approved for listing on the Nasdaq; (7) the expiration or early termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the approval of the Mergers under the antitrust and foreign investment laws of other specified jurisdictions; (8) accuracy of the other party's representations and warranties, subject to certain materiality standards set forth in the Merger Agreement and (9) compliance by the other party in all material respects with such other party's obligations under the Merger Agreement.

Without limiting the generality of the foregoing, we are subject to a variety of specified restrictions under the Merger Agreement. Unless we obtain AstraZeneca's prior written consent (which consent may not be unreasonably withheld, conditioned or delayed) and except (i) as required or expressly contemplated by the Merger Agreement, (ii) as required by applicable law or (iii) as set forth in the confidential disclosure schedule delivered by Alexion to AstraZeneca, we may not, among other things and subject to certain exceptions and aggregate limitations, incur additional indebtedness, issue additional shares of our common stock outside of our equity incentive plans, repurchase our common stock, pay dividends, acquire assets, securities or property, dispose of businesses or assets, enter into material contracts or make certain additional capital expenditures.

The transaction is not subject to a financing condition. To support the financing of the offer consideration, AstraZeneca has entered into a new committed $17,500.0 bridge-financing facility, provided by Morgan Stanley, J.P. Morgan Securities plc and Goldman Sachs.

Under the Merger Agreement, Alexion will be required to make a payment to AstraZeneca equal to $1,180.0 if the Merger Agreement is terminated in certain circumstances, including because the Alexion board of directors has changed its recommendation in favor of the Mergers or we terminated the Merger Agreement in order to enter into an agreement providing for a Company Superior Proposal (as defined in the Merger Agreement), and Alexion will be required to make a payment to AstraZeneca equal to $270.0 if the Merger Agreement is terminated because Alexion's stockholders fail to adopt the Merger Agreement. AstraZeneca will be required to make a payment to Alexion equal to $1,415.0 if the Merger Agreement is terminated in certain circumstances, including because the AstraZeneca board of directors has changed its recommendation in favor of the Mergers or because AstraZeneca's shareholders fail to approve the transactions contemplated by the Merger Agreement.

The acquisition is expected to close during the third quarter 2021, and upon completion, Alexion stockholders will own approximately 15.0% of the combined company.

Recent Developments

On November 20, 2020, we announced that the European Commission (EC) approved the ULTOMIRIS (ravulizumab) 100 mg/mL intravenous (IV) formulation for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) and for atypical hemolytic uremic syndrome (aHUS). ULTOMIRIS 100 mg/mL is an advancement in the treatment experience for patients with aHUS and PNH, as it reduces average annual infusion times by approximately 60 percent compared to ULTOMIRIS 10 mg/mL while delivering safety and efficacy consistent with the ULTOMIRIS 10 mg/mL formulation.

In January 2021, Alexion entered into a definitive asset purchase agreement with Rhythm Pharmaceuticals, Inc. ("Rhythm") to acquire its Rare Pediatric Disease Priority Review Voucher (PRV) for $100.0. Alexion's acquisition of Rhythm's PRV is subject to the satisfaction of customary closing conditions and approval from relevant regulatory agencies, including the expiration or early termination of the applicable waiting period under the Hart-Scott Rodino Antitrust Improvements Act. Upon closing, we will make a $100.0 cash payment and we expect to capitalize the PRV as an acquired in-process research and development (IPR&D) intangible asset.

COVID-19 Pandemic

During the first quarter of 2020, the World Health Organization (WHO) declared the COVID-19 public health crisis a pandemic and recommended containment and mitigation measures worldwide. On March 13, 2020, former U.S. President Trump announced a National Emergency relating to the pandemic. Government authorities worldwide have recommended or imposed various social distancing, quarantine and isolation measures on large portions of the population. While the impact of the COVID-19 pandemic to date on our business has been less than we had initially forecast, it is evolving rapidly and its future effects are difficult to predict with meaningful precision as the impact will depend on many factors beyond the Company's control and knowledge. As the pandemic continues, we continue to take steps that are designed to respond proactively to evolving events and planning for COVID-19 uncertainties. We remain focused on continuing to serve patients, protecting the health and safety of our employees and the communities in which we live and work, and supporting our patients in clinical trials.

In early March 2020, we activated a task force designed to assess, mitigate and manage the risks related to COVID-19 to avoid or minimize business disruption, including safeguarding of our facilities, and

to ensure the safety and sense of security for our staff. In early March 2020, Alexion closed all sites to non-essential employees and the Company has suspended all travel indefinitely. In early June 2020, Alexion gradually allowed re-entry to certain sites in some geographies through a pilot program, including Switzerland, Germany, Australia, and Japan in accordance with local government laws, regulations and restrictions and our own safety procedures and checklists. In September 2020, we extended our global guidance to employees to strongly encourage working remotely until at least July 2021, while offering limited access to physical sites through pilot programs. Office sites are being reconfigured to maintain physical distancing and we expect to adopt and implement additional precautions commensurate with any expansion of employees returning to worksites. To date, our remote working arrangements have not significantly affected our ability to maintain critical business operations.

We are focused on protecting patient and customer safety as well as providing an uninterrupted supply of medicines for patients around the world. We have taken proactive measures that are designed to mitigate the risk of potential supply interruptions, and we strive to maintain sufficient inventory levels to continue serving current and new patients receiving our medicines for approved indications, as well as those participating in ongoing clinical trials. We and our third-party contract manufacturing partners continue to operate manufacturing facilities at near normal levels.

We are monitoring the demand for our products as due to quarantines, travel restrictions, hospital policies and patient concerns regarding exposure to COVID-19, we have observed fewer patient/doctor interactions, we have also noted that the new patient productivity and initiation queue has decreased since the COVID-19 outbreak (particularly in our neurological indications) and our representatives are having fewer in-person visits with health care providers, including for infusion of our products which has adversely impacted our revenue growth in the current year and may continue to affect our revenue growth in the future. We have been proactively engaging with healthcare professionals virtually and through enhanced digital channels in an effort to mitigate this risk. Additionally, we continue to actively monitor potential further impacts on our business such as growth in unemployment and loss of commercial insurance coverage and/or growth in Medicaid with higher discounts.

We have preclinical studies and clinical testing ongoing across the globe. We have a business continuity plan for our preclinical and clinical trials, including a pandemic response plan. A number of clinical trial sites are restricting site visits and imposing restrictions on the initiation of new trials and patient visits to protect both site staff and patients from possible COVID-19 exposure. Given the safety concerns around COVID-19 and the associated risk to maintaining normal clinical trial operations, we are making decisions study-by-study and country-by-country to minimize the risk to the patients and facilities, and there has been and may continue to be an impact on the timing of trials that are under active enrollment. The majority of clinical trials that were paused at the onset of the pandemic have resumed, however we are continuing to experience impact to enrollment for some studies. We are actively implementing remote and local procedures per guidance of the FDA.

In May 2020, Alexion initiated a global Phase III study to investigate ULTOMIRIS® (ravulizumab-cwvz) in a subset of adult patients with COVID-19, who are hospitalized with severe COVID-19 requiring mechanical ventilation. In January 2021, we paused further enrollment in the trial due to lack of efficacy, pending further analysis of the data. This decision was made based on the recommendation of an independent data monitoring committee following their review of data from a pre-specified interim analysis.

The extent to which the COVID-19 pandemic impacts our business, including our commercial results and clinical trials, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the virus, the duration of the outbreak, governmental regulations and restrictions, travel restrictions and actions to contain the outbreak or treat its impact. We continue to be responsive to the ever-changing situation while remaining true to our core values.

Critical Accounting Policies and 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. The preparation of these financial statements in conformity with GAAP requires that management make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and other related disclosures. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

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;
- Share-based compensation;

- Valuation of acquired assets, including goodwill, intangible assets and inventory;
- Valuation of contingent consideration; and
- Income taxes.

Revenue Recognition

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.

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.

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. 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.

We believe the methodology used to accrue for discounts and rebates is reasonable and appropriate given current facts and circumstances, but actual results may differ.

We have provided balances and activity in the rebates payable account for the years ended December 31, 2020, 2019 and 2018 as follows:

	Rebates Payable
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 current year	322.7
Adjustments relating to prior years [(1)]	18.8
Payments/credits relating to sales in current year	(123.4)
Payments/credits relating to sales in prior years	(90.8)
Balances, December 31, 2019	**$ 250.1**
Current provisions relating to sales in current year	395.5
Adjustments relating to prior years	(11.1)
Payments/credits relating to sales in current year	(154.4)
Payments/credits relating to sales in prior years	(146.8)
Balances, December 31, 2020	**$ 333.3**

[(1)] Included in the adjustments related to prior years is an accrual recorded in 2019 related to the PMPRB matter. Refer to Note 11, *Commitments and Contingencies* for additional information.

Current provisions relating to sales in the current year increased by $72.8 in 2020 compared to 2019 and $87.3 in 2019 compared to 2018. The increase in 2020, 2019 and 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.

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. Significant judgment is required in both the determination of probability and the determination as to whether an exposure is reasonably estimable. Because of uncertainties related to claims and litigation, accruals are based on the best information available at the time of our assessment including the legal facts and circumstances of the case, status of the proceedings, applicable law and the likelihood of settlement, if any. 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, when facts and circumstances indicate the need for any change.

Share-Based Compensation

The Company recognizes compensation expense associated with the issuance of equity instruments that may be granted to our directors, officers, employees and consultants or advisors of the Company or any subsidiary. To date, share-based compensation issued 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.

Significant judgments and assumptions are used in estimating compensation cost for restricted stock units containing market-based performance conditions as well as non-market performance conditions relating to the achievement of operational metrics. We use payout simulation models to estimate the grant date fair value of awards with market-based performance conditions. 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. 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. Changes in estimates and probability of achieving the performance targets could have a material impact on our results of operations.

Valuation of Acquired Assets, Including Goodwill, Intangible Assets and Inventory

We have recorded goodwill, acquired intangible assets and inventory 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. An income approach, which generally relies upon forecasted cash flow models, is typically used in these valuations if quoted market prices are not available. These valuations 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, which consider competitive trends impacting the assets;
- tax rates; 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 indefinite lives are not amortized, but are tested for impairment at least annually or when a triggering event occurs that could indicate a potential impairment. Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if triggering events occur. When performing our impairment assessment for definite-lived intangible assets, we rely upon cash flow projections attributable to the asset to determine if the carrying value of the asset is recoverable, on an undiscounted cash flow basis. If the carrying value of a definite lived intangible asset is not recoverable, or if there is an indicator of impairment on an indefinite-lived intangible asset, we will recognize an impairment in the amount by which the carrying value of the asset exceeds its fair value. We calculate the fair value of these assets using discounted cash flow models which require the use of significant estimates and judgements which include, but are not limited to, probability of success of clinical events or regulatory approvals, discount rates, and estimated future cash flows from product sales. Changes to assumptions used in our cash flow projections could result in an impairment. Impairments are recorded within impairment of intangible assets in our consolidated statements of operations.

During the quarter ended June 30, 2020, based on continued challenges expanding patient growth and new alternative commercial opportunities, we revised our strategic view of KANUMA and determined that we have exhausted commercially viable initiatives related to KANUMA and will have difficulty expanding patient growth over the long term as we focus on promoting other commercial programs and growing our pipeline. As a result, we no longer expect to increase the number of KANUMA patients in the long term at the rate previously assumed. This determination resulted in reduced cash flow projections for KANUMA, which indicated that the related intangible asset value was

not fully recoverable on an undiscounted cash flows basis. As of June 30, 2020, we utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to KANUMA that, when compared with its related carrying value, resulted in an impairment charge of $2,042.3.

The estimated fair value of the KANUMA asset as of June 30, 2020 was determined using the excess earnings method, a variation of the income approach. The excess earnings method estimates the value of an intangible asset equal to the present value of the incremental after-tax cash flows attributable to that intangible asset over its remaining economic life. Long term cash flow projections for the asset require the use of significant estimates and judgements, including forecasted revenue growth rates, forecasted cost of goods sold and the discount rate, and were based on our most recent strategic plan. The fair value of the asset was determined using an estimated weighted average cost of capital of 10.0%, which reflects the risks inherent in future cash flow projections and represents a rate of return that a market participant would expect for this asset. The estimated revenue growth rates fluctuate over the life of the asset, with a weighted average growth rate in the low single digits. We believe our assumptions are consistent with the plans and estimates that a market participant would use to manage the business. The estimated fair value of the KANUMA intangible asset as of June 30, 2020 was $820.0 and will continue to be amortized over its remaining estimated useful life. The carrying value of the KANUMA intangible asset as of December 31, 2020 was $782.7.

Inventory acquired in connection with the acquisition of a business is measured at fair value as of the acquisition date and requires the use of significant estimates, which include the expected selling price of the inventory, estimated costs to complete the manufacturing process and dispose of the inventory, a reasonable profit allowance for the remaining manufacturing and selling effort, estimated holding periods based on internal forecasts of demand and discount rates. We exclude from the value of acquired inventory any excess quantities that we do not expect to be salable based on future projected inventory requirements. If future demand or market conditions are lower than our projections as of the acquisition date, we may be required to write down the value of inventory through a charge to cost of sales in the period the revision is made.

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 of December 22, 2018, our accounting for the impact of the Tax Act was complete. Refer to 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 will record adjustments to income tax expense in that period, and such adjustments may be material.

During the fourth quarter of 2013, in connection with the centralization of our global supply chain and technical operations in Ireland, our U.S. parent company became a direct partner in a captive foreign partnership. Our corporate structure, which derives income from multiple jurisdictions, requires us to interpret the related tax laws and regulations within those jurisdictions and develop estimates and assumptions regarding significant future events, such as the amount, timing and character of deductions and the applicability of foreign tax credits. From time to time, we execute intercompany transactions that may impact the valuation of the captive foreign partnership and the corresponding interest allocated to each partner, resulting in a change to deferred taxes. The transactions and related valuations require the application of transfer pricing guidelines issued by the relevant taxing authorities. Significant estimates and assumptions within discounted cash flow models are also required to calculate the valuations. These estimates and assumptions include, but are not limited to, estimated future operating cash flows, revenue growth rate assumptions, long-range pricing expectations, patient-related assumptions and other significant inputs such as discount rates and rates of return.

New Accounting Pronouncements

Accounting Standards Update (ASU) 2019-12, "Income Taxes: Simplifying the Accounting for Income Taxes": In December 2019, the Financial Accounting Standards Board (FASB) issued a new standard intended to simplify the accounting for income taxes by eliminating certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new standard also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard is effective for annual periods beginning after December 15, 2020 and interim periods within, with early adoption permitted. Adoption of the standard requires certain changes to be made prospectively, with some changes to be made retrospectively. We adopted the new standard on January 1, 2021. We have substantially completed our assessment of the standard and we do not expect the adoption of this standard to have a material impact on our financial condition and results of operations.

ASU 2020-01, "Investments - Equity Securities, Investments - Equity Method and Joint Ventures, and Derivatives and Hedging - Clarifying the Interactions Between Topic 321, Topic 323, and Topic 815": In January 2020, the FASB issued a new standard intended to clarify the interactions between Accounting Standards Codification (ASC) 321, ASC 323 and ASC 815. The new standard addresses accounting for the transition into and out of the equity method and measurement of certain purchased options and forward contracts to acquire investments. The standard is effective for annual and interim periods beginning after December 15, 2020, with early adoption permitted. Adoption of the standard requires changes to be made prospectively. We adopted the new standard on

January 1, 2021. The adoption of this standard does not have an impact on our financial condition and results of operations.

ASU 2020-04, "Reference Rate Reform, Facilitation of the Effects of Reference Rate Reform on Financial Reporting": In response to concerns about structural risks of interbank offered rates, and, particularly, the risk of cessation of the London Interbank Offered Rate (LIBOR), regulators around the world have undertaken reference rate reform initiatives to identify alternative reference rates that are more observable or transaction-based and less susceptible to manipulation. In March 2020, the FASB issued a new standard that provides optional guidance for a limited time to ease the potential burden in accounting for the effects of reference rate reform, including optional expedients and exceptions for the accounting implications of contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met.

The amendments in this new standard only apply to contracts and hedging relationships that reference LIBOR or another reference rate expected to be discontinued due to reference rate reform. The expedients and exceptions provided by the standard do not apply to contract modifications made and hedging relationships entered into or evaluated after December 31, 2022. We are currently reviewing our contracts impacted by reference rate reform and are assessing the impact of this standard on our financial condition and results of operations.

Recently Adopted Accounting Pronouncements

ASU 2018-15, "Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract": 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) that aligns the requirements for capitalizing implementation costs in a CCA service contract with existing internal-use software guidance. The standard also provides classification guidance on these implementation costs as well as additional quantitative and qualitative disclosures. The standard is effective for interim and annual periods beginning after December 15, 2019, with early adoption permitted, and can be adopted prospectively or retrospectively.

We adopted the new standard on January 1, 2020 on a prospective basis. The adoption of this standard had no impact on our financial statements at the date of adoption; however, we anticipate the adoption of this standard will result in an increase in capitalized assets related to qualifying CCA implementation costs in future periods.

Qualifying CCA implementation, set-up and other upfront costs incurred after January 1, 2020 are capitalized as other assets in our consolidated balance sheets. These assets will be expensed over the term of the hosting arrangement and such expense will be presented within the same line item in our consolidated statements of operations as the expense for fees for the associated hosting arrangement. These capitalized costs will be evaluated for impairment when events or changes in circumstances indicate that the carrying value of the capitalized implementation costs is not recoverable. For the year ended December 31, 2020, capitalized CCA implementation costs were not material.

ASU 2016-13, "Measurement of Credit Losses on Financial Instruments": 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 on financial assets measured at amortized cost be determined using an expected loss model, instead of the current incurred loss model, and requires that credit losses related to available-for-sale debt securities be recorded through an allowance for credit losses and limited to the amount by which carrying value exceeds fair value. The new standard also requires enhanced disclosure of credit risk associated with financial assets. The standard is effective for interim and annual periods beginning after December 15, 2019 with early adoption permitted.

We adopted the new standard on January 1, 2020 and completed our assessment of the standard based on the composition of our portfolio of financial instruments and current and forecasted economic conditions at that date. Our significant financial assets that are within the scope of the new standard consist of trade accounts receivable and available for sale debt securities. We have not historically experienced any material credit losses associated with our trade accounts receivable or available for debt securities.

We monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. We disaggregate our trade accounts receivable population into pools of similar risk characteristics based on underlying customer type and geographical location. Current expected credit loss allowances are estimated for each risk pool based on available information, including i) historical credit loss experience, ii) current economic conditions and, iii) reasonable and supportable forecasts of future economic conditions that may affect the collectibility of the recorded amounts. Based on the relevant facts and economic conditions as of the date of adoption, we concluded that the expected credit losses on our trade accounts receivable were immaterial. Additionally, unrealized losses on our available for sale investment

portfolio were immaterial.

As of December 31, 2020, we reassessed our estimated credit losses on our trade accounts receivable, including consideration of the potential impacts of the COVID-19 global pandemic. Based on the relevant facts and economic conditions as of December 31, 2020, we concluded that the expected credit losses on our trade accounts receivable continued to be immaterial.

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,		
	2020	2019	2018
Net product sales	$ 6,069.1	$ 4,990.0	$ 4,130.1
Other revenue	0.8	1.1	1.1
Total revenues	6,069.9	4,991.1	4,131.2
Costs and expenses:			
Cost of sales (exclusive of amortization of purchased intangible assets)	553.5	394.5	374.3
Research and development	1,002.9	886.0	730.4
Selling, general and administrative	1,399.9	1,261.1	1,111.8
Acquired in-process research and development	—	(4.1)	1,183.0
Amortization of purchased intangible assets	253.7	309.6	320.1
Change in fair value of contingent consideration	61.2	11.6	116.5
Acquisition-related costs	117.6	—	—
Restructuring expenses	10.3	12.0	25.5
Impairment of intangible assets	2,053.3	—	—
Gain on sale of asset	(14.8)	—	—
Total costs and expenses	5,437.6	2,870.7	3,861.6
Operating income	632.3	2,120.4	269.6
Other income and (expense)	(63.3)	58.4	(27.4)
Income before income taxes	569.0	2,178.8	242.2
Income tax (benefit) expense	(34.4)	(225.5)	164.6
Net income	$ 603.4	$ 2,404.3	$ 77.6
Earnings per common share:			
Basic	$ 2.74	$ 10.77	$ 0.35
Diluted	$ 2.72	$ 10.70	$ 0.35

Comparison of the Years Ended December 31, 2020, 2019, and 2018

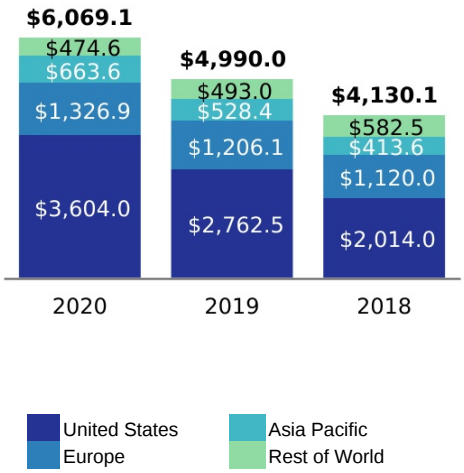
Net Product Sales

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

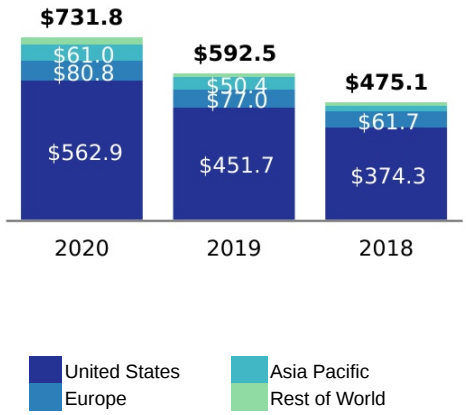
	Year Ended December 31,			% Change	
	2020	2019	2018	2020 compared to 2019	2019 compared to 2018
SOLIRIS					
United States	$ 2,259.7	$ 2,014.0	$ 1,588.4	12.2 %	26.8 %
Europe	1,033.3	1,049.8	1,036.7	(1.6)%	1.3 %
Asia Pacific	343.0	423.5	382.0	(19.0)%	10.9 %
Rest of World	428.2	459.1	555.9	(6.7)%	(17.4)%
	$ 4,064.2	$ 3,946.4	$ 3,563.0	3.0 %	10.8 %
ULTOMIRIS					
United States	$ 646.0	$ 236.8	$ —	172.8 %	**
Europe	170.4	52.2	—	226.4 %	**
Asia Pacific	255.3	49.9	—	411.6 %	**
Rest of World	5.0	—	—	**	**
	$ 1,076.7	$ 338.9	$ —	**	**
STRENSIQ					
United States	$ 562.9	$ 451.7	$ 374.3	24.6 %	20.7 %
Europe	80.8	77.0	61.7	4.9 %	24.8 %
Asia Pacific	61.0	50.4	27.9	21.0 %	80.6 %
Rest of World	27.1	13.4	11.2	102.2 %	19.6 %
	$ 731.8	$ 592.5	$ 475.1	23.5 %	24.7 %
ANDEXXA					
United States	$ 71.7	$ —	$ —	**	**
Europe	6.8	—	—	**	**
Asia Pacific	—	—	—	**	**
Rest of World	—	—	—	**	**
	$ 78.5	$ —	$ —	**	**
KANUMA					
United States	$ 63.7	$ 60.0	$ 51.3	6.2 %	17.0 %
Europe	35.6	27.1	21.6	31.4 %	25.5 %
Asia Pacific	4.3	4.6	3.7	(6.5)%	24.3 %
Rest of World	14.3	20.5	15.4	(30.2)%	33.1 %
	$ 117.9	$ 112.2	$ 92.0	5.1 %	22.0 %
Total Net Product Sales	$ 6,069.1	$ 4,990.0	$ 4,130.1	21.6 %	20.8 %

** Percentages not meaningful

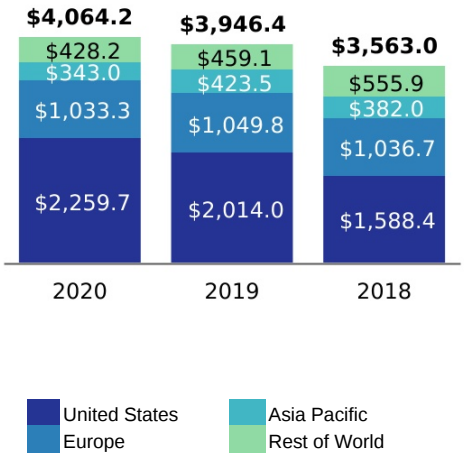
Net Product Sales (consolidated)



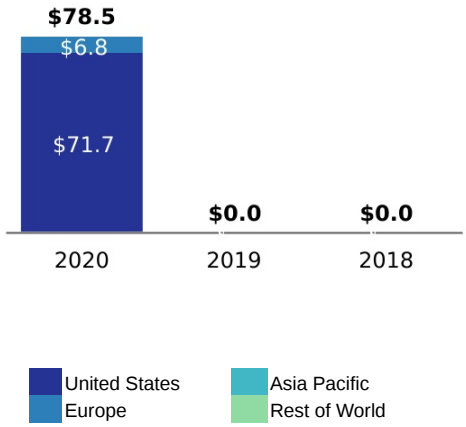
STRENSIQ net product sales



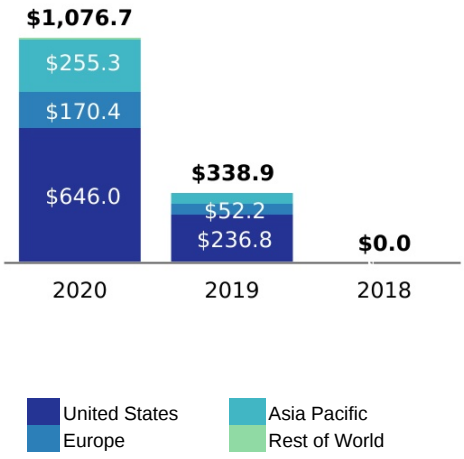
SOLIRIS net product sales



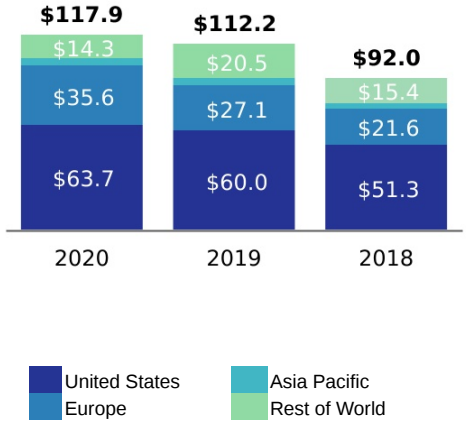
ANDEXXA net product sales



ULTOMIRIS net product sales



KANUMA net product sales



The increase in net product sales for the year ended December 31, 2020, as compared to the same period in 2019, was primarily due to an increase in unit volumes. The increase in unit volumes was primarily due to increased global demand for SOLIRIS therapy, with sales to patients with gMG and NMOSD being the largest drivers. As a result of continued patient conversion, ULTOMIRIS unit volumes for PNH and aHUS also increased due to an increase in PNH and aHUS patients on ULTOMIRIS therapy, inclusive of the loading dose impact required in a patient's first year on therapy. Partially offsetting this increase was the continued conversion of PNH and aHUS patients from SOLIRIS to ULTOMIRIS, resulting in a decrease in SOLIRIS PNH and aHUS revenues for the year ended December 31, 2020, as compared to the year ended December 31, 2019. Additional unit volume increases were due primarily to increased demand for STRENSIQ during 2020 and contributions of $78.5 from ANDEXXA as a result of the Portola acquisition that closed on July 2, 2020.

As a result of patient conversion from SOLIRIS to ULTOMIRIS, we expect variability in our revenues in future quarters due to the extended ULTOMIRIS dosing interval and infusion timing which may result in either one or two infusions in a quarter. ULTOMIRIS loading doses for PNH patients will result in increased revenues during a patient’s first year on therapy. The ULTOMIRIS annual maintenance dose for PNH and aHUS requires fewer vials as compared to the annual dose for SOLIRIS. Due to the decision to price ULTOMIRIS lower than SOLIRIS on an annual basis, we anticipate U.S. revenues will be unfavorably impacted by the lower annual cost per patient in maintenance years, with the impact more pronounced for aHUS due to the greater decrease in vials for aHUS ULTOMIRIS patients.

The increase in net product sales for the year ended December 31, 2019, as compared to same period in 2018, was primarily due to an increase in unit volumes. This increase in unit volumes was primarily due to increased global demand for SOLIRIS therapy, with sales to patients with gMG being the largest driver, as well as ULTOMIRIS volumes due to the loading doses required in a patient's first year on therapy. Partially offsetting the SOLIRIS increase was the conversion of PNH patients from SOLIRIS to ULTOMIRIS. While ULTOMIRIS contributed to 2019, the ULTOMIRIS volumes were primarily attributable to PNH patient conversion from SOLIRIS in the U.S. Additional unit volume increases were due to increased demand of STRENSIQ and KANUMA during 2019 as a result of our continued efforts to identify and reach more patients with HPP and LAL-D globally.

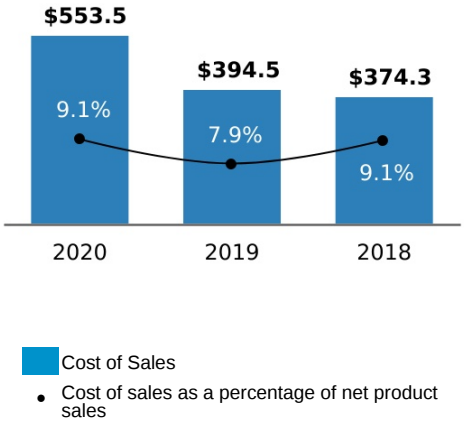
The increase in net product sales for the year ended December 31, 2019, as compared to same period in 2018, was partially offset by price decreases of which the largest driver was $29.8, or 0.7%, as a result of a judicial order issued in the second quarter 2019 related to SOLIRIS pricing in Canada. The decision led to a reduction of revenue in the second quarter of 2019 and further reductions in all subsequent quarters until the appeals process concludes. The reduction of revenue recorded for the year ended December 31, 2019 includes the impact for the period from September 2017 to December 2019.

In response to the COVID-19 pandemic, we have taken proactive measures that are designed to mitigate the risk of potential supply interruptions, and we strive to maintain sufficient inventory levels to continue serving current and new patients receiving our medicines for approved indications. Due to quarantines, travel restrictions, hospital policies and patient concerns regarding exposure to COVID-19, we have observed fewer patient/doctor interactions, we have also noted that the new patient productivity and initiation queue has decreased since the COVID-19 outbreak (particularly in our neurological indications) and our representatives are having fewer in-person visits with health care providers, including for infusion of our products which has adversely impacted our revenue growth in the current year and may continue to affect our revenue growth in the future. However, we are proactively engaging with healthcare professionals virtually and through enhanced digital channels in an effort to mitigate this risk.

Cost of Sales (exclusive of amortization of purchased intangible assets)

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, 2020, 2019 and 2018:



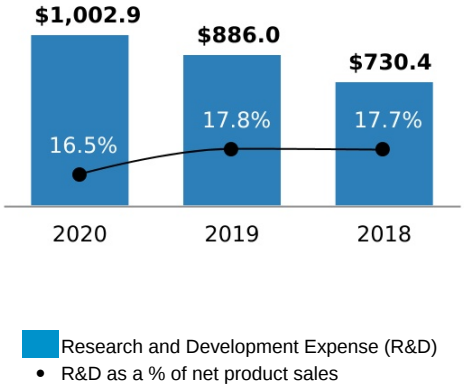
The increase of cost of sales as a percentage of net product sales for the year ended December 31, 2020, as compared to the same period in 2019, was primarily due to amortization of the ANDEXXA inventory fair value step-up recognized in purchase accounting for Portola, inventory obsolescence reserves recorded and a charge associated with excess manufacturing capacity due to COVID-19 impact.

Exclusive of the items mentioned above, cost of sales as a percentage of net product sales was 8.2% and 7.9% for the years ended December 31, 2020 and 2019, respectively.

As a result of the Portola acquisition completed on July 2, 2020, we expect cost of goods sold to increase in future periods as compared to prior periods due to the amortization of ANDEXXA inventory fair value step-up adjustments which will be recognized as the acquired ANDEXXA inventory is sold.

The decrease in cost of sales as a percentage of net product sales for the year ended December 31, 2019, as compared to the same period in 2018, was primarily due to decreases in royalty expenses due to a contract expiration that occurred in the fourth quarter 2018. Additionally, cost of sales for the year ended December 31, 2018 included asset related charges of $5.8 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 impairment of manufacturing assets.

Research and Development Expense



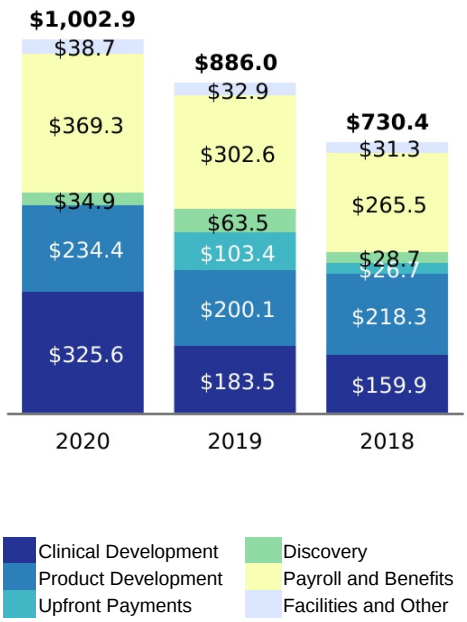
Our research and development expense includes personnel, facility and direct costs associated with the research and development (R&D) of our product candidates, as well as product development costs. For additional information on our development programs, please refer to *Product and Development Programs* 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 and R&D-related asset purchase agreements which we have entered into with third parties. Clinical development costs are comprised of costs to conduct and manage clinical trials related to product candidates. Product development costs are those incurred in performing duties related to manufacturing development and regulatory functions, including manufacturing of material for clinical and research activities and other administrative costs incurred during product development. Discovery research costs are incurred in conducting laboratory studies and performing preclinical research for other uses of our current products and other new product candidates. Upfront payments include upfront payments related to strategic licensing agreements and R&D-related asset purchase agreements. Subsequent milestone payments incurred under such agreements which relate to R&D activities are classified as clinical, discovery or product development costs based on the nature of the underlying milestone event.

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 for our clinical and preclinical candidates, our product development and our discovery research efforts. These costs have not been allocated directly to each program.

The following graph provides information regarding research and development expenses:



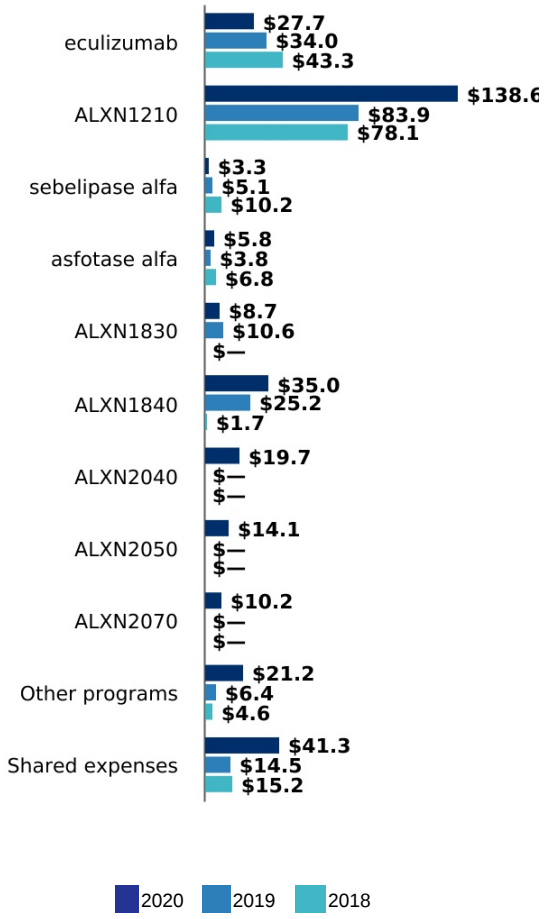
During the year ended December 31, 2020, we incurred R&D expenses of $1,002.9, an increase of $116.9, or 13.2%, versus the $886.0 incurred during the year ended December 31, 2019. The increase was primarily related to the following:

- Increase of $142.1 in clinical development primarily driven by increased clinical expenses related to ALXN1210 for multiple ongoing studies; shared expenses related to investments in enhanced systems and processes to support our clinical trial expansion; and clinical expenses related to assets acquired from Achillion and Portola in 2020. See chart below for additional details by program.
- Increase of $66.7 in payroll and benefits primarily related to increases in headcount partially offset by decreases in travel and entertainment expenses as a result of the COVID-19 pandemic.
- Increase of $34.3 in product development expenses primarily related to increased costs associated with the manufacturing of material for ALXN2070, ALXN1850 and other product development programs partially offset by a decrease in costs associated with the manufacturing of material for ALXN1210.
- Decrease of $103.4 in upfront payments relating to license payments made during the year ended December 31, 2019 in connection with the arrangements we entered into with Zealand Pharma A/S (Zealand), Affibody AB (Affibody), Eidos Therapeutics, Inc. (Eidos) and Stealth BioTherapeutics Corp. (Stealth). No upfront payments related to licensing arrangements were made during the year ended December 31, 2020.
- Decrease of $28.6 in discovery primarily driven by a decrease in target option exercise fees and research milestones associated with our agreement with Dicerna Pharmaceuticals, Inc. (Dicerna).

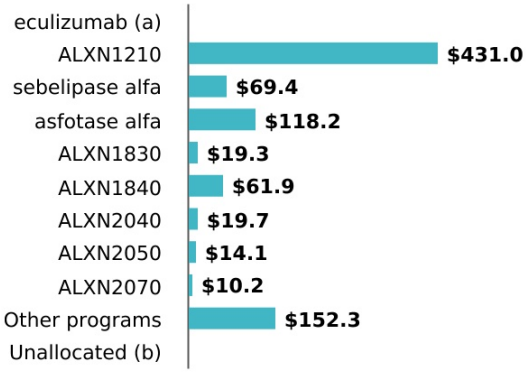
During the year ended December 31, 2019, we incurred research and development expenses of $886.0, an increase of $155.6, or 21.3%, versus the $730.4 incurred during the year ended December 31, 2018. The increase was primarily related to the following:

- Increase of $76.7 in upfront payments primarily related to the license payments made in connection with the arrangements we entered into with Zealand, Affibody, Eidos and Stealth in 2019. Upfront payments made in 2018 related to the agreement entered into with Dicerna.
- Increase of $37.1 in payroll and benefits primarily related to headcount increases.
- Increase of $34.8 in discovery mainly driven by target option exercise fees and research milestones associated with our agreement with Dicerna.
- Increase of $23.6 in direct clinical development expenses related primarily to increases in various studies (see graph on following page summarizing expenses related to our clinical development programs).
- Decrease of $18.2 in direct product development expenses related primarily to a decrease in costs associated with the manufacturing of material for ALXN1210, partially offset by an increase for material related to ALXN1830 and ALXN1840.

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



The following graph summarizes accumulated direct expenses related to our clinical development programs from January 1, 2006 to December 31, 2020:



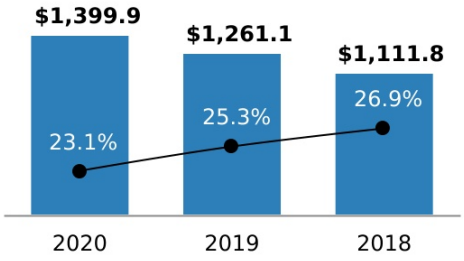
(a) From 1992 through 2006, substantially all research and development expenses were related to two products, eculizumab and pexelizumab. We obtained approval in the U.S. for eculizumab for PNH in 2007 and for aHUS in 2010, and we ceased development of pexelizumab in 2006.

(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 research and development programs, please refer to Item 1A “Risk Factors” in this Annual Report on Form 10-K.

We expect our research and development expenses to increase as a percentage of sales in 2021 as compared to 2020.

Selling, General and Administrative Expense

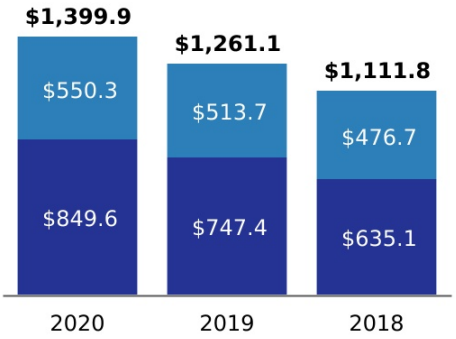


Selling General and Administrative Expense (SG&A)

- 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, 2020, we incurred selling, general and administrative expenses of $1,399.9, an increase of $138.8, or 11.0%, versus the $1,261.1 incurred during the year ended December 31, 2019. The increase was primarily related to the following:

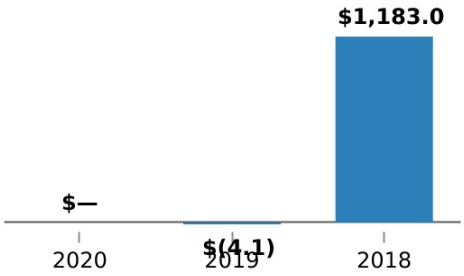
- Increase in salary, benefits, and other labor expenses of $102.2, primarily related to increases in headcount partially offset by decreases in travel and entertainment expenses as a result of the COVID-19 pandemic.
- Increase in external selling, general and administrative expenses of $36.6, primarily related to increased costs relating to businesses acquired, marketing services, and litigation charges of $21.5 recorded during the first quarter 2020 in connection with legal proceedings, partially offset by a decrease in professional services.

During the year ended December 31, 2019, we incurred selling, general and administrative expenses of $1,261.1, an increase of $149.3, or 13.4%, versus the $1,111.8 incurred during the year ended December 31, 2018. The increase was primarily related to the following:

- Increase in salary, benefits and other labor expenses of $112.3. The increase was primarily related to headcount increases driven by an increase in commercial activities related to SOLIRIS for gMG and increased staff costs associated with commercial support activities including NMOSD pre-launch efforts. Employee related costs associated with our share-based compensation plans also increased.
- Increase in external selling, general and administrative expenses of $37.0. The increase was primarily driven by an increase in charitable contributions and professional services.

We expect our selling, general and administrative expenses to remain consistent as a percentage of sales in 2021 as compared to 2020.

Acquired In-Process Research and Development

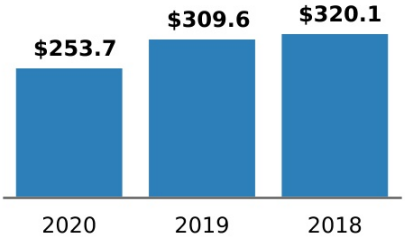


For the year ended December 31, 2019, we recorded a benefit of $4.1 to acquired in-process research and development (IPR&D) associated with

previously acquired IPR&D related to the Syntimmune acquisition as a result of the agreement of the final working capital adjustment in the second quarter 2019.

For the year ended December 31, 2018, we recorded acquired IPR&D expense of $1,183.0 related 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 $253.7, $309.6 and $320.1 for the years ended December 31, 2020, 2019 and 2018, respectively. Amortization expense is primarily associated with intangible assets related to STRENSIQ, KANUMA and ANDEXXA.

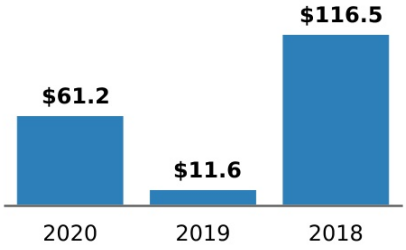
The decrease in amortization of purchased intangible assets for the year ended December 31, 2020 as compared to years ended 2019 and 2018, was primarily associated with the KANUMA and STRENSIQ intangible assets, both of which are explained below. This decrease was partially offset by an increase in amortization associated with our ANDEXXA intangible asset acquired in connection with the Portola acquisition, which closed during the third quarter 2020.

During the second quarter 2020, we recorded an impairment charge of $2,042.3 to write-down the KANUMA intangible asset to fair value. The lower asset value is contributing to lower amortization expense for the year ended December 31, 2020 as compared to the years ended December 31, 2019 and 2018.

During the third quarter 2019, the U.S. patent term extension to a composition of matter patent for STRENSIQ was granted, which resulted in an increase in the estimated useful life of the STRENSIQ intangible asset and is contributing to lower amortization expense for the year ended December 31, 2020 as compared to the years ended December 31, 2019 and 2018.

We expect amortization for finite-lived intangible assets to decrease in future periods as compared to prior periods as a result of the KANUMA impairment charge recognized during the second quarter of 2020, offset by amortization expense associated with the ANDEXXA intangible asset.

Change in Fair Value of Contingent Consideration



For the years ended December 31, 2020, 2019 and 2018, the change in fair value of contingent consideration expense associated with our prior business combinations was $61.2, $11.6 and $116.5, 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 contingent milestones, the expected timing of milestone payments in connection with previous acquisitions and the discount rates used to calculate fair value. Changes in the fair value of contingent consideration primarily relate to contingent amounts due in connection with our acquisition of Enobia in 2012 and Achillion in 2020.

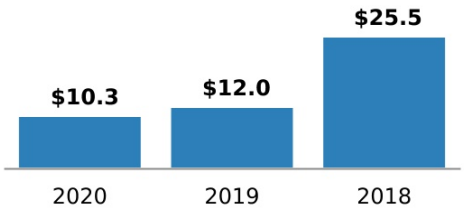
For the year ended December 31, 2020, changes in the fair value of contingent consideration expense reflected changes in the expected timing and probability of achieving contingent milestone payments and the interest component of contingent consideration related to changes in discount rates and the passage of time. For the year ended December 31, 2019, changes in the fair value of contingent consideration expense reflected changes in the expected timing of achieving contingent milestones and the interest component related to the passage of time.

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, 2020, 2019 and 2018, we recorded $10.3, $12.0 and $25.5, respectively, in restructuring expenses.

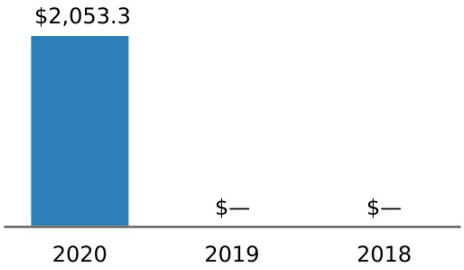
The charges for the year ended December 31, 2020 relate to restructuring activities initiated in the third quarter 2020 primarily within our commercial organization as part of an initiative intended to redefine our operating model. The actions are intended to reallocate resources necessary to align our organization with our diversifying portfolio of new products and strategic objectives, and will include investments in digital capabilities, technologies and solutions to support a more virtual and digital customer experience and tailored to the markets in which we operate.

The actions are expected to be substantially completed during 2021, with the cumulative pretax costs to be incurred by the Company to implement the program estimated to be approximately $10.0. We expect that the pretax costs will primarily result in cash outlays, as the costs primarily relate to employee separation expenses.

The charges for the year ended December 31, 2019 relate to restructuring activities initiated in the first quarter 2019 to re-align our international commercial organization.

The charges for the year ended December 31, 2018 were mainly attributable to the relocation of our corporate headquarters from New Haven, Connecticut to Boston, Massachusetts and other related costs.

Impairment of Intangible Assets

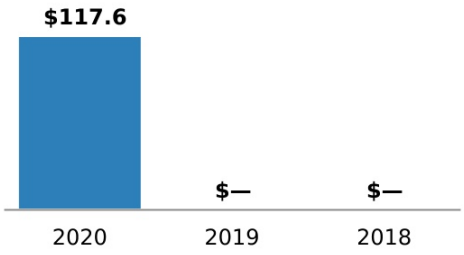


During the year ended December 31, 2020, we recorded impairment charges of $2,053.3, relating to KANUMA and ACHN-4471 (ALXN2040). No impairment charges were incurred during the years ended December 31, 2019 and 2018.

During the quarter ended June 30, 2020, based on continued challenges expanding patient growth and new alternative commercial opportunities, the Company revised its strategic view of KANUMA and determined that we have exhausted commercially viable initiatives related to KANUMA and will have difficulty expanding patient growth over the long term as we focus on promoting other commercial programs and growing our pipeline. As a result, we no longer expect to increase the number of KANUMA patients in the long term at the rate previously assumed. This determination resulted in reduced cash flow projections for KANUMA, which indicated that the related intangible asset value was not fully recoverable on an undiscounted cash flows basis. On June 30, 2020, the Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to KANUMA that, when compared with its related carrying value, resulted in an impairment charge of $2,042.3.

During the quarter ended June 30, 2020, we recognized an impairment charge of $11.0 to write off the cost basis of our ACHN-4471 (ALXN2040) acquired in-process research and development asset due to clinical results received during the quarter.

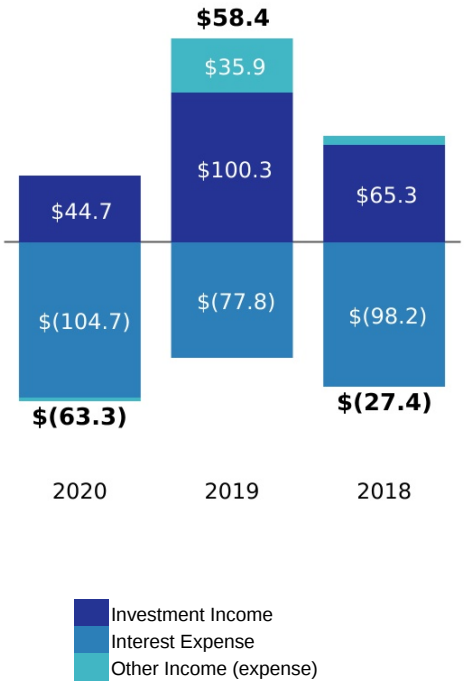
Acquisition-Related Costs



For the year ended December 31, 2020, we recorded $117.6 of acquisition-related costs. Acquisition-related costs were primarily recorded in connection with the Achillion and Portola acquisitions. Acquisition-related costs consist primarily of transaction costs, costs associated with the accelerated vesting of equity awards previously granted to Achillion and Portola employees, and Achillion and Portola employee separation costs. No acquisition-related costs were incurred during the years ended December 31, 2019 and 2018.

Other Income and (Expense)

The following table provides information regarding other income and expense:

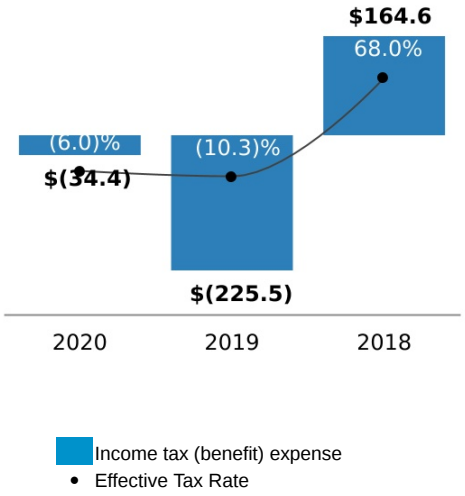


For the years ended December 31, 2020 and 2019, we recognized other income (expense) of $(3.3) and $35.9, respectively. The decrease in other income is primarily related to a gain of $32.0 resulting from an amendment to the terms of our option agreement with Caelum in the fourth quarter of 2019.

For the years ended December 31, 2020, 2019 and 2018, we recognized investment income of $44.7, $100.3 and $65.3, respectively, primarily related to unrealized and realized gains and losses on our strategic equity investments recorded at fair value. For the year ended December 31, 2020, we recorded gains of $76.5 on our strategic equity investments, primarily driven by an unrealized gain of $45.4 from our Eidos equity investment and a realized gain of $29.7 from our Portola equity investment which was derecognized and included in the fair value of consideration transferred in connection with the Portola acquisition. Gains recorded on our strategic equity investments were partially offset by a $49.0 impairment of our Caelum investment option to reduce the carrying value of our investment in the option to its fair value. For the year ended December 31, 2019, we recorded unrealized gains of $26.9 on our strategic equity investments and recognized a net realized gain of $32.8 related to the sale of our Moderna Therapeutics Inc. (Moderna) equity investment. For the year ended December 31, 2018, we recorded unrealized gains of $43.0 on our strategic equity investments, primarily related to our Moderna equity investment.

For the years ended December 31, 2020, 2019 and 2018, we recorded $104.7, $77.8 and $98.2, respectively, in interest expense. The increase in interest expense for the year ended December 31, 2020 as compared with the same period in 2019 is driven by an increase in the average interest rates associated with our interest rate swaps, partially offset by lower term loan borrowings and lower interest rates, which are based on market rates, on the unhedged portion of our outstanding term loan. The decrease in interest expense for the year ended December 31, 2019 as compared with the same period in 2018 is driven by the derecognition of certain previously recorded build-to-suit arrangements in the first quarter 2019 due to the adoption of the new lease accounting standard.

Income Taxes



The income tax expense (benefit) for the years ended December 31, 2020, 2019 and 2018 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. During the year ended December 31, 2020, we recorded income tax (benefit) expense of $(34.4) and an effective tax rate of (6.0)%, compared to an income tax (benefit) expense of $(225.5) and $164.6 and an effective tax rate of (10.3)% and 68.0% for the years ended December 31, 2019 and 2018, respectively.

During the second quarter 2020, we recognized an impairment charge of $2,042.3 related to the KANUMA intangible asset, resulting in a deferred tax benefit of $377.3. Refer to Note 4, *Intangible Assets and Goodwill*, for additional information on the impairment charge. These deferred tax benefits decreased the effective tax rate for the year ended December 31, 2020 by approximately 19.2%.

In April 2020 we became aware of a European withholding tax regulation that could be interpreted to apply to certain of our previous intra-group transactions. We continue to evaluate whether the interpretation of this regulation applies to our facts and circumstances, and, based on our preliminary analysis, we recorded an immaterial reserve related to this matter during the second quarter of 2020.

In August 2020, we received a notice of examination from the Dutch Tax Authorities (“DTA”) regarding certain matters relating to our 2014 through 2017 tax years. We entered into an agreement with the DTA in December 2020 and have agreed to pay approximately $73.8 in connection with the settlement, inclusive of the 2018 and 2019 tax years. After taking into account the $56.1 U.S. foreign tax credit claimed on the settlement, the net cash outflow was $17.7, representing a 3.1% net increase to the effective tax rate.

In 2017, the Internal Revenue Service (IRS) commenced an examination of our U.S. income tax returns for 2015. During the second quarter of 2020 we received a Revenue Agent Report (RAR) and held discussions with the IRS regarding a proposed adjustment related to the valuation of certain intellectual property that was contributed into our captive partnership during 2015. The Company agreed with the adjustment outlined in the RAR and recognized a previously unrecognized tax benefit in the second quarter of 2020 that did not result in a significant impact to the financial statements. The IRS concluded its examination during the third quarter 2020 without additional adjustments.

For the year ended December 31, 2019, we recognized certain one-time deferred tax benefits including $95.7 and $30.3 associated with a tax election made with respect to intellectual property of Wilson Therapeutics and a valuation allowance release and corresponding recognition of net operating losses, respectively. These deferred tax benefits are offset by income tax expense of $10.2 associated with the July 1, 2019 integration of the Wilson Therapeutics intellectual property into the Alexion corporate structure.

A comprehensive analysis of our prior year estimate related to our foreign-derived intangible income (“FDII”) was completed during the third quarter 2019 based on additional guidance provided in the proposed regulations issued by the U.S. Treasury Department in 2019. The analysis resulted in income tax benefit of $17.0 related to the prior year, which was recorded as a change in estimate in income tax expense in our 2019 consolidated statements of operations, resulting in a decrease of approximately 0.8% to our effective tax rate.

During the fourth quarter 2019, we completed an intra-entity asset transfer of certain intellectual property to an Irish subsidiary within our captive foreign partnership. We recognized deferred tax benefits of $2,221.5 which represents the difference between the basis of the intellectual property for financial statement purposes and the basis of the intellectual property for tax purposes, applying the appropriate enacted statutory tax rates. We will receive future tax deductions associated with amortization of the intellectual property, and any amortization not deducted for tax purposes will be carried forward indefinitely under Irish tax law. An offsetting deferred tax expense of $1,839.3 has been recognized to reflect the reduction of future foreign tax credits associated with the foreign local tax amortization deductions. These net deferred tax benefits resulted in a decrease of approximately 17.5% to our effective tax rate.

The income tax expense for the year ended December 31, 2018 includes an increase in the effective tax rate of 102.6% 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.

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 recorded adjustments to our Tax Act 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.

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, 2020 and 2019:

	December 31, 2020	December 31, 2019	$ Change
Cash and cash equivalents	$ 2,964.5	$ 2,685.5	$ 279.0
Marketable securities	34.9	64.0	(29.1)
Long-term debt (includes current portion & revolving credit facility)	2,570.9	2,514.5	56.4
Current assets	$ 5,833.0	$ 5,076.4	$ 756.6
Current liabilities	1,624.7	1,194.3	430.4
Working capital	$ 4,208.3	$ 3,882.1	$ 326.2

The aggregate increase in cash and cash equivalents and marketable securities of $249.9 at December 31, 2020 as compared to December 31, 2019 was primarily attributable to cash generated from operations and proceeds from maturity or sale of available-for-sale debt securities. Partially offsetting these increases was $2,023.0 of cash utilized to fund the Achillion and Portola acquisitions, net of $480.9 of cash and cash equivalents and marketable securities acquired in the transactions and $196.9 of cash paid to settle preexisting debt held by Portola; cash utilized to repurchase shares of common stock, payments on our term loan facility, purchases of property, plant, and equipment and strategic equity investments and options.

Excluding the impact of any significant future asset acquisitions, licenses or collaboration agreements, we expect our annual operating expenses to decrease as a percentage of sales in 2021 as compared to 2020, primarily due to the impairments of intangible assets of $2,053.3 recorded during the second quarter 2020. We expect increased capital investment in 2021 as compared to 2020. 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.

Without limiting the generality of the foregoing, we are subject to a variety of specified restrictions under the Merger Agreement. Unless we obtain AstraZeneca's prior written consent (which consent may not be unreasonably withheld, conditioned or delayed) and except (i) as required or expressly contemplated by the Merger Agreement, (ii) as required by applicable law or (iii) as set forth in the confidential disclosure schedule delivered by Alexion to AstraZeneca, we may not, among other things and subject to certain exceptions and aggregate limitations, incur additional indebtedness, issue additional shares of our common stock outside of our equity incentive plans, repurchase our common stock, pay dividends, acquire assets, securities or property, dispose of businesses or assets, enter into material contracts or make certain additional capital expenditures.

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, royalty-based debt and contingent payments associated with our in-licenses and 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), especially in light of increased volatility within the global financial markets as a result of the COVID-19 pandemic, 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, 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. As of December 31, 2020, four customers accounted for 66.8% of the accounts receivable balance, with these individual customers accounting for 11.7% to 22.1% of the accounts receivable balance. As of December 31, 2019, four customers accounted for 66.9% of the accounts receivable balance, with these individual customers accounting for 11.6% to 20.3% of the accounts receivable balance.

For the year ended December 31, 2020, three customers accounted for 47.4% of our net product sales with these individual customers accounting for 14.7% to 16.7% of our net product sales. For the year ended December 31, 2019, four customers accounted for 56.4% of our net product sales with these individual customers accounting for 10.0% to 16.8% of our net product sales. For the year ended December 31, 2018, four customers accounted for 50.3% of our net product sales with these individual customers accounting for 10.0% to 16.4% of our net product sales.

We continue to monitor economic conditions, including volatility associated with international economies and the COVID-19 pandemic, 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. As a result of the COVID-19 pandemic, we have experienced an increase in requests for extended payment terms with certain customers. To date, we have not experienced any significant losses with respect to collection of our accounts receivable and do not currently anticipate any material credit losses on our accounts receivable as a result of the pandemic.

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, 2020, we had foreign exchange forward contracts with notional amounts totaling $3,253.5. These outstanding foreign exchange forward contracts had a net fair value liability of $55.2, of which $26.1 is included in other current assets and $81.3 is included in other current liabilities and other noncurrent liabilities. As of December 31, 2020, we had interest rate swap contracts with notional amounts totaling $1,750.0. These outstanding interest rate swap contracts had a net fair value liability of $91.3, which is included in other current liabilities and other noncurrent liabilities. The counterparties to these contracts are large domestic and multinational commercial banks, and we believe the risk of nonperformance is not material.

As of December 31, 2020, our financial assets and liabilities were recorded at fair value. We have classified our financial assets and liabilities as Level 1, 2 or 3 within the fair value hierarchy. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Our Level 1 assets consist of mutual fund investments and equity securities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, but substantially the full term of the financial instrument. Our Level 2 assets consist primarily of money market funds, 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 business acquisitions.

Business Combinations and Contingent Consideration Obligations

On January 28, 2020, we completed the acquisition of Achillion. Under the terms of the agreement, we acquired all outstanding common stock of Achillion for $6.30 per share, or an aggregate of $926.2, inclusive of the settlement of Achillion's outstanding equity awards. The acquisition was funded with cash on hand. The transaction includes the potential for additional consideration in the form of non-tradeable contingent value rights, which will be paid to Achillion shareholders if certain clinical and regulatory milestones are achieved within specified periods. These include $1.00 per share for the U.S. Food and Drug Administration (FDA) approval of

danicopan and $1.00 per share for the initiation of a Phase III clinical trial in ACH-5228 (ALXN2050).

On July 2, 2020, we completed the acquisition of Portola. Under the terms of the agreement, we acquired all outstanding common stock of Portola for $18.00 per share, or an aggregate of approximately $1,380.8, including the settlement of certain of Portola's outstanding equity awards but excluding shares of Portola stock held by Alexion at closing. The acquisition was funded with cash on hand. In connection with the acquisition, we also paid $196.9 to settle certain debt held by Portola that was subject to preexisting change of control provisions. The repayment of Portola's debt was funded with cash acquired from Portola. Additionally, we assumed royalty-based debt which requires repayment through tiered royalties on future net worldwide sales of ANDEXXA.

As of December 31, 2020, the purchase agreements for our business combinations, including Achillion, include contingent payments totaling up to $905.6 that will become payable if and when certain development and commercial milestones are achieved. Of these milestone amounts, $670.6 of the contingent payments relate to development and regulatory milestones and $235.0 of the contingent payments relate to commercial milestones, respectively. We do not expect these amounts to have a significant impact on our liquidity in the near-term. During the next 12 months, we expect to make milestone payments of $120.0 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 In-License Agreements

In January 2019, we entered into an agreement with Caelum, a biotechnology company that is developing CAEL101 for AL amyloidosis. Under the terms of the agreement, we acquired a minority equity interest in preferred stock of Caelum and an exclusive option to acquire the remaining equity in Caelum based on Phase II data, for pre-negotiated economics. We paid $30.0 in the first quarter 2019 and agreed to pay up to an additional $30.0 in contingent development milestones prior to exercising the option to acquire the remaining equity in Caelum. Following discussions with the FDA, Caelum changed its clinical development plan for CAEL-101 in the fourth quarter 2019. In December 2019, we amended the terms of the agreement with Caelum to modify the option to acquire the remaining equity in Caelum based on data from the modified Phase II/III trials. The amendment also modified the development-related milestone events associated with the initial $30.0 in contingent payments, provided for an additional $20.0 in upfront funding, as well as funding of $60.0 in exchange for an additional equity interest at fair value upon achievement of a specific development-related milestone event. We paid the additional $20.0 in upfront funding and the initial $30.0 in contingent payments in 2020. The agreement with Caelum also provides for additional payments, in the event Alexion exercises the purchase option, for up to $500.0, which includes an upfront option exercise payment and potential regulatory and commercial milestone payments.

In March 2019, we entered into an agreement with Zealand which provides us with exclusive worldwide licenses, as well as development and commercial rights, for subcutaneously delivered preclinical peptide therapies directed at up to four complement pathway targets. Pursuant to the agreement, Zealand will lead joint discovery and research efforts through the preclinical stage, and Alexion will lead development efforts beginning with the investigational new drug filing and Phase I studies. In addition to the agreement, we made an equity investment in Zealand (refer to Note 7, *Other Investments*). Under the terms of the agreement, we made an upfront payment of $40.0 for an exclusive license to the lead target and the equity investment, as well as for preclinical research services to be performed by Zealand in relation to the lead target. As of December 31, 2020, we could be required to pay up to $610.0, for the lead target, upon the achievement of specified development, regulatory and commercial milestones, as well as royalties on commercial sales. In addition, we could be required to pay up to an additional $115.0 in development and regulatory milestones if both a long-acting and short-acting product are developed with respect to the lead target. Each of the three subsequent targets can be selected for an option fee of $15.0 and has the potential for additional development, regulatory and commercial milestones, as well as royalty payments, at a reduced price to the lead target.

In September 2019, we entered into an agreement with Eidos through which Alexion obtained an exclusive license to develop and commercialize AG10 in Japan. AG10 is a small molecule designed to treat the root cause of transthyretin amyloidosis (ATTR) and is currently in a Phase III study in the U.S., Europe, and Japan for ATTR cardiomyopathy (ATTR-CM). In addition, we made an equity investment in Eidos (refer to Note 7, *Other Investments*). Under the terms of the agreement, we made an upfront payment of $50.0 for the exclusive license to AG10 in Japan and the equity investment. As of December 31, 2020, we could also be required to pay $30.0 upon achievement of a Japanese-based regulatory milestone as well as royalties on commercial sales.

In October 2018, we entered into a collaboration agreement with 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. In December 2019, we exercised our option for exclusive rights to two additional targets within the complement pathway under an existing agreement with Dicerna, which expands our existing research collaboration and license agreement with Dicerna to include a total of four targets within the complement pathway. In connection with the option exercise, we paid Dicerna $20.0 in the fourth quarter 2019. As of December 31, 2020, excluding accrued milestones, we could be required to pay up to $604.1 for amounts due upon the achievement of specified research, development, regulatory and commercial milestones on the four licensed targets, 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. Under the terms of the agreement, we made an upfront payment of $40.0 for an exclusive license to two of the four potential targets during the fourth quarter 2017. During the second quarter 2020, we forfeited our rights to one of the two targets we initially licensed. As of December 31, 2020, we could be required to pay up to $155.0 for the remaining licensed target upon achievement of specified development, regulatory and sales-based milestones, as well as royalties on commercial sales. Each of the two subsequent targets can be licensed for an option fee of $8.0, with contingent payments of up to $160.0 per target, subject to development, regulatory and commercial milestones, as well as royalties on commercial sales.

In connection with our prior acquisition of Syntimmune, Inc., a clinical-stage biotechnology company developing an antibody therapy targeting the FcRn, we could be required to pay up to $800.0 upon the achievement of specified development, regulatory and commercial milestones, of which $130.0 is specific to the subcutaneous formulation. We are currently subject to a claim in litigation in connection with the Syntimmune acquisition alleging that Alexion failed to meet its obligations under the merger agreement to use commercially reasonable efforts to achieve the milestones and plaintiff has requested payment of the full earn-out amount. The outcome on this litigation may have an impact on the results of our operations in the future.

In addition, excluding accrued milestones, as of December 31, 2020, we have other license agreements under which we may be required to pay up to an additional $114.0 for currently licensed targets, if certain development, regulatory and commercial milestones are met, including up to $71.5 for the development of cerdulatinib in multiple indications pursuant to an in-licensing agreement with Astellas Pharma, Inc. which was assumed through the acquisition of Portola in the third quarter 2020. Additional amounts may be payable if we elect to acquire licenses to additional targets, as applicable, under the terms of these agreements.

We do not expect the payments associated with milestones under our asset acquisitions, option and in-license 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 $71.1, excluding milestones which were accrued as of December 31, 2020.

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.

Operating and Financing Lease Liabilities

Operating and financing lease liabilities are recorded at lease commencement and upon remeasurement events, if applicable, based on the present value of fixed, or in substance fixed, lease payments over the expected lease term. Lease liabilities are amortized over the lease term.

As of December 31, 2020, we have $278.1 of total financing and operating lease liabilities recorded on our consolidated balance sheets. The total undiscounted lease commitments as of December 31, 2020 was $329.3, of which $43.4 is payable during the next 12 months. Refer to Note 10, *Leases* for a summary of the maturity of our lease liabilities by year. We do not expect the payments associated with the maturity of lease liabilities to have a significant impact on our liquidity in the near-term.

Long-term Debt

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 amended and restated our credit agreement dated as of June 22, 2015.

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 the term loan facility mature on June 7, 2023. Beginning with the quarter ending June 30, 2019, we are required to make payments of 5.0% of the original principal amount of the term loan facility annually, payable in equal quarterly installments.

As of December 31, 2020, we had $2,383.9 outstanding on the term loan. We had no outstanding borrowings under the revolving credit facility as of December 31, 2020. As of December 31, 2020, we had open letters of credit of $1.0 that offset our borrowing availability on the revolving credit facility.

In connection with our acquisition of Portola during the third quarter 2020, we assumed royalty-based debt relating to a royalty sales agreement Portola had entered into with HealthCare Royalty Partners (HCR) whereby HCR acquired a tiered royalty interest in future worldwide net sales of ANDEXXA. Portola received $50.0 upon closing of the agreement in February 2017 and an additional $100.0 following the U.S. regulatory approval of ANDEXXA in May 2018. Tiered royalties ranging from 4.2% to 8.5% are required to be paid to HCR based on net worldwide sales of ANDEXXA. The applicable rate decreases as worldwide net annual sales levels increase above defined thresholds. Total potential royalty payments are capped at 195.0% of the funding received less certain transaction expenses, or $290.6.

As of December 31, 2020, the royalty-based debt has a carrying value of $187.0, net of unamortized debt discount of $84.9, of which $15.5 was recorded within current portion of long-term debt. The maximum remaining royalty payments are capped at $271.9, as of December 31, 2020.

Manufacturing Obligations

We have supply agreements with Lonza relating to the manufacture of SOLIRIS, STRENSIQ, ULTOMIRIS and ANDEXXA which require 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 $1,137.8 through 2030. 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 pay Lonza a royalty on the sales of SOLIRIS and ULTOMIRIS manufactured at Lonza facilities.

In addition to Lonza, we have non-cancellable commitments of approximately $175.6 through 2023 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. In February 2017, our Board of Directors increased the amount that we are authorized to expend on future repurchases to $1,000.0 under our repurchase program, which superseded all prior repurchase programs. The entire amount authorized pursuant to this February 2017 Board approval has been utilized. On October 22, 2019, the Board of Directors approved a share repurchase authorization of up to $1,000.0. On July 28, 2020, the Board of Directors approved a new share repurchase authorization of up to an additional $1,500.0. 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 our discretion. Under the program, we repurchased 4.9 and 3.8 shares of our common stock at a cost of $510.8 and $416.0 during the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, there is a total of $2,024.7 remaining for repurchases under the repurchase programs.

Cash Flows

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

	Year Ended December 31,		
	2020	2019	$ Change
Net cash provided by operating activities	$ 3,002.9	$ 2,084.9	$ 918.0
Net cash (used in) provided by investing activities	(2,099.5)	9.7	(2,109.2)
Net cash used in financing activities	(611.9)	(739.1)	127.2
Effect of exchange rate changes on cash and cash equivalents and restricted cash	19.5	0.8	18.7
Net change in cash and cash equivalents and restricted cash	$ 311.0	$ 1,356.3	$ (1,045.3)

Operating Activities

Cash flows provided by operations in 2020 was $3,002.9 compared to $2,084.9 in 2019. The increase in cash provided by operating activities was primarily due to cash generated from operations, including the timing of cash receipts, payments and other changes in working capital during 2020 as compared to 2019. Additionally, the prior year included upfront payments made in connection with agreements entered into with Zealand, Affibody, Eidos and Stealth BioTherapeutics Corp. and a payment of a sales-based milestone to the former equity holders of Enobia Pharma Corp.

Investing Activities

Cash used in investing activities in 2020 was $2,099.5 compared to cash provided by investing activities of $9.7 in 2019. The increase in cash used in investing activities as compared to the prior year was primarily due to payments for the acquisition of Achillion and Portola, net of cash acquired, of $2,111.9. Partially offsetting these impacts were decreases in purchases of property, plant and equipment and purchases of strategic equity investments and options during 2020 as compared to 2019.

Financing Activities

Cash flows used in financing activities in 2020 was $611.9 compared to $739.1 in 2019. The decrease in cash used in financing activities was primarily due to a decrease in payments on our revolving credit facility, partially offset by an increase of $94.8 in common stock repurchases and an increase of $32.6 in payments on our term loan during 2020, as compared to 2019.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2020 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 as of December 31, 2020, 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]	$ 2,655.8	$ 146.1	$ 2,326.1	$ 140.1	$ 43.5
Interest expense [2]	239.1	94.0	124.7	20.1	0.3
Financing leases	91.4	9.0	18.4	19.0	45.0
Operating leases	237.9	34.4	57.2	43.2	103.1
Total contractual obligations	$ 3,224.2	$ 283.5	$ 2,526.4	$ 222.4	$ 191.9
Commercial commitments:					
Clinical and manufacturing development [3]	$ 1,313.4	$ 348.8	$ 397.7	$ 232.0	$ 334.9
Total commercial commitments	$ 1,313.4	$ 348.8	$ 397.7	$ 232.0	$ 334.9

[1] Includes our term loan facility and royalty-based debt balances. We are required to make payments of 5.0% of the original principal amount of the term loan facility annually, payable in equal quarterly installments. We have no outstanding borrowings under the revolving credit facility as of December 31, 2020. We are required to make tiered royalty payments based on net worldwide sales of ANDEXXA. This requires estimation of the timing and amount of future royalty payments to be generated from future sales of ANDEXXA.

[2] Interest on variable rate debt is calculated based on interest rates at December 31, 2020. Interest that is fixed, associated to our interest rate swaps, is calculated based on the fixed interest swap rate at December 31, 2020. Royalty-based debt interest expense is recognized using the effective interest rate method over the estimated period the related debt will be paid.

[3] Clinical and manufacturing development commitments include only non-cancellable commitments, including all Lonza agreements, at December 31, 2020.

Except for our royalty-based debt, 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 $163.4 as of December 31, 2020 was not included within the table above. The timing of the settlement of these amounts was not reasonably estimable as of December 31, 2020.

Contingent payments related to business acquisitions, asset acquisitions, option or in-license agreements are not included within the table above, as the satisfaction of the contingent consideration obligations and if satisfied, the timing of payment for these amounts is uncertain as of December 31, 2020. Contingent payments associated with prior business combinations total up to $905.6, 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 $120.0 associated with our prior business combinations. Commitments related to asset acquisitions, option and in-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, option and in-license agreements of approximately $71.1, excluding milestones accrued as of December 31, 2020.

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, 2020. The total unfunded obligation on our defined benefit plans as of December 31, 2020 was $33.6. 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 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 5.0% of the aggregate original 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. We were in compliance with all applicable covenants under the Credit Agreement as of December 31, 2020.

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.

Royalty-Based Debt

In connection with our acquisition of Portola during the third quarter 2020, we assumed royalty-based debt relating to a royalty sales agreement Portola had entered into with HealthCare Royalty Partners (HCR) whereby HCR acquired a tiered royalty interest in future worldwide net sales of ANDEXXA. Portola received $50.0 upon closing of the agreement in February 2017 and an additional $100.0 following the U.S. regulatory approval of ANDEXXA in May 2018. Tiered royalties ranging from 4.2% to 8.5% are required to be paid to HCR based on net worldwide sales of ANDEXXA. The applicable rate decreases as worldwide net annual sales levels increase above defined thresholds. Total potential royalty payments are capped at 195.0% of the funding received less certain transaction expenses, or $290.6.

Interest expense is recognized using the effective interest rate method over the estimated period the related debt will be paid. This requires estimation of the timing and amount of future royalty payments to be generated from future sales of ANDEXXA. We reassess the expected royalty payments each reporting period and account for any changes through an adjustment to the effective interest rate on a prospective basis. The assumptions used in determining the expected repayment term of the debt require that we make estimates that could impact the short and long term classification of the debt carrying values.

Operating and Financing Leases

Our operating and financing 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

We have historically invested our cash in a variety of financial instruments, principally money market funds, bank deposits, corporate bonds, municipal bonds, commercial paper and government-related obligations which are subject to interest rate risk and could decline in value if interest rates fluctuate. Our investment portfolio has historically been 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. During the second quarter of 2020, we liquidated all of our available-for-sale debt securities to fund the acquisition of Portola. As of December 31, 2020, our investment portfolio primarily consists of money market funds and mutual funds. Based on the type of securities we hold, we do not believe a change in interest rates would have a material impact on our financial statements. If interest rates were to increase or decrease by 1%, the fair value of our investment portfolio would increase (decrease) by an insignificant amount.

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 amended and restated our credit agreement dated as of June 22, 2015. 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, 2020, we had cash flow hedges with aggregate amounts of approximately 73.4% 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 $5.7, based on the unhedged portion of our outstanding term loan as of December 31, 2020.

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 39.0% of our net product sales were denominated in foreign currencies during 2020, 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 intended to achieve the following: (1) limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet, using contracts with durations of up to 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, 2020 and 2019, we held foreign exchange forward contracts with notional amounts totaling $3,253.5 and $3,078.5, respectively. As of December 31, 2020 and 2019, our outstanding foreign exchange forward contracts had a net fair value of $(55.2) and $2.8, 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, 2020, 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 $127.5 at December 31, 2020. 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, the COVID-19 pandemic 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 and while we have begun to see an increase in requests for extended payment terms with certain customers as a result of the COVID-19 pandemic, we have not experienced any significant losses with respect to collection of our accounts receivable and 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 of this Annual Report on Form 10-K.

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, 2020. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of December 31, 2020, 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, 2020 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, 2020. Management's assessment of the effectiveness of the company's internal control over financial reporting as of December 31, 2020 did not include the Portola Pharmaceuticals, Inc. (Portola) business, which was acquired on July 2, 2020 and accounted for under the acquisition method of accounting for business combinations. Total assets and total revenues of the Portola business represented approximately 2.4% and 1.3%, respectively, of the accompanying consolidated financial statement amounts as of and for the year ended December 31, 2020. As permitted by guidelines established by the Securities and Exchange Commission, companies are allowed to exclude certain acquisitions from their assessments of internal control over financial reporting during the first year of an acquisition while integrating the acquired companies.

The effectiveness of our internal control over financial reporting as of December 31, 2020 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, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9A(T). CONTROLS AND PROCEDURES.

Not applicable

Item 9B. OTHER INFORMATION.

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this item with respect to our executive officers is provided under the caption entitled “Information about our Executive Officers” 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 or, alternatively, an amendment to this Annual Report on Form 10-K, under the captions “General Information About the Board of Directors” and “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 or an amendment to this Annual Report.

DELINQUENT SECTION 16(a) REPORTS

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 or, alternatively, an amendment to this Annual Report on Form 10-K, under the caption “Delinquent Section 16(a) Reports”, 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 or an amendment to this Annual Report.

CODE OF ETHICS

We have adopted the Alexion Pharmaceuticals, Inc. Code of Conduct, or code of ethics, that applies to directors, officers and employees of Alexion and its subsidiaries and complies with the requirements of Item 406 of Regulation S-K and the listing standards of the Nasdaq Global Select Market. Our code of ethics is available on our website within the Investor Relations portal (https://ir.alexion.com/corporate-governance). We amended the code of ethics in September 2019 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 or, alternatively, will be provided by an amendment to this Annual Report, 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 or an amendment to this Annual Report.

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 or, alternatively, will be provided by an amendment to this Annual Report, 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 or an amendment to this Annual Report.

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 or, alternatively, will be provided by an amendment to this Annual Report, 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 or an amendment to this Annual Report.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this Item will be set forth in our definitive Proxy Statement or, alternatively, will be provided by an amendment to this Annual Report, 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 or an amendment to this Annual Report.

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 Annual Report on Form 10-K.

(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)+

2.7 Agreement and Plan of Merger, dated October 15, 2019, by and among Alexion Pharmaceuticals, Inc., Beagle Merger Sub, Inc. and Achillion Pharmaceuticals, Inc. (28)

2.8 Agreement and Plan of Merger, dated as of May 5, 2020, between Portola Pharmaceuticals, Inc., Alexion Pharmaceuticals, Inc. and Odyssey Merger Sub Inc. (32)

2.9 Agreement and Plan of Merger, dated as of December 12, 2020, by and among AstraZeneca PLC, Delta Omega Sub Holdings Inc., Delta Omega Sub Holdings Inc. 1, Delta Omega Sub Holdings LLC 2, and Alexion Pharmaceuticals, Inc. (33)

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)

4.2 Description of Securities of the Registrant

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

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

10.3 Employment Agreement, dated June 5, 2017, by and between Anne-Marie Law and Alexion Pharmaceuticals, Inc. (29)**

10.4 Confidential Release and Separation Agreement by and between Anne-Marie Law and Alexion Pharmaceuticals, Inc. effective September 26, 2020 (34)**

10.5 Employment Agreement, dated as of June 5, 2017, by and between John J. Orloff and Alexion Pharmaceuticals, Inc. (29)**

10.6 Employment Agreement, dated as of September 17, 2019, by and between Aradhana Sarin and Alexion Pharmaceuticals, Inc. (31)**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10.25 Amended and Restated Credit Agreement, dated as of June 7, 2018, by and among Alexion Pharmaceuticals, 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)

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

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

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

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

10.30 Form of 2017 Incentive Plan Restricted Stock Unit Agreement for Director Annual Grant.(30)**

10.31 Form of 2017 Incentive Plan Restricted Stock Unit Agreement for Director Fees.(30)**

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

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

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

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

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

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

10.38 Alexion's Non-Employee Director Nonqualified Deferred Compensation Plan. (37)

10.39	Confidential Settlement and License Agreement, dated as of May 28, 2020, by and between Alexion Pharmaceuticals, Inc., Alexion Pharma International Operations Unlimited Company and Amgen Inc. (35)*
10.40	Contingent Value Rights Agreement dated as of January 28, 2020 among Alexion Pharmaceuticals, Inc. and Computershare Inc. (36)
21.1	Subsidiaries of Alexion Pharmaceuticals, Inc.
23.1	Consent of PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm
31.1	Certificate of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002.
31.2	Certificate of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
32.1	Certificate of Chief Executive Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.
32.2	Certificate of Chief Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.
101	The following materials from the Alexion Pharmaceuticals, Inc. Annual Report on Form 10-K for the year ended December 31, 2020 formatted in Inline eXtensible Business Reporting Language (iXBRL): (i) the Consolidated Balance Sheets as of December 31, 2020 and December 31, 2019, (ii) the Consolidated Statements of Operations for the years ended December 31, 2020, 2019 and 2018, (iii) the Consolidated Statements of Comprehensive Income for the years ended December 31, 2020, 2019 and 2018, (iv) the Consolidated Statements of Cash Flows for years ended December 31, 2020, 2019 and 2018, (v) the Consolidated Statements of Changes in Stockholders' Equity the years ended December 31, 2020, 2019 and 2018, and (vi) Notes to Consolidated Financial Statements.
104	The cover page from this Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL.

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(1) Incorporated by reference to our Report on Form 8-K, filed on February 3, 2011.
(2) Incorporated by reference to our Report on Form 8-K, filed on January 4, 2012.
(3) Incorporated by reference to our Report on Form 8-K, filed on February 7, 2012.
(4) Incorporated by reference to our 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.
(28) Incorporated by reference to our Report on Form 8-K, filed on October 16, 2019.
(29) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019.
(30) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019.
(31) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019.
(32) Incorporated by reference to our Report on Form 8-K, filed on May 7, 2020.

(33) Incorporated by reference to our Report on Form 8-K, filed on December 14, 2020.
(34) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020.
(35) Incorporated by reference to our Report on Form 8-K, filed on June 3, 2020.
(36) Incorporated by reference to our Report on Form 8-K, filed on January 28, 2020.
(37) Incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2019

+ Confidential treatment was granted for portions of such exhibit.
* Certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

** 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.

Date: February 8, 2021

Ludwig N. Hantson, Ph.D.
Chief Executive Officer
(principal executive officer)

By: /s/ Aradhana Sarin, M.D.

Date: February 8, 2021

Aradhana Sarin, M.D.
Executive Vice President and Chief Financial Officer
(principal financial officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Ludwig N. Hantson **Ludwig N. Hantson, Ph.D.**	Chief Executive Officer and Director (principal executive officer)	February 8, 2021
/s/ Aradhana Sarin **Aradhana Sarin, M.D.**	Executive Vice President and Chief Financial Officer (principal financial officer)	February 8, 2021
/s/ Daniel A. Bazarko **Daniel A. Bazarko, C.P.A.**	Senior Vice President and Chief Accounting Officer (principal accounting officer)	February 8, 2021
/s/ David R. Brennan **David R. Brennan**	Chairman	February 8, 2021
/s/ Felix J. Baker **Felix J. Baker, Ph.D.**	Director	February 8, 2021
/s/ Christopher J. Coughlin **Christopher J. Coughlin**	Director	February 8, 2021
/s/ Deborah Dunsire **Deborah Dunsire, M.D.**	Director	February 8, 2021
/s/ Paul A. Friedman **Paul A. Friedman, M.D.**	Director	February 8, 2021
/s/ John T. Mollen **John T. Mollen**	Director	February 8, 2021
/s/ Francois Nader **Francois Nader, M.D.**	Director	February 8, 2021
/s/ Judith A. Reinsdorf **Judith A. Reinsdorf, J.D.**	Director	February 8, 2021
/s/ Andreas Rummelt **Andreas Rummelt, Ph.D.**	Director	February 8, 2021

Alexion Pharmaceuticals, Inc.

Contents
For the Years Ended December 31, 2020, 2019 and 2018

Report of Independent Registered Public Accounting Firm

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

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Alexion Pharmaceuticals, Inc. and its subsidiaries (the “Company”) as of December 31, 2020 and 2019, and the related consolidated statements of operations, of comprehensive income, of changes in stockholders’ equity and of cash flows for each of the three years in the period ended December 31, 2020, including the related notes (collectively referred to as the “consolidated financial statements”). We also have audited the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management’s Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company’s consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As described in Management’s Report on Internal Control Over Financial Reporting, management has excluded Portola Pharmaceuticals, Inc. (“Portola”) from its assessment of internal control over financial reporting as of December 31, 2020 because it was acquired by the Company in a purchase business combination during 2020. We have also excluded Portola from our audit of internal control over financial reporting. Portola is a wholly-owned subsidiary whose total assets and total revenues excluded from management’s assessment and our audit of internal

control over financial reporting represent 2.4% and 1.3%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2020.

Definition and Limitations of Internal Control over Financial Reporting

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Definite-lived Intangible Asset Impairment - KANUMA Purchased Technology Intangible Asset

As described in Note 4 to the consolidated financial statements, the carrying value of the Company's purchased technology definite-lived intangible assets balance was $2,061.8 million as of December 31, 2020. During the quarter ended June 30, 2020, based on continued challenges expanding patient growth and new alternative commercial opportunities, the Company revised its strategic view of KANUMA, determined that they had exhausted commercially viable initiatives related to KANUMA, and will have difficulty expanding patient growth over the long term as the Company focuses on promoting other commercial programs and growing its pipeline. As a result, the Company no longer expects to increase the number of KANUMA patients in the long term at the rate previously assumed. This determination resulted in reduced cash flow projections for KANUMA, which indicated that the related intangible asset value was not fully recoverable on an undiscounted cash flows basis. As of June 30, 2020, management utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to KANUMA that, when compared with its related carrying value, resulted in an impairment charge of $2,042.3 million being recorded in the statement of operations. The estimated fair value of the KANUMA asset as of June 30, 2020 was determined using the excess earnings method, a variation of the income approach. The excess earnings method estimates the value of an intangible asset equal to the present value of the incremental after-tax cash flows attributable to that intangible asset over its remaining economic life. Long term cash flow projections for the asset require the use of significant estimates and judgements, including forecasted revenue growth rates, forecasted cost of goods sold and the discount rate.

The principal considerations for our determination that performing procedures relating to definite-lived intangible asset impairment – KANUMA purchased technology intangible asset is a critical audit matter are (i) the significant judgment by management when determining the fair value of the intangible asset; (ii) a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's significant assumptions related to the forecasted revenue growth rates, which included assumed net patient additions per year and assumed net price per vial; forecasted cost of goods sold; and the discount rate; and (iii) the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's identification of triggering events and definite-lived intangible asset impairment assessments, including controls over management's valuation of the KANUMA purchased technology intangible asset. These procedures also included, among others, (i) testing management's process for determining the fair value of the KANUMA purchased technology intangible asset; (ii) evaluating the appropriateness of the excess earnings method; (iii) testing the completeness and accuracy of underlying data used in the estimate; and (iv) evaluating the significant assumptions used by management related to the forecasted revenue growth rates, including assumed net patient additions per year and assumed net price per vial; forecasted cost of goods sold; and the discount rate. Evaluating management's assumptions related to the forecasted revenue growth rates involved evaluating whether the assumptions used by management were reasonable considering the current and past net patient additions per year and net price per vial invoiced within significant territories. Evaluating management's assumptions related to forecasted cost of goods sold involved evaluating whether the assumptions used by management were reasonable considering the current and past costs of manufacturing KANUMA. Professionals with specialized skill and knowledge were used to assist in the evaluation of the appropriateness of the Company's excess earnings method and the reasonableness of the discount rate assumption.

Valuation of Purchased Technology Intangible Assets Acquired in the Portola Pharmaceuticals, Inc. Acquisition

As described in Note 2 to the consolidated financial statements, the Company completed the acquisition of Portola Pharmaceuticals, Inc. for net consideration of $1,621.6 million in 2020, which resulted in a purchased technology intangible asset of $1,036.0 million being recorded. The purchased technology intangible asset relates to Portola's lead product ANDEXXA. The estimated fair value was determined using the excess earnings valuation method, a variation of the income valuation approach. The excess earnings valuation method estimates the value of an intangible asset equal to the present value of the incremental after-tax cash flows attributable to that intangible asset. Some of the more significant assumptions utilized in the asset valuation included the estimated net cash flows for ANDEXXA, including net revenues, cost of sales, research and development and other operating expenses, the potential regulatory and commercial success rates associated with ANDEXXA's current conditional approval status and planned extension into the urgent surgery setting, competitive trends impacting the assets, and tax rates. The fair value using the excess earnings valuation method was determined using a discount rate commensurate with the risks of ANDEXXA of 17.5%, which represents a rate of return that a market participant would expect for the asset. The acquired purchased technology intangible asset is being amortized over an estimated useful life of approximately 10 years. This fair value measurement was based on significant inputs not observable in the market and thus represents a Level 3 fair value measurement.

The principal considerations for our determination that performing procedures relating to the valuation of purchased technology intangible assets acquired in the Portola Pharmaceuticals, Inc. acquisition is a critical audit matter are (i) the significant judgment by management when determining the fair value of intangible assets acquired, which in turn led to a high degree of auditor judgment and subjectivity in performing procedures relating to the fair value measurement of intangible assets acquired; (ii) the significant audit effort in evaluating management's significant assumptions relating to the forecasted net cash flow projections including assumptions relating to the potential regulatory and commercial success rates associated with ANDEXXA's current conditional approval status and planned extension into the urgent surgery setting, and the estimated net revenues and the discount rate; and (iii) the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the acquisition accounting, including controls over management's valuation of the purchased technology intangible assets and controls over development of the cash flow projections and the discount rate assumptions utilized in the valuation of the intangible assets. These procedures also included, among others reading the purchase agreement and testing management's process for determining the fair value of purchased technology intangible assets. Testing management's process included (i) evaluating the appropriateness of the valuation method, (ii) testing the completeness and accuracy of data provided by management; (iii) evaluating the reasonableness of significant assumptions related to the cash flow projections, including the reasonableness of the potential regulatory and commercial success rates associated with ANDEXXA's current conditional approval status and planned extension into the urgent surgery setting, and the estimated net revenues by considering the past performance of the acquired business, as well as internal and external market data; and (iv) evaluating the reasonableness of the discount rate selected by management by evaluating a range of relevant benchmarks including the cost of debt, cost of equity, internal rate of return, and weighted average cost of capital. Professionals

with specialized skill and knowledge were used to assist in the evaluation of the appropriateness of the Company's excess earnings method and the reasonableness of the discount rate assumption.

/s/PricewaterhouseCoopers LLP
Boston, Massachusetts
February 8, 2021

We have served as the Company's auditor since 2002.

Alexion Pharmaceuticals, Inc.

Consolidated Balance Sheets
(amounts in millions, except per share amounts)

	December 31, 2020	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	$ 2,964.5	$ 2,685.5
Marketable securities	34.9	64.0
Trade accounts receivable, net	1,409.3	1,243.2
Inventories	775.7	627.6
Prepaid expenses and other current assets	648.6	456.1
Total current assets	5,833.0	5,076.4
Property, plant and equipment, net	1,238.8	1,163.3
Intangible assets, net	3,002.4	3,344.3
Goodwill	5,100.1	5,037.4
Right of use operating assets	223.1	204.0
Deferred tax assets	2,199.4	2,290.2
Other assets	506.2	429.0
Total assets	$ 18,103.0	$ 17,544.6
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 118.6	$ 74.0
Accrued expenses	1,084.7	892.7
Current portion of long-term debt	142.4	126.7
Current portion of contingent consideration	114.9	—
Other current liabilities	164.1	100.9
Total current liabilities	1,624.7	1,194.3
Long-term debt, less current portion	2,419.6	2,375.0
Contingent consideration	299.4	192.4
Deferred tax liabilities	1,632.2	2,081.4
Noncurrent operating lease liabilities	177.1	164.1
Other liabilities	298.8	265.6
Total liabilities	6,451.8	6,272.8
Commitments and contingencies (Note 11)		
Stockholders' Equity:		
Common stock, $.0001 par value; 290.0 shares authorized; 240.9 and 237.8 shares issued at 2020 and 2019, respectively	—	—
Additional paid-in capital	9,152.9	8,804.7
Treasury stock, at cost, 21.4 and 16.5 shares at 2020 and 2019, respectively	(2,620.3)	(2,105.9)
Accumulated other comprehensive loss	(124.6)	(66.8)
Retained earnings	5,243.2	4,639.8
Total stockholders' equity	11,651.2	11,271.8
Total liabilities and stockholders' equity	$ 18,103.0	$ 17,544.6

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

Alexion Pharmaceuticals, Inc.

Consolidated Statements of Operations
(amounts in millions, except per share amounts)

	Year Ended December 31,		
	2020	2019	2018
Net product sales	$ 6,069.1	$ 4,990.0	$ 4,130.1
Other revenue	0.8	1.1	1.1
Total revenues	6,069.9	4,991.1	4,131.2
Costs and expenses:			
Cost of sales (exclusive of amortization of purchased intangible assets)	553.5	394.5	374.3
Research and development	1,002.9	886.0	730.4
Selling, general and administrative	1,399.9	1,261.1	1,111.8
Acquired in-process research and development	—	(4.1)	1,183.0
Amortization of purchased intangible assets	253.7	309.6	320.1
Change in fair value of contingent consideration	61.2	11.6	116.5
Acquisition-related costs	117.6	—	—
Restructuring expenses	10.3	12.0	25.5
Impairment of intangible assets	2,053.3	—	—
Gain on sale of asset	(14.8)	—	—
Total costs and expenses	5,437.6	2,870.7	3,861.6
Operating income	632.3	2,120.4	269.6
Other income and expense:			
Investment income, net	44.7	100.3	65.3
Interest expense	(104.7)	(77.8)	(98.2)
Other income and (expense)	(3.3)	35.9	5.5
Income before income taxes	569.0	2,178.8	242.2
Income tax (benefit) expense	(34.4)	(225.5)	164.6
Net income	$ 603.4	$ 2,404.3	$ 77.6
Earnings per common share			
Basic	$ 2.74	$ 10.77	$ 0.35
Diluted	$ 2.72	$ 10.70	$ 0.35
Shares used in computing earnings per common share			
Basic	220.1	223.2	222.7
Diluted	222.0	224.8	224.5

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

Alexion Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Income
(amounts in millions)

	Year Ended December 31,		
	2020	2019	2018
Net income	$ 603.4	$ 2,404.3	$ 77.6
Other comprehensive income (loss), net of tax:			
Foreign currency translation	5.7	(1.0)	(0.5)
Unrealized gains (losses) on debt securities	0.1	0.2	(0.5)
Unrealized (losses) gains on pension obligation	(1.0)	(6.6)	2.2
Unrealized (losses) gains on hedging activities, net of tax (benefit) expense of $(18.8), $(14.5) and $7.3, respectively	(62.6)	(49.7)	23.5
Other comprehensive (loss) income, net of tax	(57.8)	(57.1)	24.7
Comprehensive income	$ 545.6	$ 2,347.2	$ 102.3

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

Alexion Pharmaceuticals, Inc.

Consolidated Statements of Changes in Stockholders' Equity
(amounts in millions)

	Common Stock		Additional Paid-In Capital	Treasury Stock at Cost		Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
	Shares Issued	Amount		Shares	Amount			
Balances, December 31, 2017	234.3	$ —	$ 8,290.3	12.0	$ (1,604.9)	$ (34.4)	$ 2,242.1	$ 8,893.1
Repurchase of common stock	—	—	—	0.7	(85.0)	—	—	(85.0)
Issuance of common stock under stock option and stock purchase plans	0.6	—	47.6	—	—	—	—	47.6
Issuance of restricted common stock	1.3	—	(0.3)	—	—	—	—	(0.3)
Share-based compensation expense	—	—	201.5	—	—	—	—	201.5
Net income	—	—	—	—	—	—	77.6	77.6
Other comprehensive income	—	—	—	—	—	24.7	—	24.7
Adoption of new accounting standards	—	—	—	—	—	—	6.1	6.1
Balances, December 31, 2018	236.2	$ —	$ 8,539.1	12.7	$ (1,689.9)	$ (9.7)	$ 2,325.8	$ 9,165.3
Repurchase of common stock	—	—	—	3.8	(416.0)	—	—	(416.0)
Issuance of common stock under stock option and stock purchase plans	0.4	—	29.9	—	—	—	—	29.9
Issuance of restricted common stock	1.2	—	—	—	—	—	—	—
Share-based compensation expense	—	—	235.7	—	—	—	—	235.7
Net income	—	—	—	—	—	—	2,404.3	2,404.3
Other comprehensive loss	—	—	—	—	—	(57.1)	—	(57.1)
Adoption of new accounting standards	—	—	—	—	—	—	(90.3)	(90.3)
Balances, December 31, 2019	237.8	$ —	$ 8,804.7	16.5	$ (2,105.9)	$ (66.8)	$ 4,639.8	$ 11,271.8
Repurchase of common stock	—	—	—	4.9	(510.8)	—	—	(510.8)
Issuance of common stock under stock option and stock purchase plans	0.9	—	60.2	—	—	—	—	60.2
Issuance of restricted common stock	2.2	—	—	—	—	—	—	—
Share-based compensation expense	—	—	280.8	—	(3.6)	—		277.2
Portola replacement equity awards attributable to the pre-combination period	—	—	7.2	—	—	—	—	7.2
Net income	—	—	—	—	—	—	603.4	603.4
Other comprehensive loss	—	—	—	—	—	(57.8)	—	(57.8)
Balances, December 31, 2020	240.9	$ —	$ 9,152.9	21.4	$ (2,620.3)	$ (124.6)	$ 5,243.2	$ 11,651.2

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

Alexion Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows
(amounts in millions)

	Year Ended December 31,		
	2020	2019	2018
Cash flows from operating activities:			
Net income	$ 603.4	$ 2,404.3	$ 77.6
Adjustments to reconcile net income to net cash flows from operating activities:			
Depreciation and amortization	329.4	376.8	405.3
Impairment of intangible assets	2,053.3	—	13.5
Change in fair value of contingent consideration	61.2	11.6	116.5
Payments of contingent consideration	—	(100.0)	—
Share-based compensation expense	281.1	237.0	203.0
Non-cash expense for acquired IPR&D	—	—	64.6
Deferred tax (benefit) expense	(283.4)	(455.4)	32.9
Unrealized foreign currency (gain) loss	(5.2)	(2.1)	4.8
Unrealized loss (gain) on forward contracts	6.4	(16.5)	(15.8)
Unrealized loss (gain) on strategic equity investments	3.0	(26.9)	(40.2)
Gain on sale of strategic equity investments	—	(32.8)	—
Gain on sale of asset	(14.8)	—	—
Gain on modification of purchase option	—	(32.0)	—
Gain on derecognition of Portola strategic equity investment	(29.7)	—	—
Inventory obsolescence charge	27.5	3.3	20.5
Other	4.5	(2.7)	(2.0)
Changes in operating assets and liabilities, excluding the effect of acquisitions:			
Accounts receivable	(139.4)	(319.2)	(208.8)
Inventories	95.0	(160.2)	(35.2)
Prepaid expenses, right of use operating assets and other assets	(111.9)	(31.0)	(155.6)
Accounts payable, accrued expenses, lease liabilities and other liabilities	122.5	230.7	(55.1)
Net cash provided by operating activities	3,002.9	2,084.9	426.0
Cash flows from investing activities:			
Purchases of available-for-sale debt securities	(19.4)	(80.2)	(782.7)
Proceeds from maturity or sale of available-for-sale debt securities	184.2	222.2	1,473.5
Purchases of mutual funds related to nonqualified deferred compensation plan	(19.7)	(17.6)	(12.1)
Proceeds from sale of mutual funds related to nonqualified deferred compensation plan	12.1	14.7	12.3
Purchases of property, plant and equipment	(106.7)	(154.7)	(213.0)
Payments for acquisitions of businesses, net of cash and restricted cash acquired	(2,111.9)	—	—
Purchases of strategic equity investments and options	(38.1)	(73.3)	(10.3)
Proceeds from sale of strategic equity investments	—	114.7	—
Purchases of intangible assets	—	(16.0)	—
Other	—	(0.1)	2.8
Net cash (used in) provided by investing activities	(2,099.5)	9.7	470.5
Cash flows from financing activities:			
Proceeds from revolving credit facility	—	—	250.0
Payments on revolving credit facility	—	(250.0)	—
Payments on term loan	(130.6)	(98.0)	(293.8)
Repurchase of common stock	(510.8)	(416.0)	(85.0)
Net proceeds from issuance of stock under share-based compensation arrangements	58.7	29.9	47.3
Other	(29.2)	(5.0)	(20.9)
Net cash used in financing activities	(611.9)	(739.1)	(102.4)
Effect of exchange rate changes on cash and cash equivalents and restricted cash	19.5	0.8	(11.2)
Net change in cash and cash equivalents and restricted cash	311.0	1,356.3	782.9
Cash and cash equivalents and restricted cash at beginning of period	2,723.6	1,367.3	584.4
Cash and cash equivalents and restricted cash at end of period	$ 3,034.6	$ 2,723.6	$ 1,367.3

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

Alexion Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows
(amounts in millions)

	Year Ended December 31,		
	2020	2019	2018
Supplemental cash flow disclosures:			
Cash paid for interest (net of amounts capitalized)	$ 99.9	$ 72.6	$ 90.9
Cash paid for income taxes	$ 248.9	$ 187.9	$ 163.9
Supplemental non-cash disclosures from investing and financing activities:			
Fair value of strategic investment and purchase option acquired, less upfront cash paid	$ —	$ 75.0	$ —
Operating ROU lease assets obtained in exchange for operating lease liabilities	$ 31.6	$ 27.5	$ —
Capitalization of construction costs related to facility lease obligations	$ —	$ —	$ 44.8
Accounts payable and accrued expenses for purchases of property, plant and equipment and intangible assets	$ 14.9	$ 13.3	$ 21.4
Contingent consideration issued in acquisition	$ 155.0	$ —	$ —
Fair value of equity shares in Portola settled at closing of the acquisition	$ 47.8	$ —	$ —
Fair value of replacement equity awards issued to Portola employees attributable to the pre-combination period	$ 7.2	$ —	$ —
Exchange of intellectual property rights for equity shares in Inozyme	$ 14.8	$ —	$ —

The following provides a reconciliation of cash and cash equivalents and restricted cash reported within the consolidated balance sheets to the total of such amounts shown in the consolidated statement of cash flows:

	Year Ended December 31,		
	2020	2019	2018
Cash and cash equivalents	$ 2,964.5	$ 2,685.5	$ 1,365.5
Restricted cash included in other current assets	$ 70.0	$ 37.8	$ 0.1
Restricted cash included in other noncurrent assets	$ 0.1	$ 0.3	$ 1.7
Total cash and cash equivalents and restricted cash reported in the consolidated statement of cash flows	$ 3,034.6	$ 2,723.6	$ 1,367.3

Amounts included in restricted cash primarily represent funds placed in escrow as a result of the judicial order issued by the Federal Court of Canada related to SOLIRIS pricing (Note 11, *Commitments and Contingencies)*.

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

1. Business Overview and Summary of Significant Accounting Policies

Business

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

As a leader in rare diseases for more than 25 years, Alexion has developed and commercializes two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), as well as the first and only approved complement inhibitor to treat anti-acetylcholine receptor (AChR) antibody-positive generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive. Alexion also has two highly innovative enzyme replacement therapies and the first and only approved therapies for patients with life-threatening and ultra-rare metabolic disorders, hypophosphatasia (HPP) and lysosomal acid lipase deficiency (LAL-D). With the acquisition of Portola Pharmaceuticals, Inc. (Portola) in July 2020, we added the first and only approved Factor Xa inhibitor reversal agent for patients treated with rivaroxaban or apixaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

In addition to our marketed therapies, we have a diverse pipeline resulting from internal innovation and business development. 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, metabolic disorders, cardiology, ophthalmology and acute care. We were incorporated in 1992 under the laws of the State of Delaware.

Merger Agreement with AstraZeneca

On December 12, 2020, we entered into an Agreement and Plan of Merger (the Merger Agreement) with AstraZeneca PLC, a public limited company incorporated under the laws of England and Wales (AstraZeneca), Delta Omega Sub Holdings Inc., a Delaware corporation and a wholly owned subsidiary of AstraZeneca (Bidco), Delta Omega Sub Holdings Inc. 1, a Delaware corporation and a direct, wholly owned subsidiary of Bidco (Merger Sub I) and Delta Omega Sub Holdings LLC 2, a Delaware limited liability company and a direct, wholly owned subsidiary of Bidco (Merger Sub II). The Merger Agreement provides, among other things, that subject to the satisfaction or waiver of the conditions set forth therein (1) Merger Sub I will merge with and into Alexion (the “First Merger”), with Alexion surviving the First Merger as a wholly owned subsidiary of Bidco, and (2) immediately following the effective time of the First Merger (the Effective Time), Alexion will merge with and into Merger Sub II (the Second Merger and, together with the First Merger, the Mergers), with Merger Sub II surviving the Second Merger as a wholly owned subsidiary of Bidco and an indirect wholly owned subsidiary of AstraZeneca.

Under the Merger Agreement, at the Effective Time (as defined in the Merger Agreement), each share of common stock, par value $0.0001 per share, of Alexion issued and outstanding immediately prior to the Effective Time (other than certain excluded shares as described in the Merger Agreement) will be converted into the right to receive (1) 2.1243 American depositary shares of AstraZeneca (or, at the election of the holder thereof, a number of ordinary shares of AstraZeneca equal to the number of underlying ordinary shares represented by such American depositary shares) and (2) $60.00 in cash, without interest (collectively, the Merger Consideration).

The boards of directors of both companies have unanimously approved the acquisition.

The respective obligations of Alexion and AstraZeneca to consummate the transactions contemplated by the Merger Agreement are subject to the satisfaction or waiver of a number of customary conditions, including: (1) the adoption of the Merger Agreement by Alexion’s stockholders; (2) approval of the transactions contemplated by the Merger Agreement by AstraZeneca’s shareholders; (3) the absence of any law or order prohibiting consummation of the Mergers; (4) AstraZeneca’s registration statement on Form F-4 having been declared effective by the Securities and Exchange Commission; (5) AstraZeneca’s shareholder circular (or, if required, prospectus) having been approved by the U.K. Financial Conduct Authority; (6) the American depository shares of AstraZeneca issuable in the Mergers (and the ordinary shares of AstraZeneca represented thereby) having been approved for listing on the Nasdaq; (7) the expiration or early termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the approval of the Mergers under the antitrust and foreign investment laws of other specified jurisdictions; (8) accuracy of the other party’s representations and warranties, subject to

certain materiality standards set forth in the Merger Agreement and (9) compliance by the other party in all material respects with such other party's obligations under the Merger Agreement.

Without limiting the generality of the foregoing, we are subject to a variety of specified restrictions under the Merger Agreement. Unless we obtain AstraZeneca's prior written consent (which consent may not be unreasonably withheld, conditioned or delayed) and except (i) as required or expressly contemplated by the Merger Agreement, (ii) as required by applicable law or (iii) as set forth in the confidential disclosure schedule delivered by Alexion to AstraZeneca, we may not, among other things and subject to certain exceptions and aggregate limitations, incur additional indebtedness, issue additional shares of our common stock outside of our equity incentive plans, repurchase our common stock, pay dividends, acquire assets, securities or property, dispose of businesses or assets, enter into material contracts or make certain additional capital expenditures.

Under the Merger Agreement, Alexion will be required to make a payment to AstraZeneca equal to $1,180.0 if the Merger Agreement is terminated in certain circumstances, including because the Alexion board of directors has changed its recommendation in favor of the Mergers or we terminated the Merger Agreement in order to enter into an agreement providing for a Company Superior Proposal (as defined in the Merger Agreement), and Alexion will be required to make a payment to AstraZeneca equal to $270.0 if the Merger Agreement is terminated because Alexion's stockholders fail to adopt the Merger Agreement. AstraZeneca will be required to make a payment to Alexion equal to $1,415.0 if the Merger Agreement is terminated in certain circumstances, including because the AstraZeneca board of directors has changed its recommendation in favor of the Mergers or because AstraZeneca's shareholders fail to approve the transactions contemplated by the Merger Agreement.

The acquisition is expected to close during the third quarter 2021, and upon completion, Alexion stockholders will own approximately 15.0% of the combined company.

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Alexion and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. For each of our business combinations, all of the assets acquired and liabilities assumed were recorded at their respective fair values as of the date of acquisition, and their results of operations are included in the consolidated financial statements from the date of acquisition.

Use of Estimates

Preparation of the consolidated financial statements in conformity with U.S. GAAP requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingent liabilities in our consolidated financial statements.

Due to the COVID-19 pandemic, there has been uncertainty and disruption in the global economy and financial markets. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including sales, expenses, reserves and allowances, manufacturing, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain. We are not aware of any specific event or circumstance that would require an update to our estimates, judgments and assumptions or a revision of the carrying value of our assets or liabilities as of February 8, 2021, the date of issuance of this Annual Report on Form 10-K. These estimates may change, as new events occur and additional information is obtained. Actual results may differ from these estimates under different assumptions or conditions and such differences may be material.

Dividend Policy

We have never paid a cash dividend on shares of our stock. We currently intend to retain our earnings to finance future operations and do not anticipate paying any cash dividends on our stock in the foreseeable future.

Critical Accounting Estimates

The preparation of our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S., requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities in our financial statements. We believe the most complex judgments result primarily from the need to make estimates about the effects of matters that are inherently uncertain and are significant to our

consolidated financial statements. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. We evaluate our estimates, judgments and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions and such differences may be material.

The most significant areas involving estimates, judgments and assumptions used in the preparation of our consolidated financial statements are as follows:

- Revenue recognition;
- Contingent liabilities;
- Share-based compensation;
- Valuation of acquired assets, including goodwill, intangible assets and inventory;
- Valuation of contingent consideration; and
- Income taxes.

Foreign Currency Translation

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

Cash and Cash Equivalents

Cash and cash equivalents are stated at cost plus accrued interest, which approximates fair value, and include short-term highly liquid investments with original maturities of three months or less. As of December 31, 2020 and 2019, cash equivalents were comprised of money market funds and other debt securities with maturities less than three months from the date of purchase.

Fair Value of Financial Instruments

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, other assets, accounts payable, accrued expenses and other liabilities approximate fair value due to their short-term maturities. Our marketable securities are valued based upon pricing of securities with similar investment characteristics and holdings. Our mutual fund investments and equity securities are valued based on quoted market prices in active markets with no valuation adjustment. Investments in equity securities of publicly traded companies which are subject to holding period restrictions are carried at fair value using an option pricing valuation model and observable market inputs such as the historical volatility of similar companies and risk-free interest rates. Our derivative financial instruments are measured at fair value using observable market inputs such as forward rates, interest rates, our own credit risk and our counterparties' credit risks. Our credit agreement and royalty-based debt obligations are recorded at historical cost, which approximates fair value. Our contingent consideration liabilities related to our acquisitions and derivative liabilities associated with certain option agreements are valued based on various estimates, including probability of success, estimated revenues, discount rates and amount of time until the conditions of the milestone payments are met.

Marketable Securities

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

Credit losses related to our available-for-sale debt securities are recorded through an allowance for credit losses within operating results and are limited to the amount by which the carrying value of the security exceeds its fair value. Unrealized gains and losses on our marketable debt securities related to interest rate changes and other

factors are included in accumulated other comprehensive income (loss) as a separate component of stockholders' equity.

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

Accounts Receivable

Our standard credit terms vary based on the country of sale and range from 30 to 120 days and all arrangements are payable within one year of the transfer of the product. Our consolidated average days' sales outstanding ranges from 70 to 80 days. 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. We monitor economic conditions and calculate allowances for estimated credit losses on our trade accounts receivable on a quarterly basis using an expected loss model. We assess whether collectibility is probable at the time of sale and on an ongoing basis. We use judgment as to our ability to collect outstanding receivables and provide allowances for the portion of receivables if and when collection becomes doubtful. As of December 31, 2020 and 2019, allowances on receivables were not material.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk are limited to cash equivalents, marketable securities, accounts receivable and our foreign exchange derivative contracts. We invest our cash reserves in money market funds or high-quality marketable 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.

As of December 31, 2020, four customers accounted for 66.8% of the accounts receivable balance, with these individual customers ranging from 11.7% to 22.1% of the accounts receivable balance. As of December 31, 2019, four customers accounted for 66.9% of the accounts receivable balance, with these individual customers ranging from 11.6% to 20.3% of the accounts receivable balance.

For the year ended December 31, 2020, three customers accounted for 47.4% of our product sales, with these individual customers ranging from 14.7% to 16.7% of our product sales. For the year ended December 31, 2019, four customers accounted for 56.4% of our product sales, with these individual customers ranging from 10.0% to 16.8% of our product sales. 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 our product sales. No other customers accounted for more than 10.0% of accounts receivable or net 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. We disaggregate our trade accounts receivable population into pools of similar risk characteristics based on underlying customer type and geographical location and assess current expected credit loss allowances based on available information. 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. To date, we have not experienced any significant losses with respect to collection of our accounts receivable.

(amounts in millions except per share amounts)

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined in a manner that approximates average costs.

The components of inventory are as follows:

	December 31,	
	2020	2019
Raw materials	$ 91.2	$ 41.2
Work-in-process	260.8	180.8
Finished goods	510.3	405.6
	$ 862.3	$ 627.6
Balance Sheet Classification:		
Inventories	$ 775.7	$ 627.6
Other assets	$ 86.6	$ —

Total inventories include ANDEXXA inventory acquired in connection with the July 2, 2020 Portola acquisition, but exclude acquired ANDEXXA validation batches of $60.9 that were manufactured under processes which are subject to regulatory approval. The acquired ANDEXXA inventory includes the acquisition-date fair value step-up, which is expensed within cost of sales as the inventory is sold to customers. For additional information on our acquisition of Portola, please refer to Note 2, *Acquisitions*.

We classify our inventory costs as long-term when we expect to utilize the inventory beyond our normal operating cycle and include these costs in other assets in our consolidated balance sheets. Inventories classified as long-term relate to ANDEXXA inventory, including inventory acquired in connection with the Portola acquisition.

Capitalization of Inventory Costs

We capitalize inventory produced for commercial sale, which may include costs incurred for certain products awaiting regulatory approval, or for inventory produced at new production facilities, when management considers it probable that the pre-approval inventories will be saleable. 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 of the product and facilities 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, the compilation of the regulatory application, and how far a facility has progressed along the approval process. 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. As of December 31, 2020 and 2019, the carrying value of inventory at unapproved production facilities was $39.8 and $60.5, respectively. We also capitalize costs associated with technology transfer, including engineering and validation activities, to our external CMO's within prepaid expenses and other current assets and other assets in our consolidated balance sheets. Upon regulatory approval, saleable inventory produced during the validation process is reclassified to inventory and expensed to cost of goods sold as the product is sold. Any costs associated with non-saleable inventory will remain in prepaid expenses and other current assets and other assets in our consolidated balance sheets, and will be amortized to costs of goods sold over the remaining life of the contract.

Products that have been approved by the U.S. Food and Drug Administration (FDA) or other regulatory authorities are also used in clinical programs to assess the safety and efficacy of the products for usage in diseases that have not been approved by the FDA or other regulatory authorities. The form of the products utilized for both commercial and clinical programs is identical and, as a result, the inventory has an "alternative future use" as defined in authoritative guidance. Raw materials and purchased drug product associated with clinical development programs are included in inventory and charged to research and development expense when the product enters the research and development process and no longer can be used for commercial purposes and, therefore, does not have an "alternative future use".

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

Inventory Write-Offs

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

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

Derivative Instruments

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

All qualifying hedging activities are documented at the inception of the hedge and must meet the definition of highly effective in offsetting changes to future cash. On a quarterly basis, we perform an assessment to confirm that outstanding hedges remain highly effective and continue to qualify for hedge accounting. We record the fair value of the qualifying hedges in prepaid expenses and other current assets, other assets, other current liabilities and other liabilities. All unrealized gains and losses on derivatives that are designated and qualify for hedge accounting are reported in other comprehensive income (loss) and recognized when the underlying hedged transaction affects earnings. When the forecasted transaction occurs, this amount is reclassified into the consolidated statement of operations and presented in the same financial statement line item as the hedged item.

Derivative instruments for which hedge accounting is not applied are recorded at fair value in prepaid expenses and other current assets and other current liabilities. Unrealized gains and losses resulting from changes in the fair value of these derivatives are reported in other income and expense.

Property, Plant and Equipment

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

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

Leasehold improvements and assets under financing lease arrangements are amortized over the lesser of the asset’s estimated useful life or the term of the respective lease. Maintenance costs are expensed as incurred.

Construction-in-progress reflects amounts incurred for property, plant, or equipment construction or improvements that have not been placed in service.

Leases

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. We adopted the new standard on January 1, 2019 using the modified retrospective approach. Upon adoption of the new lease standard, on January 1, 2019, we derecognized $472.8 of property, plant and equipment and other assets and $372.2 of facility lease obligations associated with previously existing build-to suit arrangements. We capitalized right of use (ROU) assets of $326.1, inclusive of opening adjustments of $70.8 primarily related to prepaid rent existing at transition, and $255.3 of lease liabilities, within our consolidated balance sheets upon adoption. At transition, we recorded a decrease of $90.3 to retained earnings, net of tax, primarily related to our derecognition of previously recorded build-to-suit arrangements.

At the inception of an arrangement, we determine if an arrangement is, or contains, a lease based on the unique facts and circumstances present in that arrangement. Lease classification, recognition, and measurement are then determined at the lease commencement date. For arrangements that contain a lease we (i) identify lease and non-lease components, (ii) determine the consideration in the contract, (iii) determine whether the lease is an operating or financing lease; and (iv) recognize lease ROU assets and liabilities. Lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable and as such, we use our incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

Most leases include options to renew and, or, terminate the lease, which can impact the lease term. The exercise of these options is at our discretion and we do not include any of these options within the expected lease term as we are not reasonably certain we will exercise these options. We have elected to combine lease components (for example fixed payments including rent) with non-lease components (for example, non-dedicated parking and common-area maintenance costs) on our real estate and commercial fleet asset classes. We separate lease and non-lease components on our embedded contract manufacturing organization (CMO) arrangements. Lease and non-lease components on these CMO arrangements are determined based on an allocation of the consideration in the contract to the embedded lease and non-lease components of the arrangement based on the relative standalone prices of these components.

Fixed, or in substance fixed, lease payments on operating leases are recognized over the expected term of the lease on a straight-line basis, while fixed, or in substance fixed, payments on financing leases are recognized using the effective interest method. Variable lease expenses that are not considered fixed, or in substance fixed, are recognized as incurred. Fixed and variable lease expense on operating leases is recognized within operating expenses within our consolidated statements of operations. Financing lease ROU asset amortization and interest costs are recorded within operating expenses and interest expense, respectively, within our consolidated statements of operations. We have operating and financing leases for corporate offices, research and development facilities, regional executive and sales offices, commercial fleet, and CMO embedded lease arrangements. We have elected the short-term lease exemption and, therefore, do not recognize a ROU asset or corresponding liability for lease arrangements with an original term of 12 months or less.

Operating leases are included in right of use operating assets, other current liabilities, and noncurrent operating lease liabilities in our consolidated balance sheet as of December 31, 2020 and 2019. Financing leases are included in property, plant and equipment, other current liabilities, and other liabilities in our consolidated balance sheet as of December 31, 2020 and 2019.

Manufacturing Facilities

We capitalize costs incurred for the construction of facilities which support commercial manufacturing. We also capitalize costs related to validation activities which are directly attributable to preparing the facility for its intended use, including engineering runs and inventory production necessary to obtain approval of the facility from government regulators for the production of a commercially approved drug. When the facility is substantially complete and ready

for its intended use and regulatory approval for commercial production has been received, we will place the asset in service.

The production of inventory for preparing the facility for its intended use requires two types of production: engineering runs which are used for testing purposes only and do not result in saleable inventory, and validation runs which are used for validating equipment and may result in saleable inventory. The costs associated with inventory produced during engineering runs and normal production losses during validation runs are capitalized to fixed assets and depreciated over the asset's useful life. Saleable inventory produced during the validation process is initially recorded as a fixed asset; however, upon regulatory approval, this inventory is reclassified to inventory and expensed in cost of goods sold as product is sold, or in research and development expenses as product is utilized in R&D activities. Abnormal production costs incurred during the validation process are expensed as incurred.

Acquisitions

Business combinations are accounted for using the acquisition method of accounting. Under the acquisition method of accounting, the tangible and intangible assets acquired and the liabilities assumed are recorded as of the acquisition date at their respective fair values. We evaluate a business as an integrated set of activities and assets that is capable of being conducted and managed for the purpose of providing a return in the form of dividends, lower costs or other economic benefits and consists of inputs and substantive processes applied to those inputs that have the ability to contribute to the creation of outputs. If substantially all of the fair value of gross assets acquired is concentrated in a single asset or group of similar identifiable assets, the assets do not represent a business. In an acquisition of a business, the excess of the fair value of the consideration transferred over the fair value of the net assets acquired is recorded as goodwill.

Acquisitions of assets or a group of assets that do not meet the definition of a business are accounted for as asset acquisitions using the cost accumulation method, whereby the cost of the acquisition, including certain transaction costs, is allocated to the assets acquired on the basis of relative fair values. No goodwill is recognized in an asset acquisition. Intangible assets that are acquired in an asset acquisition for use in research and development activities which have an alternative future use are capitalized as in-process research and development (IPR&D). Acquired IPR&D which has no alternative future use is recognized as research and development expense at acquisition. Contingent milestone payments associated with asset acquisitions are recognized when probable and estimable. These amounts are expensed to research and development if there is no alternative future use associated with the asset, or capitalized as an intangible asset if alternative future use of the asset exists.

Our consolidated financial statements include the results of operations of an acquired business after the completion of the acquisition.

Contingent Consideration

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

Intangible Assets

Our intangible assets generally consist of licensing rights, patents, purchased technology, acquired IPR&D and other intangibles. Intangible assets with definite lives are amortized based on their pattern of economic benefit over their estimated useful lives and reviewed periodically for impairment.

Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment. 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.

Goodwill

Goodwill represents the excess of purchase price over fair value of net assets acquired in a business combination and is not amortized. Goodwill is subject to impairment testing at least annually or when a triggering event occurs that could indicate a potential impairment. We are organized and operate as a single reporting unit and therefore the goodwill impairment test is performed using our overall market value, as determined by our traded share price, compared to our book value of net assets.

Impairment of Long-Lived Assets

Our long-lived assets are primarily comprised of intangible assets, right of use assets and property, plant and equipment. We evaluate our finite-lived intangible assets, right of use assets and property, plant and equipment for impairment whenever events or changes in circumstances indicate the carrying value of an asset or group of assets is not recoverable. If these circumstances exist, recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to future undiscounted net cash flows expected to be generated by the asset group. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets.

In addition, indefinite-lived intangible assets, comprised of IPR&D, are reviewed for impairment annually and whenever events or changes in circumstances indicate that it is more likely than not that the asset is impaired by comparing the fair value to the carrying value of the asset.

If the carrying value of a finite-lived intangible asset is not recoverable, or if there is an indicator of impairment on an indefinite-lived intangible asset, we will recognize an impairment in the amount by which the carrying value of the asset exceeds its fair value. We calculate the fair value of these assets using discounted cash flow models which require the use of significant estimates and judgements which include, but are 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, tax rates and discount rates. Changes to assumptions used in our cash flow projections could result in an impairment. Impairments are recorded within impairment of intangible assets in our consolidated statements of operations.

During the year-ended December 31, 2020, we recognized impairment charges of $2,053.3, related to a $2,042.3 impairment charge of our KANUMA intangible asset and an impairment charge of $11.0 to write off the cost basis of our ACHN-4471 (ALXN2040) acquired in-process research and development asset. Refer to Note 4, *Intangible Assets and Goodwill*, for additional information on the impairment charges recorded.

Other Investments

From time to time, we make strategic investments in equity securities of certain biotechnology companies which we acquire in connection with license and option agreements. Our strategic investment portfolio may include equity securities in publicly traded companies, as well as investments in companies with securities that are not publicly traded and where fair value is not readily available. These investments are included in other assets in our consolidated balance sheets.

We record our investments in securities that are not publicly traded at cost, less impairments and also adjust the investment for any changes resulting from an observable price change in an orderly transaction for identical or similar investments of the same issuer. We assess relevant transactions that occur on or before the balance sheet date to identify observable price changes, and we regularly monitor these investments to evaluate whether there is an indication that the investment is impaired, based on the implied value of recent company financings, public market prices of comparable companies, and general market conditions.

Our investments in equity securities in publicly traded companies which are unrestricted are regularly measured and carried at fair value and classified as Level 1 equity securities within the fair value hierarchy. Investments in publicly traded companies which are subject to holding period restrictions are carried at fair value using an option pricing valuation model and classified as Level 2 equity securities within the fair value hierarchy. The most significant assumptions within the option pricing valuation model are the term of the restrictions and the stock price volatility, which is based upon the historical volatility of the applicable company or similar companies.

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 the best information available at the time of our assessment including the legal facts and circumstances of the case, status of the proceedings, applicable law and the likelihood of settlement, if any. 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 when facts and circumstances indicate the need for changes.

Treasury Stock

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

Revenue Recognition

In May 2014, the 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.

Upon adoption of the new revenue recognition standard, on January 1, 2018, we reduced our deferred revenue balance by $10.4, with an offsetting increase of $6.0 in retained earnings due to the cumulative impact of adopting this new standard. The impact to net product sales and net income for the year ended December 31, 2018 was an increase of $5.3 and $4.8, respectively. The new standard also resulted in a decrease of $17.9 in deferred revenue and an increase of $10.8 in retained earnings as of December 31, 2018. The adoption of the new revenue standard did not have a material impact on any other balances within the consolidated financial statements as of and for the year ended December 31, 2018. The adoption of the new standard did not significantly change our accounting policies.

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, range from 30 to 120 days and all arrangements 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.

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. 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.

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. 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.

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 for ULTOMIRIS, SOLIRIS, STRENSIQ, and KANUMA generally provide for returns only if the product is damaged or defective upon delivery. 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 for SOLIRIS, ULTOMIRIS, STRENSIQ and KANUMA, our customers often carry limited inventory. Our contracts with customers for ANDEXXA generally provide for returns if the product

(amounts in millions except per share amounts)

is damaged or defective upon delivery and if the product is within an eligible expiry window. While ANDEXXA inventory on hand is also limited, there may be a longer period from product sale to patient use and a greater risk of return for product expiry. 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.

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.

Refer to Note 18, *Segment Information* for a summary of revenue from contracts with customers by product and geographical region.

Contract Balances and Receivables

Contract liabilities relate to consideration received and/or billed for goods that have not been delivered to the customer and for which the performance obligation has not yet been completed. These amounts are included within other current liabilities in the consolidated statements of operations.

The following table provides information about receivables and contract liabilities from our contracts with customers.

	December 31, 2020	December 31, 2019
Receivables, which are included in "Trade accounts receivable, net"	$ 1,409.3	$ 1,243.2
Contract liabilities, which are included in "Other current liabilities"	$ 3.0	$ 6.8

Contract balances and receivables associated with collaboration agreements assumed through the acquisition of Portola in the third quarter 2020, which were included in the table above, were not material as of December 31, 2020.

Research and Development Expenses

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

Share-Based Compensation

We have two share-based compensation plans pursuant to which awards are currently being made: (i) the 2017 Incentive Plan (2017 Plan) and (ii) the 2015 Employee Stock Purchase Plan (ESPP). The 2017 Plan replaced the Amended & Restated 2004 Incentive Plan (2004 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

(amounts in millions except per share amounts)

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

For our non-market performance-based awards, we estimate the anticipated achievement of the performance targets, including forecasting the achievement of future financial targets. These estimates are revised periodically based on the probability of achieving the performance targets and adjustments are made throughout the performance period as necessary. We use payout simulation models to estimate the grant date fair value of awards with market-based performance conditions. 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 85.0% 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 15.0% discount is recognized as compensation expense over the 6 month purchase period.

Restructuring and Restructuring Related Expenses

We record liabilities associated with one-time employee termination benefits and exit or disposal activities in the period in which the liability is incurred. One-time employee benefits are incurred when communicated to employees and / or where detailed action plans have been approved. For existing benefit arrangements, employee termination costs are accrued when the exit or disposal cost are probable and estimable. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive benefits are recognized ratably over the service period.

Restructuring related expenses include accelerated depreciation costs and impairment charges associated with assets impacted by a restructuring exit activity. Accelerated depreciation costs represent the difference between the depreciation expense recognized over the revised useful life of the asset, based upon the anticipated date an impacted site closure, and the depreciation expense as determined using the useful life prior to the restructuring activities.

Earnings Per Common Share

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

The following table summarizes the calculation of basic and diluted EPS for years ended December 31, 2020, 2019 and 2018:

	Year Ended December 31,		
	2020	2019	2018
Net income used for basic and diluted calculation	$ 603.4	$ 2,404.3	$ 77.6
Shares used in computing earnings per common share—basic	220.1	223.2	222.7
Weighted-average effect of dilutive securities:			
Stock awards	1.9	1.6	1.8
Shares used in computing earnings per common share—diluted	222.0	224.8	224.5
Earnings per common share:			
Basic	$ 2.74	$ 10.77	$ 0.35
Diluted	$ 2.72	$ 10.70	$ 0.35

We exclude from EPS the weighted-average number of securities whose effect is anti-dilutive. Excluded from the calculation of EPS for the years ended December 31, 2020, 2019 and 2018 were 1.7, 3.0 and 2.8 shares of common stock, respectively, because their effect is anti-dilutive.

Income Taxes

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

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

During the fourth quarter of 2013, in connection with the centralization of our global supply chain and technical operations in Ireland, our U.S. parent company became a direct partner in a captive foreign partnership. Our corporate structure, which derives income from multiple jurisdictions, requires us to interpret the related tax laws and regulations within those jurisdictions and develop estimates and assumptions regarding significant future events, such as the amount, timing and character of deductions and the applicability of foreign tax credits. From time to time, we execute intercompany transactions that may impact the valuation of the captive foreign partnership and the corresponding interest allocated to each partner, resulting in a change to deferred taxes. The transactions and related valuations require the application of transfer pricing guidelines issued by the relevant taxing authorities. Significant estimates and assumptions within discounted cash flow models are also required to calculate the valuations.

In December 2017, the Tax Cuts and Jobs Act (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 related to intangible assets (GILTI), a one-time transition tax on previously unremitted foreign earnings, and modified the taxation of other income and expense items. With regard to the GILTI minimum tax, foreign earnings are reduced by the profit attributable to tangible assets and a deductible allowance of up to 50.0%, subject to annual limitations. We have elected to account for the impact of the minimum tax in deferred taxes.

Comprehensive Income

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

Reclassifications

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

New Accounting Pronouncements

Accounting Standards Update (ASU) 2019-12, “Income Taxes: Simplifying the Accounting for Income Taxes”: In December 2019, the Financial Accounting Standards Board (FASB) issued a new standard intended to simplify the accounting for income taxes by eliminating certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new standard also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard is effective for annual periods beginning after December 15, 2020 and interim periods within, with early adoption permitted. Adoption of the standard requires certain changes to be made

prospectively, with some changes to be made retrospectively. We adopted the new standard on January 1, 2021. We have substantially completed our assessment of the standard and we do not expect the adoption of this standard to have a material impact on our financial condition and results of operations.

ASU 2020-01, "Investments - Equity Securities, Investments - Equity Method and Joint Ventures, and Derivatives and Hedging - Clarifying the Interactions Between Topic 321, Topic 323, and Topic 815": In January 2020, the FASB issued a new standard intended to clarify the interactions between Accounting Standards Codification (ASC) 321, ASC 323 and ASC 815. The new standard addresses accounting for the transition into and out of the equity method and measurement of certain purchased options and forward contracts to acquire investments. The standard is effective for annual and interim periods beginning after December 15, 2020, with early adoption permitted. Adoption of the standard requires changes to be made prospectively. We adopted the new standard on January 1, 2021. The adoption of this standard does not have an impact on our financial condition and results of operations.

ASU 2020-04, "Reference Rate Reform, Facilitation of the Effects of Reference Rate Reform on Financial Reporting": In response to concerns about structural risks of interbank offered rates, and, particularly, the risk of cessation of the London Interbank Offered Rate (LIBOR), regulators around the world have undertaken reference rate reform initiatives to identify alternative reference rates that are more observable or transaction-based and less susceptible to manipulation. In March 2020, the FASB issued a new standard that provides optional guidance for a limited time to ease the potential burden in accounting for the effects of reference rate reform, including optional expedients and exceptions for the accounting implications of contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met.

The amendments in this new standard only apply to contracts and hedging relationships that reference LIBOR or another reference rate expected to be discontinued due to reference rate reform. The expedients and exceptions provided by the standard do not apply to contract modifications made and hedging relationships entered into or evaluated after December 31, 2022. We are currently reviewing our contracts impacted by reference rate reform and are assessing the impact of this standard on our financial condition and results of operations.

Recently Adopted Accounting Pronouncements

ASU 2018-15, "Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract": 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) that aligns the requirements for capitalizing implementation costs in a CCA service contract with existing internal-use software guidance. The standard also provides classification guidance on these implementation costs as well as additional quantitative and qualitative disclosures. The standard is effective for interim and annual periods beginning after December 15, 2019, with early adoption permitted, and can be adopted prospectively or retrospectively.

We adopted the new standard on January 1, 2020 on a prospective basis. The adoption of this standard had no impact on our financial statements at the date of adoption; however, we anticipate the adoption of this standard will result in an increase in capitalized assets related to qualifying CCA implementation costs in future periods.

Qualifying CCA implementation, set-up and other upfront costs incurred after January 1, 2020 are capitalized as other assets in our consolidated balance sheets. These assets will be expensed over the term of the hosting arrangement and such expense will be presented within the same line item in our consolidated statements of operations as the expense for fees for the associated hosting arrangement. These capitalized costs will be evaluated for impairment when events or changes in circumstances indicate that the carrying value of the capitalized implementation costs is not recoverable. For the year ended December 31, 2020, capitalized CCA implementation costs were not material.

ASU 2016-13, "Measurement of Credit Losses on Financial Instruments": 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 on financial assets measured at amortized cost be determined using an expected loss model, instead of the current incurred loss model, and requires that credit losses related to available-for-sale debt securities be recorded through an allowance for credit losses and limited to the amount by which carrying value exceeds fair value. The new standard also requires enhanced disclosure of credit risk associated with financial assets. The standard is effective for interim and annual periods beginning after December 15, 2019 with early adoption permitted.

We adopted the new standard on January 1, 2020 and completed our assessment of the standard based on the composition of our portfolio of financial instruments and current and forecasted economic conditions at that date. Our significant financial assets that are within the scope of the new standard consist of trade accounts receivable and available for sale debt securities. We have not historically experienced any material credit losses associated with our trade accounts receivable or available for debt securities.

We monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. We disaggregate our trade accounts receivable population into pools of similar risk characteristics based on underlying customer type and geographical location. Current expected credit loss allowances are estimated for each risk pool based on available information, including i) historical credit loss experience, ii) current economic conditions and, iii) reasonable and supportable forecasts of future economic conditions that may affect the collectibility of the recorded amounts. Based on the relevant facts and economic conditions as of the date of adoption, we concluded that the expected credit losses on our trade accounts receivable were immaterial. Additionally, unrealized losses on our available for sale investment portfolio were immaterial.

As of December 31, 2020, we reassessed our estimated credit losses on our trade accounts receivable, including consideration of the potential impacts of the COVID-19 global pandemic. Based on the relevant facts and economic conditions as of December 31, 2020, we concluded that the expected credit losses on our trade accounts receivable continued to be immaterial.

2. Acquisitions

Business Combinations

Achillion Pharmaceuticals, Inc.

In October 2019, Alexion entered into a definitive agreement to acquire Achillion Pharmaceuticals, Inc. (Achillion), a clinical-stage biopharmaceutical company focused on the development of oral Factor D inhibitors. Achillion was developing oral small molecule Factor D inhibitors to treat people with complement alternative pathway-mediated rare diseases, such as PNH and C3 glomerulopathy (C3G). Achillion had two clinical stage medicines in development, including danicopan (ACH-4471/ALXN2040) and ACH-5228 (ALXN2050).

The acquisition of Achillion closed on January 28, 2020. Under the terms of the agreement, we acquired all outstanding common stock of Achillion for $6.30 per share, or an aggregate of $926.2, inclusive of the settlement of Achillion's outstanding equity awards. The acquisition was funded with cash on hand. The transaction includes the potential for additional consideration in the form of non-tradeable contingent value rights (CVRs), which will be paid to Achillion shareholders if certain clinical and regulatory milestones are achieved within specified periods. These include $1.00 per share for the U.S. Food and Drug Administration (FDA) approval of danicopan and $1.00 per share for the initiation of a Phase III clinical trial in ACH-5228.

The transaction was accounted for as a business combination. The following table summarizes the total consideration transferred to acquire Achillion and the estimated fair value of the identified assets acquired and liabilities assumed at the acquisition date:

(amounts in millions except per share amounts)

Consideration	
Upfront payment to shareholders and option holders	$ 926.2
Upfront payment, fair value of equity compensation attributable to the post-combination service period	(20.0)
Upfront cash paid, net	906.2
Contingent consideration	160.7
Contingent consideration, fair value of equity compensation attributable to the post-combination service period	(5.7)
Total consideration	$ 1,061.2
Assets Acquired and Liabilities Assumed	
Cash and cash equivalents	$ 68.5
Marketable securities	106.1
In-process research & development assets (IPR&D)	918.0
Goodwill	37.8
Deferred tax liabilities, net	(62.9)
Other assets and liabilities, net	(6.3)
Total net assets acquired	$ 1,061.2

Our accounting for this acquisition was finalized during the second quarter of 2020. Measurement period adjustments increased goodwill by $3.1 during the second quarter of 2020 due to purchase price allocation increases to deferred tax liabilities, net. Measurement period adjustments were recorded as a result of studies completed during the second quarter of 2020 to determine the tax deductibility of certain acquisition-related costs and the valuation of historical net operating loss and income tax credit carryforwards.

The initial fair value estimate of the contingent consideration in the form of non-tradeable CVRs was $160.7, which was recorded as a noncurrent liability in our consolidated balance sheet, including $5.7 related to compensation attributable to the post-combination service period. We determined the fair value of these milestone-related payment obligations using various estimates, including probabilities of success prior to expiration of the specified period, discount rates and the amount of time until the conditions of the milestone payments are expected to be met. This fair value measurement was based on significant inputs not observable in the market, representing Level 3 measurements within the fair value hierarchy. The resulting probability-weighted cash flows were discounted using a cost of debt rate ranging from 2.1% to 2.3%. The range of estimated milestone payments upon closing of the acquisition is from zero, if no milestones are achieved for any product, to $306.3 if certain development and regulatory milestones are achieved.

Subsequent to the acquisition date, we have adjusted the contingent consideration to fair value with changes in fair value recognized in operating earnings. Changes in fair values reflect new information about the probability and timing of meeting the conditions of the milestone payments. In the absence of new information, changes in fair value will only reflect the interest component of contingent consideration related to changes in the discount rates and the passage of time as development work progresses towards the potential achievement of the milestones. As of December 31, 2020, the fair value of the contingent consideration for the Achillion acquisition was $210.6 based on the probability-weighted cash flows, discounted using a cost of debt ranging from 2.8% to 3.3%. Changes in fair value of the contingent consideration associated with the Achillion acquisition for the year ended December 31, 2020 was $49.9.

The aggregate fair value of equity compensation attributable to the post-combination service period was $25.7. This amount was excluded from the total consideration transferred and was recognized as a charge to acquisition-related costs in our consolidated statements of operations. These amounts were associated with the accelerated vesting of stock options previously granted to Achillion employees. Excluding the $5.7 of contingent consideration related to equity compensation attributable to the post-combination service period, such amounts were paid during the first quarter 2020.

Intangible assets associated with IPR&D relate to two development-stage programs, ACH-4471 (ALXN2040) and ACH-5228 (ALXN2050). The estimated fair value of $918.0 was determined using the excess earnings valuation

method, a variation of the income valuation approach. The excess earnings valuation method estimates the value of an intangible asset equal to the present value of the incremental after-tax cash flows attributable to that intangible asset. Some of the more significant assumptions utilized in our asset valuations included the estimated net cash flows for each asset, including net revenues, cost of sales, research and development and other operating expenses, the potential regulatory and commercial success rates, competitive trends impacting the assets, and tax rates. The fair value using the excess earnings valuation method was determined using an estimated weighted average cost of capital for Achillion of 11.5%, which represents a rate of return that a market participant would expect for these assets. These fair value measurements were based on significant inputs not observable in the market and thus represent Level 3 fair value measurements. In the second quarter 2020, we recognized an impairment charge of $11.0 to write off our ACHN-4471 (ALXN2040) IPR&D asset due to clinical results received during the quarter.

The excess of purchase price over the fair value of the assets acquired and liabilities assumed represents the goodwill resulting from the acquisition. The goodwill, which is not tax-deductible, has been recorded as a noncurrent asset and is not amortized, but is subject to an annual review for impairment. The factors that contributed to the recognition of goodwill include the value of the acquired workforce, synergies that are specific to our business and not available to market participants, and early research in preclinical Factor D inhibitors, as well as the effects of the establishment of a deferred tax liability for the acquired IPR&D intangible assets, which has no tax basis.

We recorded a net deferred tax liability of $62.9, inclusive of measurement period adjustments recorded during the second quarter 2020. This amount was primarily comprised of $205.3 of deferred tax liabilities relating to the IPR&D acquired, offset by $142.4 of deferred tax assets related to net operating loss carryforwards (NOLs), income tax credits, and other temporary differences.

Achillion's results of operations are included in the consolidated financial statements from the date of acquisition. For the year ended December 31, 2020 we recorded $66.8 of pre-tax operating losses exclusive of acquisition-related costs, $49.9 of changes in contingent consideration and $11.0 of impairment charges, associated with the operations of Achillion in our consolidated statements of operations. We also recorded acquisition-related costs in connection with the acquisition for the year ended December 31, 2020 as presented below. No revenues were recorded in the results of operations for the year ended December 31, 2020 as neither ALXN2040 nor ALXN2050 has been approved for commercial sale by any regulatory agency.

Portola Pharmaceuticals, Inc.

In May 2020, Alexion entered into a definitive merger agreement to acquire Portola Pharmaceuticals, Inc. (Portola), a commercial-stage biopharmaceutical company focused on life-threatening blood-related disorders. Portola’s commercialized medicine, ANDEXXA®, marketed as ONDEXXYA® in Europe, is the first and only approved Factor Xa inhibitor reversal agent, and has demonstrated transformative clinical value by rapidly reversing the anticoagulant effects of Factor Xa inhibitors rivaroxaban and apixaban in severe and uncontrolled bleeding. The acquisition provides the opportunity to grow Alexion's commercial portfolio and is a strategic fit with our existing expertise in acute care, hematology and neurology.

Alexion completed the acquisition through a tender offer and subsequent merger of Portola which closed on July 2, 2020. Under the terms of the tender offer and merger agreement, Alexion purchased all outstanding common stock of Portola for $18.00 per share, or an aggregate of approximately $1,380.8, including the settlement of certain of Portola's outstanding equity awards but excluding shares of Portola stock held by Alexion at closing. The acquisition was funded by cash on hand.

Prior to the acquisition of Portola, in March 2020 and April 2020, we purchased $14.5 and $3.6, respectively, of common stock of Portola, which we recorded at fair value. Upon the closing of the acquisition of Portola, the fair value of the equity investment of $47.8 was derecognized and included in the fair value of consideration transferred. For additional information on our Portola equity investment, refer to Note 7, *Other Investments.*

The aggregate fair value of equity compensation attributable to the post-combination service period was $11.1. This amount was excluded from the total consideration transferred and was recognized as a charge to acquisition-related costs in our consolidated statements of operations. These amounts were primarily associated with the accelerated vesting of stock options previously granted to Portola employees and were paid during the third quarter 2020.

(amounts in millions except per share amounts)

We issued $41.5 of equity compensation replacement awards, of which the portion attributable to services performed prior to the acquisition date, or $7.2, was allocated to purchase consideration. The remaining fair value is attributable to future services and will be expensed as share-based compensation over the remaining service periods. Expense associated with the accelerated-vesting of the replacement awards in connection with employee terminations will be recognized as acquisition-related employee separation costs.

In connection with the acquisition, Alexion also paid $196.9 to settle certain debt held by Portola that was subject to preexisting change of control provisions.

The transaction was accounted for as a business combination. The following table summarizes the total consideration transferred to acquire Portola and the estimated fair value of the identified assets acquired and liabilities assumed at the acquisition date:

Consideration	
Upfront payment to shareholders and equity holders	$ 1,380.8
Upfront payment, fair value of equity compensation attributable to the post-combination service period	(11.1)
Upfront cash paid, net	1,369.7
Fair value of equity shares held by Alexion at closing	47.8
Fair value of replacement equity awards attributable to the pre-combination period	7.2
Total consideration to acquire outstanding equity, net	1,424.7
Total consideration to settle preexisting debt	196.9
Total consideration	$ 1,621.6
Assets Acquired and Liabilities Assumed	
Cash and cash equivalents	$ 288.5
Marketable securities	17.8
Inventories, including noncurrent portion of $169.1 and validation batches of $60.9	362.5
Intangible assets	1,051.0
Goodwill	24.9
Deferred tax assets, net	116.6
Other assets	41.9
Accounts payable and accrued expenses	(75.6)
Long-term debt, including current portion of $7.7	(182.0)
Other liabilities	(24.0)
Total net assets acquired	$ 1,621.6

Our accounting for this acquisition was finalized during the fourth quarter of 2020. Measurement period adjustments decreased goodwill by $0.6 during the fourth quarter of 2020 due to purchase price allocation increases to deferred tax assets, net. Measurement period adjustments were recorded as a result of studies completed during the fourth quarter of 2020 to determine the tax deductibility of certain acquisition-related costs and the valuation of historical net operating loss and income tax credit carryforwards.

We acquired $362.5 of ANDEXXA inventory, inclusive of $60.9 of validation batches manufactured under processes which are subject to regulatory approval and expected to be commercially saleable following approval. The estimated fair value of raw material inventory was valued at replacement cost, which is equal to the value a market participant would pay to acquire the inventory. The estimated fair value of work-in-process and finished goods inventory was based on the expected selling price of the inventory, adjusted for incremental costs to complete the manufacturing process, for direct selling efforts, and for a normal profit on the remaining manufacturing and selling

costs. Additionally, as the inventory acquired, inclusive of validation batches, is expected to be realized over a period of approximately 3 years, the fair value of the inventory was determined using a discount rate of 17.5%, representing the rate of return that a market participant would expect for the inventory, which shares risk that is similar to the underlying intellectual property. These fair value measurements were based on significant inputs not observable in the market and thus represent Level 3 fair value measurements. The acquired inventory, inclusive of the acquisition-date fair value step-up, will be expensed within cost of sales as the inventory is sold to customers. We classified the ANDEXXA inventory that is expected to be utilized beyond our normal operating cycle as a long-term asset. The fair value of the non-current portion of inventory, in addition to the validation batches, are classified within other assets in our consolidated balance sheet.

Intangible assets consist of purchased technology of $1,036.0 and IPR&D of $15.0. The purchased technology intangible asset relates to Portola's lead product ANDEXXA. The estimated fair value was determined using the excess earnings valuation method, a variation of the income valuation approach. The excess earnings valuation method estimates the value of an intangible asset equal to the present value of the incremental after-tax cash flows attributable to that intangible asset. Some of the more significant assumptions utilized in our asset valuation included the estimated net cash flows for ANDEXXA, including net revenues, cost of sales, research and development and other operating expenses, the potential regulatory and commercial success rates associated with ANDEXXA's current conditional approval status and planned extension into the urgent surgery setting, competitive trends impacting the assets, and tax rates. The fair value using the excess earnings valuation method was determined using a discount rate commensurate with the risks of ANDEXXA of 17.5%, which represents a rate of return that a market participant would expect for the asset. The acquired purchased technology intangible asset is being amortized over an estimated useful life of approximately 10 years. IPR&D relates to the cerdulatinib development-stage asset. The estimated fair value of the IPR&D asset was determined using a relief from royalty (RFR) method, a variation of the income approach that is based on the cost savings that accrue to the owner of an intangible asset who would otherwise have to pay royalties on revenues earned through the use of the asset. The RFR method was modified to reflect the cash flow forecast of Portola's pre-existing in-license of cerdulatinib from Astellas Pharma, Inc. The acquired fair value of $15.0 represents an increase in the value of the asset relative to when it was initially in-licensed by Portola. Some of the more significant assumptions utilized in the IPR&D asset valuation included the estimated net revenue, royalty rate, and tax rates. The fair value using the RFR method was determined using an estimated discount rate commensurate with the risks of cerdulatinib of 17.5%, which represents a rate of return that a market participant would expect for the asset. These fair value measurements were based on significant inputs not observable in the market and thus represent Level 3 fair value measurements.

In connection with the acquisition, we assumed royalty-based debt which requires repayment through tiered royalties on future net worldwide sales of ANDEXXA. Total potential royalty payments are capped at $290.6, of which $13.7 were paid by Portola prior to the acquisition. The fair value of the remaining $276.9 in royalty-based payments as of the date of acquisition was $182.0. The estimated fair value was measured using Level 3 inputs and was calculated using a real options method, which runs simulations using various estimates, including probability-weighted net sales of ANDEXXA and volatility. Using the simulation results, the fair value was calculated based on the expected probability-weighted risk-neutral royalties, discounted at our estimated cost of debt, ranging from 3.3% to 7.1%, commensurate with the cost of debt at each period in which the royalty-based payments are estimated to be made.

We recorded net deferred tax assets of $116.6, inclusive of measurement period adjustments recorded during the fourth quarter 2020. This amount was primarily comprised of $301.6, $41.8, $42.4 and $39.3 of deferred tax assets relating to net operating loss carryforwards (NOLs), income tax credits, royalty-based debt, and other temporary differences, respectively, offset by $245.1 and $63.4 of deferred tax liabilities relating to intangible assets acquired and inventory fair value adjustments, respectively.

The excess of purchase price over the fair value of the assets acquired and liabilities assumed represents the goodwill resulting from the acquisition. The goodwill, which is not tax-deductible, has been recorded as a noncurrent asset and is not amortized, but is subject to an annual review for impairment. The factors that contributed to the recognition of goodwill primarily include the value of the acquired workforce and the effects of the establishment of a deferred tax liability for the fair value step-up of acquired inventory and intangible assets which exceed the incremental book value of acquired deferred tax assets over their fair value.

Portola's results of operations are included in the consolidated financial statements from the date of acquisition. For the year ended December 31, 2020, we recorded $78.8 of revenue primarily associated with

(amounts in millions except per share amounts)

ANDEXXA in our consolidated statements of operations. For the year ended December 31, 2020, we recorded $80.5 of pre-tax operating losses excluding acquisition-related costs and $51.8 of intangible asset amortization, associated with the operations of Portola in our consolidated statements of operations. We also recorded acquisition-related costs in connection with the acquisition during the year ended December 31, 2020 as presented below.

Pro forma financial information (unaudited)

The following unaudited pro forma information presents the combined results of Alexion, Achillion, and Portola as if the acquisitions of Achillion and Portola had been completed on January 1, 2019, with adjustments to give effect to pro forma events that are directly attributable to the acquisitions. The unaudited pro forma results do not reflect operating efficiencies or potential cost savings that may have resulted from the consolidation of operations. Accordingly, the unaudited pro forma financial information is not necessarily indicative of the results of operations had we completed the transaction on January 1, 2019.

	Year ended December 31,	
	2020	2019
Pro forma revenue	$ 6,118.3	$ 5,107.7
Pro forma net income	$ 519.9	$ 1,813.6

The unaudited pro forma consolidated results for the years ended December 31, 2020 and 2019 primarily include the following pro forma adjustments related to non-recurring activity, net of tax:

- Reclassification of Alexion, Achillion and Portola acquisition-related costs. Acquisition-related costs of $150.8 were excluded from net income for the year ended December 31, 2020. Expenses of $136.4 were included in net income for the year ended December 31, 2019.
- Incremental amortization expense related to Portola purchased technology intangible assets for the year ended December 31, 2020 was $39.8 and for the year ended December 31, 2019 was $79.5.
- Incremental cost of goods sold related to Portola inventory fair value step-up adjustments calculated based on the fair value of finished goods inventory for the year ended December 31, 2020 was $11.0 and for the year ended December 31, 2019 was $24.4.

Acquisition-Related Costs

Acquisition-related costs recorded within the consolidated statement of operations associated with our acquisitions of Achillion and Portola and our definitive merger agreement with AstraZeneca for the years ended December 31, 2020, 2019 and 2018 include the following:

	Year ended December 31,		
	2020	2019	2018
Transaction costs [1]	$ 9.9	$ —	$ —
Integration costs	13.0	—	—
Fair value of equity compensation attributable to the post-combination service period	36.8	—	—
Employee separation costs [2]	57.9	—	—
	$ 117.6	$ —	$ —

(1) Transaction costs primarily include legal fees related to the acquisition of Portola as well as costs incurred to effectuate the settlement of the Achillion outstanding options

(2) Employee separation costs include liabilities recognized, and subsequent changes in estimates recorded for, severance payments, one-time short-term retention awards agreed to in connection with the acquisition of Achillion and share-based compensation expense relating to awards accelerated in connection with terminations of Portola employees.

Acquisition-related costs attributable to the Achillion acquisition for the year ended December 31, 2020 were $38.1. Acquisition-related costs attributable to the Portola acquisition for the year ended December 31, 2020 were $77.5. Acquisition-related costs attributable to the Merger Agreement with AstraZeneca for the year ended December 31, 2020 were $2.0.

(amounts in millions except per share amounts)

Asset Acquisitions

Wilson Therapeutics AB

On May 25, 2018, we completed the acquisition of Wilson Therapeutics AB (publ), a biopharmaceutical company based in Stockholm, Sweden (Wilson Therapeutics) that developed a novel therapy for patients with rare copper-mediated disorders, pursuant to a recommended public cash offer of SEK 232 for each share of stock of Wilson Therapeutics. As a result of the acquisition, we added WTX101 (ALXN1840), a highly innovative drug candidate that is currently in Phase III clinical trials for the treatment of patients with Wilson disease, to our clinical pipeline.

The acquisition of Wilson Therapeutics was accounted for as an asset acquisition, as substantially all of the fair value of the gross assets acquired was concentrated in a single asset, WTX101.

The following table summarizes the total consideration for the acquisition and the value of assets acquired and liabilities assumed:

Consideration	
Cash paid for acquisition of Wilson Therapeutics outstanding shares	$ 749.3
Transaction costs	15.1
Total consideration	$ 764.4
Assets Acquired and Liabilities Assumed	
Cash	$ 45.1
In-process research & development	803.7
Employee related liabilities	(71.4)
Other assets and liabilities	(13.0)
Total net assets acquired	$ 764.4

The acquired in-process research and development asset relates to WTX101. Due to the stage of development of this asset at the date of acquisition, significant risk remained and it was not yet probable that there was future economic benefit from this asset. Absent successful clinical results and regulatory approval for the asset, there was no alternative future use associated with WTX101. Accordingly, the value of this asset was expensed during the second quarter of 2018.

Employee related liabilities include the value of outstanding employee equity incentive awards that were accelerated in connection with the Wilson Therapeutics acquisition that have been settled in cash. Also included in this amount were employer tax obligations associated with the employee equity incentive awards.

In connection with rights to WTX101 that were previously acquired by Wilson Therapeutics from third parties, we could be required to pay up to approximately $19.0 if certain development, regulatory and commercial milestones are met over time, as well as royalties on commercial sales.

Syntimmune, Inc.

In September 2018, we entered into a definitive agreement to acquire Syntimmune, Inc. (Syntimmune), a clinical-stage biotechnology company developing an antibody therapy targeting the FcRn. Syntimmune's lead candidate, SYNT001 (ALXN1830), is a monoclonal antibody that is designed to inhibit the interaction of FcRn with Immunoglobulin G (IgG) and IgG immune complexes, that is being studied for the treatment of IgG-mediated autoimmune diseases. The acquisition of Syntimmune closed in November 2018. Under the terms of the acquisition agreement, Alexion acquired Syntimmune for an upfront cash payment of $400.0, with the potential for additional milestone-dependent payments of up to $800.0, for a total potential value of up to $1,200.0.

The acquisition of Syntimmune was accounted for as an asset acquisition, as substantially all of the fair value of the gross assets acquired was concentrated in a single in-process research and development asset, SYNT001.

In connection with the agreement of the final working capital adjustment for the Syntimmune acquisition, we recognized a benefit of $4.1 associated with previously acquired in-process research and development in the second quarter 2019.

(amounts in millions except per share amounts)

The following table summarizes the total consideration for the acquisition and the value of the assets acquired and liabilities assumed:

Consideration	
Upfront payment for acquisition of Syntimmune outstanding shares	$ 400.0
Cash acquired	4.2
Working capital adjustment	2.3
Transaction costs	0.9
Total consideration	$ 407.4
Assets Acquired and Liabilities Assumed	
Cash	$ 4.2
In-process research & development	375.2
Deferred tax assets	25.1
Other assets and liabilities	2.9
Total net assets acquired	$ 407.4

The acquired in-process research and development asset relates to SYNT001. Due to the stage of development of this asset at the date of acquisition, significant risk remained and it was not yet probable that there was future economic benefit from this asset. Absent successful clinical results and regulatory approval for the asset, there was no alternative future use associated with SYNT001. Accordingly, the value of this asset was expensed during the fourth quarter of 2018.

3. Property, Plant and Equipment, Net

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

	December 31, 2020	December 31, 2019
Land	$ 9.6	$ 9.6
Buildings and improvements	216.7	208.7
Machinery and laboratory equipment	134.1	126.0
Computer hardware and software	171.9	155.1
Furniture and office equipment	24.9	23.4
Construction-in-progress	828.7	734.2
Financing lease right of use assets	127.2	127.2
	1,513.1	1,384.2
Less: Accumulated depreciation and amortization	(274.3)	(220.9)
	$ 1,238.8	$ 1,163.3

Depreciation and amortization of property, plant and equipment was $56.3, $56.8 and $77.9 recorded within our consolidated statement of operations for the years ended December 31, 2020, 2019 and 2018, respectively. Included within this amount for the year ended December 31, 2018 were charges related to the 2017 restructuring activities. Refer to Note 17, *Restructuring and Related Expenses* for additional information.

As of December 31, 2020 and 2019, computer software costs included in property, plant and equipment were $53.1 and $53.4, respectively, net of accumulated amortization of $87.7 and $72.9, respectively. Depreciation and amortization expense for capitalized computer software costs was $16.4, $15.3 and $17.4 for the years ended December 31, 2020, 2019 and 2018, respectively.

(amounts in millions except per share amounts)

4. Intangible Assets and Goodwill

The following table summarizes the carrying amount of our intangible assets and goodwill, net of accumulated amortization:

		December 31, 2020			December 31, 2019		
	Estimated Life (years)	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Licensing Rights	3-8	$ 57.0	$ (38.5)	$ 18.5	$ 57.0	$ (34.7)	$ 22.3
Patents	7	10.5	(10.5)	—	10.5	(10.5)	—
Purchased technology	6-16	5,746.5	(3,684.7)	(a) 2,061.8	4,710.5	(1,388.7)	3,321.8
Other Intangibles	5	0.4	(0.3)	0.1	0.4	(0.2)	0.2
Acquired IPR&D	Indefinite	922.0	—	922.0	—	—	—
Total		$ 6,736.4	$ (3,734.0)	$ 3,002.4	$ 4,778.4	$ (1,434.1)	$ 3,344.3
Goodwill	Indefinite	$ 5,103.0	$ (2.9)	$ 5,100.1	$ 5,040.3	$ (2.9)	$ 5,037.4

(a) Includes an impairment charge of $2,042.3 recognized during the second quarter related to the KANUMA intangible asset

In connection with our acquisition of Achillion during the first quarter 2020, we acquired IPR&D programs with a fair value of $918.0 and recorded goodwill of $37.8. For additional information on our acquisition of Achillion, refer to Note 2, *Acquisitions*. In the second quarter 2020, we recognized an impairment charge of $11.0 to write off the cost basis of our ACHN-4471 (ALXN2040) acquired in-process research and development asset due to clinical results received during the quarter.

In connection with our acquisition of Portola during the third quarter 2020, we acquired purchased technology and IPR&D programs with a fair value of $1,036.0 and $15.0, respectively and recorded goodwill of $24.9. For additional information on our acquisition of Portola, refer to Note 2, *Acquisitions*.

During the year ended December 31, 2019 we capitalized $18.0 related to regulatory approval and commercial milestones related to in-licensing arrangements.

Amortization expense was $257.6, $315.0 and $321.1 for the years ended December 31, 2020, 2019 and 2018, respectively. Assuming no changes in the gross cost basis of intangible assets, the total estimated amortization expense for finite-lived intangible assets is approximately $216.0 for each of the years ending December 31, 2021 through December 31, 2025.

During the quarter ended June 30, 2020, based on continued challenges expanding patient growth and new alternative commercial opportunities, we revised our strategic view of KANUMA and determined that we have exhausted commercially viable initiatives related to KANUMA and will have difficulty expanding patient growth over the long term as we focus on promoting other commercial programs and growing our pipeline. As a result, we no longer expect to increase the number of KANUMA patients in the long term at the rate previously assumed. This determination resulted in reduced cash flow projections for KANUMA, which indicated that the related intangible asset value was not fully recoverable on an undiscounted cash flows basis. As of June 30, 2020, we utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to KANUMA that, when compared with its related carrying value, resulted in an impairment charge of $2,042.3.

The estimated fair value of the KANUMA asset as of June 30, 2020 was determined using the excess earnings method, a variation of the income approach. The excess earnings method estimates the value of an intangible asset equal to the present value of the incremental after-tax cash flows attributable to that intangible asset over its remaining economic life. Long term cash flow projections for the asset require the use of significant estimates and judgements, including forecasted revenue growth rates, forecasted cost of goods sold and the discount rate, and were based on our most recent strategic plan. The fair value of the asset was determined using an estimated weighted average cost of capital of 10.0%, which reflects the risks inherent in future cash flow projections and represents a rate of return that a market participant would expect for this asset. The estimated revenue growth rates fluctuate over the life of the asset, with a weighted average growth rate in the low single digits. We believe our assumptions are consistent with the plans and estimates that a market participant would use to manage the business. The estimated fair value of the KANUMA intangible asset as of June 30, 2020 was $820.0 and will continue to be amortized over its remaining estimated useful life. This fair value measurement was based on

(amounts in millions except per share amounts)

significant inputs not observable in the market and thus represents a Level 3 fair value measurement. The carrying value of the KANUMA intangible asset as of December 31, 2020 was $782.7.

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

	December 31, 2020
Balance as of December 31, 2019	$ 5,037.4
Goodwill resulting from the acquisitions of Achillion and Portola	62.7
Balance as of December 31, 2020	$ 5,100.1

5. Marketable Securities

The proceeds from maturities and sales of available-for-sale debt securities and resulting realized gains and losses are summarized below. In the second quarter of 2020, we liquidated all of our available-for-sale debt securities to fund the acquisition of Portola. Additionally, we liquidated all available-for-sale debt securities acquired in connection with the Portola acquisition.

	Year ended December 31,		
	2020	2019	2018
Proceeds from maturities and sales [1]	$ 1,042.5	$ 2,832.8	$ 10,196.8
Realized gains	$ —	$ —	$ 1.1
Realized losses	$ —	$ —	$ 0.4

(1) Proceeds from maturities and sales of available-for-sale debt securities include securities previously classified as cash and cash equivalents and marketable securities in the consolidated balance sheet

We utilize the specific identification method in computing realized gains and losses.

As a result of our liquidation of all available-for-sale debt securities during the second quarter 2020, we have no remaining available-for-sale debt securities as of December 31, 2020. The amortized cost, gross unrealized holding gains, gross unrealized holding losses and fair value of available-for-sale debt securities by type of security as of December 31, 2019 were as follows:

	December 31, 2019			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Commercial paper	$ 246.9	$ —	$ —	$ 246.9
Corporate bonds	24.3	—	—	24.3
Other government related obligations:				
U.S.	70.4	—	—	70.4
Bank certificates of deposit	27.4	—	—	27.4
Total available-for-sale debt securities	$ 369.0	$ —	$ —	$ 369.0

The aggregate fair value of available-for-sale debt securities in an unrealized loss position as of December 31, 2019 was $21.5. We did not have any investments in a continuous unrealized loss position for more than twelve months as of December 31, 2019.

The fair values of available-for-sale debt securities by classification in the consolidated balance sheet were as follows:

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ —	$ 328.1
Marketable securities	—	40.9
	$ —	$ 369.0

(amounts in millions except per share amounts)

We sponsor a nonqualified deferred compensation plan which allows certain highly-compensated employees to make voluntary deferrals of up to 80% of their base salary and incentive bonuses. The plan is designed to work in conjunction with the 401(k) plan and provides for a total combined employer match of up to 6% of an employee's eligible earnings, up to the IRS annual 401(k) contribution limitations. Participants in the plan earn a return on their deferrals based on several investment options, which mirror returns on underlying mutual fund investments. We choose to invest in the underlying mutual fund investments to offset the liability associated with our nonqualified deferred compensation plan. These mutual fund investments are valued at net asset value per share and are carried at fair value with gains and losses included in investment income. The changes in the underlying liability to the employee are recorded in operating expenses. As of December 31, 2020 and December 31, 2019, the fair value of these investments was $34.9 and $23.1, respectively. Employer matching contributions under the plan for the years ended December 31, 2020, 2019 and 2018 were not material.

6. Derivative Instruments and Hedging Activities

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

We enter into foreign exchange forward contracts to hedge exposures resulting from portions of our forecasted revenues, including intercompany revenues, and certain forecasted expenses that are denominated in currencies other than the U.S. dollar. Revenue and expense related foreign exchange forward contracts in effect as of December 31, 2020 had durations of up to 23 months and 60 months, respectively. The purpose of these hedges is to reduce the volatility of exchange rate fluctuations on our operating results. These hedges are designated as cash flow hedges upon contract inception. As of December 31, 2020, we had open revenue related foreign exchange forward contracts with notional amounts totaling $1,174.7 that qualified for hedge accounting with current contract maturities through June 2022. As of December 31, 2020, we had open expense related foreign exchange forward contracts with notional amounts totaling $8.7 that qualified for hedge accounting with contract maturities through September 2022.

To achieve a desired mix of floating and fixed interest rates on our term loan, we enter into interest rate swap agreements that qualify for and are designated as cash flow hedges. These contracts convert the floating interest rate on a portion of our debt to a fixed rate, plus a borrowing spread.

The following table summarizes the total interest rate swap contracts executed as of December 31, 2020:

Type of Interest Rate Swap	Notional Amount	Effective Date	Termination Date	Fixed Interest Rate or Rate Range
Floating to Fixed	$450.0	December 2018	December 2022	2.60% - 2.79%
Floating to Fixed	$1,300.0	December 2019	December 2022	2.37% - 2.83%

The amount of gains and (losses) recognized in the consolidated statements of operations for the years ended December 31, 2020, 2019 and 2018 from foreign exchange and interest rate swap contracts that qualified as cash flow hedges were as follows:

	Year ended December 31,					
	2020		2019		2018	
Financial Statement Line Item in which the Effects of Cash Flow Hedges are Recorded	Net Product Sales	Interest Expense	Net Product Sales	Interest Expense	Net Product Sales	Interest Expense
Total amount presented in the Consolidated Statements of Operations	$ 6,069.1	$ (104.7)	$ 4,990.0	$ (77.8)	$ 4,130.1	$ (98.2)
Impact of cash flow hedging relationships:						
Foreign exchange forward contracts	$ 4.7	$ —	$ 36.8	$ —	$ (1.8)	$ —
Interest rate swap contracts	$ —	$ (37.5)	$ —	$ 13.3	$ —	$ 13.6

(amounts in millions except per share amounts)

The impact on accumulated other comprehensive income (AOCI) and earnings from foreign exchange and interest rate swap contracts that qualified as cash flow hedges, for the years ended December 31, 2020, 2019, and 2018 were as follows:

	Year Ended December 31,		
	2020	2019	2018
Foreign Exchange Forward Contracts:			
(Loss) gain recognized in AOCI, net of tax	$ (36.4)	$ 27.9	$ 37.7
Gain (loss) reclassified from AOCI to net product sales, net of tax	$ 3.6	$ 28.4	$ (1.4)
Interest Rate Swap Contracts:			
Loss recognized in AOCI, net of tax	$ (52.3)	$ (39.0)	$ (4.8)
(Loss) gain reclassified from AOCI to interest expense, net of tax	$ (29.1)	$ 10.2	$ 10.8

Assuming no change in foreign exchange rates from market rates at December 31, 2020, $44.2 of losses recognized in AOCI will be reclassified to revenue over the next 12 months. Assuming no change in LIBOR-based interest rates from market rates at December 31, 2020, $45.9 of losses recognized in AOCI will be reclassified to interest expense over the next 12 months. Amounts recognized in AOCI for expense related foreign exchange forward contracts were immaterial as of December 31, 2020.

We enter into foreign exchange forward contracts 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. Balance sheet hedges related foreign exchange forward contracts in effect as of December 31, 2020 had durations of up to 6 months. Hedge accounting is not applied to these derivative instruments as gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. As of December 31, 2020, the notional amount of foreign exchange contracts where hedge accounting is not applied was $2,070.1.

We recognized a (loss) gain of $(3.6), $(0.4) and $23.0, in other income and (expense) for the years ended December 31, 2020, 2019 and 2018, respectively, associated with the foreign exchange contracts not designated as hedging instruments. These amounts were partially offset by gains or losses on monetary assets and liabilities.

The following tables summarize the fair value of outstanding derivatives as of December 31, 2020 and 2019:

	December 31, 2020			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	$ —	Other current liabilities	$ 44.3
Foreign exchange forward contracts	Other assets	—	Other liabilities	1.2
Interest rate contracts	Prepaid expenses and other current assets	—	Other current liabilities	45.9
Interest rate contracts	Other assets	—	Other liabilities	45.4
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	26.1	Other current liabilities	35.8
Total fair value of derivative instruments		**$ 26.1**		**$ 172.6**

(amounts in millions except per share amounts)

	December 31, 2019			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	$ 12.7	Other current liabilities	$ 6.2
Foreign exchange forward contracts	Other assets	0.6	Other liabilities	1.1
Interest rate contracts	Prepaid expenses and other current assets	—	Other current liabilities	19.5
Interest rate contracts	Other assets	—	Other liabilities	41.9
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	17.2	Other current liabilities	20.4
Total fair value of derivative instruments		**$ 30.5**		**$ 89.1**

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

	December 31, 2020					
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/Liabilities Presented in the Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 26.1	$ —	$ 26.1	$ (26.1)	$ —	$ —
Derivative liabilities	$ (172.6)	$ —	$ (172.6)	$ 26.1	$ —	$ (146.5)

	December 31, 2019					
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/Liabilities Presented in the Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 30.5	$ —	$ 30.5	$ (21.4)	$ —	$ 9.1
Derivative liabilities	$ (89.1)	$ —	$ (89.1)	$ 21.4	$ —	$ (67.7)

7. Other Investments

Other investments include strategic investments in equity securities of certain biotechnology companies which we acquired in connection with strategic business development transactions, including license and option agreements. These investments are included in other assets in our consolidated balance sheets.

Moderna

During 2014, we purchased $37.5 of preferred stock of Moderna Therapeutics, Inc. (Moderna), a privately held biotechnology company, which was recorded at cost. During the first quarter 2018, Moderna announced the completion of a new round of financing. We considered this transaction and the rights of the new shares issued in the new round, compared to the rights of the preferred equity that we held, and concluded that Moderna's new round of financing represented an observable price change in an orderly transaction for a similar investment. We further concluded, based on the respective rights of the stock and consideration of potential liquidity events, that the value of our preferred stock was equivalent to the value of the newly issued preferred stock. As a result, we recognized an unrealized gain of $100.8 in investment income during the first quarter 2018 to adjust our equity investment in Moderna to fair value as of the date of the observable price change, based on the per share price in Moderna's new round of financing.

On December 6, 2018, Moderna completed its initial public offering (IPO) and shares of Moderna began trading on the Nasdaq Global Select Market under the symbol "MRNA." As part of the IPO, our preferred stock was converted into Moderna common stock and subject to a one year lock-up period. As our equity investment in Moderna common stock now had a readily determinable fair value, we began to record the investment at fair value, with the effects of the holding period restriction estimated using an option pricing valuation model. During the fourth quarter 2018, we recognized an unrealized loss of $56.4 in investment income to adjust our investment in Moderna to fair value as of December 31, 2018.

On December 9, 2019, we sold our investment in Moderna. We received $114.7 in net proceeds, resulting in a realized gain of $77.2 on our initial investment. During the year ended December 31, 2019, we recognized a gain of $32.8 in investment income.

Dicerna

In October 2018, we purchased $10.3 of Dicerna Pharmaceuticals Inc. (Dicerna) common stock in connection with an agreement that we entered into with Dicerna, a publicly-traded biopharmaceutical company. As our equity investment in Dicerna common stock has a readily determinable fair value, we are recording the investment at fair value. During the year ended December 31, 2020, there was no unrealized gain or loss recognized in investment income as the fair value of the common stock as of December 31, 2020 was consistent with the fair value as of December 31, 2019. During the years ended December 31, 2019 and 2018, we recognized an unrealized gain of $9.5 and an unrealized loss of $1.4, respectively, in investment income to adjust our equity investment in Dicerna to fair value.

The fair value of this investment was $18.4 as of December 31, 2020 and 2019.

Caelum

In January 2019, we purchased $41.0 of preferred stock of Caelum Biosciences (Caelum), a privately-held biotechnology company, and a $16.1 option to acquire the remaining equity in Caelum, based on Phase II data, in connection with an agreement that we entered into with Caelum. Following discussions with the FDA, Caelum changed its clinical development plan for CAEL-101 in the fourth quarter 2019. In December 2019, we amended the terms of the agreement with respect to the option to acquire the remaining equity in Caelum based on data from the modified Phase II/III trials. We accounted for the amendment as an exchange transaction as the terms of the modified option were determined to be substantially different than the terms of the original option. In conjunction with this amendment, we recognized a gain of $32.0 during the fourth quarter 2019 in other income and (expense), which reflects an increase in the fair value of the option, less $20.0 in incremental upfront funding which we accrued as of December 31, 2019 and paid during the first quarter 2020, and $4.1 associated with the change in the fair value of contingent payments which we also modified as part of the amendment. Refer to Note 11, *Commitments and Contingencies*, for additional information on the agreement. As our equity investment in Caelum and the option to acquire the remaining equity in Caelum does not have a readily determinable fair value, we only adjust the carrying value of the assets for impairment and any subsequent changes resulting from an observable price change in an orderly transaction for identical or similar equity securities of the same issuer.

There were no observable price changes associated with these assets during the year ended December 31, 2020 and 2019. A Phase II trial for CAEL-101 commenced during the first quarter of 2020 and met its primary objectives, supporting the safety and tolerability of CAEL-101 and confirmed the dose and regimen to be adopted for the Phase III studies. In September 2020, Alexion and Caelum announced the initiation of the Cardiac Amyloid Reaching for Extended Survival (CARES) program. This includes two parallel Phase III trials to evaluate the survival benefits of CAEL-101. In December 2020, in connection with entering into the Merger Agreement with AstraZeneca (refer to Note 1, *Business Overview and Summary of Significant Accounting Policies*), we determined that the fair value of our option to acquire the remaining equity of Caelum decreased as a result of a change to the expected option exercise date. This resulted in a $49.0 impairment charge which we recorded to investment income, net. The carrying value of the preferred stock was unaffected.

As of December 31, 2020, the carrying value of the investment and option, respectively, was $41.0 and $15.0. As of December 31, 2019, the carrying value of the investment and option, respectively, was $41.0 and $64.0.

Zealand

In March 2019, we purchased $13.8 (Kr. 90.9) of Zealand Pharma A/S (Zealand) common stock in connection with an agreement that we entered into with Zealand, a publicly-traded biopharmaceutical company based in Copenhagen, Denmark. Refer to Note 11, *Commitments and Contingencies* for additional information on the agreement. As our equity investment in Zealand common stock has a readily determinable fair value, we are recording the investment at fair value. During the years ended December 31, 2020 and 2019, we recognized an unrealized loss of $1.9 and an unrealized gain of $14.7, respectively, in investment income to adjust our equity investment in Zealand to fair value.

The fair value of this investment was $29.1 and $28.5 as of December 31, 2020 and 2019, respectively.

Eidos

In September 2019, we purchased $19.9 of Eidos Therapeutics, Inc. (Eidos) common stock, in connection with an agreement that we entered into with Eidos, a publicly-traded biopharmaceutical company and subsidiary of BridgeBio Pharma, Inc. Refer to Note 11, *Commitments and Contingencies,* for additional information on the agreement. As our equity investment in Eidos common stock has a readily determinable fair value, we are recording the investment at fair value. During the years ended December 31, 2020 and 2019, we recognized an unrealized gain of $45.4 and $7.9, respectively, in investment income to adjust our equity investment in Eidos to fair value.

The fair value of this investment was $73.2 and $27.8 as of December 31, 2020 and 2019, respectively.

Stealth

In October 2019, we purchased $9.6 of Stealth BioTherapeutics Corp. (Stealth) common stock, in connection with an agreement that we entered into with Stealth, a publicly traded clinical-stage biotechnology company. As our equity investment in Stealth common stock has a readily determinable fair value, we are recording the investment at fair value. During the years ended December 31, 2020 and 2019, we recognized an unrealized loss of $2.4 and $5.2, respectively, in investment income to adjust our equity investment in Stealth to fair value.

The fair value of this investment was $2.0 and $4.4 as of December 31, 2020 and 2019, respectively.

Portola

In March 2020 and April 2020, we purchased $14.5 and $3.6, respectively, of common stock of Portola Pharmaceuticals, Inc., a publicly traded commercial-stage biological company which we acquired on July 2, 2020. As our equity investment in Portola common stock had a readily determinable fair value, we recorded the investment at fair value. Upon the closing of the acquisition of Portola on July 2, 2020, the fair value of the equity investment of $47.8 was derecognized and included in the fair value of consideration transferred, resulting in a realized gain of $29.7 in investment income on our initial investment. Refer to Note 2, *Acquisitions*, for additional information.

Inozyme

On July 17, 2020, we sold certain intellectual property rights and assets focusing on ENPP1 gene deficiencies to Inozyme Pharma (Inozyme), a publicly traded biopharmaceutical company, in exchange for $14.8 of Inozyme Pharma common stock, which was initially recorded at its IPO offering price, net of the effects of a nine month holding period restriction. We recognized the $14.8 of consideration received as a gain within gain on sale of asset in our consolidated statement of operations. As our equity investment in Inozyme common stock has a readily determinable fair value, we are recording the investment at fair value, with the effects of a nine month holding period

(amounts in millions except per share amounts)

restriction estimated using an option pricing valuation model. During the year ended December 31, 2020, we recognized an unrealized gain of $5.7 in investment income to adjust our equity investment in Inozyme to fair value.

The fair value of this investment was $20.5 as of December 31, 2020.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	December 31, 2020	December 31, 2019
Accounts payable	$ 118.6	$ 74.0
Royalties	27.6	20.1
Payroll and employee benefits	242.3	187.5
Taxes payable	150.9	103.9
Rebates payable	333.3	250.1
Clinical	97.0	67.3
Manufacturing	58.2	72.8
Accrued severance and restructuring costs	31.7	12.8
Other	143.7	178.2
	$ 1,203.3	$ 966.7

9. Debt

Credit Agreement

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 amended and restated our credit agreement dated as of June 22, 2015 (the Prior Credit 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 the term loan facility mature on June 7, 2023. Beginning with the quarter ended June 30, 2019, we are required to make payments of 5.0% of the original 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 a 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). As of December 31, 2020, the interest rate on our outstanding loans under the Credit Agreement was 1.4%. Our obligations under the Credit Agreement are guaranteed by certain of Alexion Pharmaceuticals, Inc.'s 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. We were in compliance with all applicable covenants under the Credit Agreement as of December 31, 2020.

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 a consolidated net leverage ratio, as defined in the Credit Agreement, within predefined ranges, subject to certain increases following designated material acquisitions.

In connection with entering into the Credit Agreement and the Prior Credit Agreement, we paid an aggregate of $53.1 in financing costs in 2018. Financing costs are amortized as interest expense over the life of the debt. Amortization expense associated with deferred financing costs for the years ended December 31, 2020, 2019, and

(amounts in millions except per share amounts)

2018 was $4.7, $5.0 and $8.0, respectively. Remaining unamortized deferred financing costs as of December 31, 2020 and 2019 were $11.1 and $15.8, respectively.

We made principal payments of $130.6 on the term loan during 2020 and as of December 31, 2020, we had $2,383.9 outstanding on the term loan. We made principal payments of $98.0 on the term loan during 2019 and as of December 31, 2019, we had $2,514.5 outstanding on the term loan. We had no outstanding borrowings under the revolving credit facility during the years ended December 31, 2020 and 2019. As of December 31, 2020 and 2019, we had open letters of credit of $1.0 that offset our availability in the revolving facility.

The amount outstanding under the term loan of $2,383.9 as of December 31, 2020 is subject to variable interest rates, which are based on current market rates, and as such, the Company believes the carrying amount of the obligation approximates fair value.

In connection with the planned merger with AstraZeneca, we evaluated the terms of the Credit Agreement and determined that the agreement could require acceleration of payments upon a change of control.

Royalty-based Financing

In connection with our acquisition of Portola during the third quarter 2020, we assumed royalty-based debt relating to a royalty sales agreement Portola had entered into with HealthCare Royalty Partners (HCR) whereby HCR acquired a tiered royalty interest in future worldwide net sales of ANDEXXA. Portola received $50.0 upon closing of the agreement in February 2017 and an additional $100.0 following the U.S. regulatory approval of ANDEXXA in May 2018. Tiered royalties ranging from 4.2% to 8.5% are required to be paid to HCR based on net worldwide sales of ANDEXXA. The applicable rate decreases as worldwide net annual sales levels increase above defined thresholds. Total potential royalty payments are capped at 195.0% of the funding received less certain transaction expenses, or $290.6. As of the date of acquisition, the remaining due to HCR was $276.9 in royalty-based payments.

We recorded the HCR debt at its fair value of $182.0 upon closing of the acquisition, representing an initial debt discount of $94.9. We have also recognized a deferred tax asset of $42.4 related to the royalty-based debt as of the acquisition date. For additional information on our acquisition of Portola, refer to Note 2, *Acquisitions.* Interest expense is recognized using the effective interest rate method over the estimated period the related debt will be paid. This requires estimation of the timing and amount of future royalty payments to be generated from future sales of ANDEXXA. We reassess the expected royalty payments each reporting period and account for any changes through an adjustment to the effective interest rate on a prospective basis. The assumptions used in determining the expected repayment term of the debt require that we make estimates that could impact the short and long term classification of the debt carrying values.

Each period, we amortize the initial debt discount using the effective interest rate implied from the projected timing of royalty payments to HCR. The effective interest rate for the HCR royalty-based debt as of December 31, 2020 was 11.5%. During the year ended December 31, 2020, we recognized interest expense associated with the amortization of the debt discount of $10.0. We made royalty-based debt payments of $5.0 during 2020. As of December 31, 2020, the carrying value of the royalty-based debt includes approximately $3.0 of royalty payments on fourth quarter sales of ANDEXXA which will be paid during the first quarter 2021.

As of December 31, 2020, the carrying value of the HCR royalty-based debt was $187.0, of which $15.5 was recorded within current portion of long-term debt and $171.5 was recorded within long-term debt, less current portion on our consolidated balance sheet. Our payment obligations for HCR royalty-based debt are as follows:

	Year ended December 31, 2020
Total repayment obligation as of the acquisition date	$ 276.9
Less: interest to be accreted in future periods	(84.9)
Less: payments made	(5.0)
Carrying value as of December 31, 2020	$ 187.0

The carrying value of the royalty-based debt as of December 31, 2020 approximates fair value.

(amounts in millions except per share amounts)

Contractual Maturities:

The contractual maturities of our Credit Agreement and estimated royalty-based debt obligations due subsequent to December 31, 2020 are as follows:

Year	
2021	$ 146.1
2022	158.4
2023	2,167.7
2024	63.6
2025	76.5
Thereafter	43.5

10. Leases

The following table summarizes our lease assets and liabilities as of December 31, 2020:

ROU Assets and Liabilities

	Balance Sheet Location	Financing	Operating
ROU - Asset	*Right of use operating assets*	$ —	$ 223.1
ROU - Asset	*Property, plant, and equipment*	105.4	—
Lease liabilities (current)	*Other current liabilities*	5.6	28.1
Lease liabilities (noncurrent)	*Noncurrent operating lease liabilities*	—	177.1
Lease liabilities (noncurrent)	*Other liabilities*	67.3	—

The following table summarizes our lease assets and liabilities as of December 31, 2019:

ROU Assets and Liabilities

	Balance Sheet Location	Financing	Operating
ROU - Asset	*Right of use operating assets*	$ —	$ 204.0
ROU - Asset	*Property, plant, and equipment*	116.3	—
Lease liabilities (current)	*Other current liabilities*	5.2	18.8
Lease liabilities (noncurrent)	*Noncurrent operating lease liabilities*	—	164.1
Lease liabilities (noncurrent)	*Other liabilities*	72.9	—

The following table summarizes our lease related costs for the years ended December 31, 2020 and 2019:

Lease Cost:

	Statement of Operations Location	Years ended December 31, 2020	Years ended December 31, 2019
Financing Lease Cost		$ 14.5	$ 14.8
Amortization of ROU Assets	*Operating Expenses*	10.9	10.9
Interest on Lease Liabilities	*Interest Expense*	3.6	3.9
Operating Lease Cost	*Operating Expenses*	38.1	34.3
Variable Lease Cost	*Operating Expenses*	8.7	11.8
Total Lease Cost		$ 61.3	$ 60.9

Amounts above include $11.9 and $15.6, of lease costs associated with our CMO embedded lease arrangement for the years ended December 31, 2020 and 2019, respectively, which have been capitalized as part of the cost of product being manufactured at the site.

The following table summarizes supplemental cash flow information for the years ended December 31, 2020 and 2019:

(amounts in millions except per share amounts)

Other Information

	Years ended	
	December 31, 2020	December 31, 2019
Cash Paid For Amounts Included In Measurement of Liabilities	$ 39.4	$ 32.3
Operating Cash Flows From Financing Leases	3.6	3.9
Operating Cash Flows From Operating Leases	30.7	23.5
Financing Cash Flows From Financing Leases	5.1	4.9
ROU Assets Obtained In Exchange For New Financing Liabilities [1]	—	—
ROU Assets Obtained In Exchange For New Operating Liabilities [2]	31.6	27.5

(1) We capitalized $83.1 of ROU financing assets upon adoption of the new lease standard in the first quarter of 2019 that are excluded from the figures for the year ended December 31, 2019. This figure excludes $44.2 of opening adjustments to ROU finance assets related, primarily, to prepayments of rent.

(2) We capitalized $172.2 of ROU operating assets upon adoption of the new lease standard in the first quarter of 2019 that are excluded from the figures for the year ended December 31, 2019. This figure excludes $26.6 of opening adjustments to ROU operating assets related, primarily, to prepayments of rent.

The following tables summarize maturities of lease liabilities and the reconciliation of lease liabilities as of December 31, 2020:

Lease Liability Maturity Summary

Year	Financing	Operating	Total
2021	$ 9.0	$ 34.4	$ 43.4
2022	9.2	32.0	41.2
2023	9.2	25.2	34.4
2024	9.4	22.5	31.9
2025	9.6	20.7	30.3
Thereafter	45.0	103.1	148.1

Reconciliation of Lease Liabilities:	Financing	Operating	Total
Weighted-average Remaining Lease Term *(years)*	9.67	8.87	9.08
Weighted-average Discount Rate	4.9 %	3.4 %	3.8 %
Total Undiscounted Lease Liability	$ 91.4	$ 237.9	$ 329.3
Imputed Interest	18.5	32.7	51.2
Total Discounted Lease Liability	72.9	205.2	278.1

The following table summarizes the reconciliation of lease liabilities as of December 31, 2019:

Reconciliation of Lease Liabilities:	Financing	Operating	Total
Weighted-average Remaining Lease Term *(years)*	10.67	10.17	10.32
Weighted-average Discount Rate	4.9 %	4.1 %	4.3 %
Total Undiscounted Lease Liability	$ 100.2	$ 223.6	$ 323.8
Imputed Interest	22.1	40.7	62.8
Total Discounted Lease Liability	78.1	182.9	261.0

11. Commitments and Contingencies

Asset Acquisition and In-License Agreements

We have entered into asset purchase agreements, license agreements, and option arrangements in order to advance and obtain technologies and services related to our business. These agreements generally require us to pay an initial fee and certain agreements call for future payments upon the attainment of agreed upon development, regulatory and/or commercial milestones. These agreements may also require minimum royalty payments based on sales of products developed from the applicable technologies, if any.

In January 2019, we entered into an agreement with Caelum, a biotechnology company that is developing CAEL-101 for light chain (AL) amyloidosis. Under the terms of the agreement, we acquired a minority equity interest in preferred stock of Caelum and an exclusive option to acquire the remaining equity in Caelum based on Phase II data, for pre-negotiated economics. We paid $30.0 in the first quarter 2019 and agreed to pay up to an additional

$30.0 in contingent development milestones prior to exercising the option to acquire the remaining equity in Caelum. These contingent payments meet the definition of a derivative liability and were initially recorded at fair value of $27.1. We allocated the total consideration of $57.1, inclusive of the fair value of the contingent payments, to the equity investment in Caelum and the option to acquire the remaining equity in Caelum based on the relative fair values of the assets. Following discussions with the FDA, Caelum changed its clinical development plan for CAEL-101 in the fourth quarter 2019. In December 2019, we amended the terms of the agreement with Caelum to modify the option to acquire the remaining equity in Caelum based on data from the modified Phase II/III trials. The amendment also modified the development-related milestone events associated with the initial $30.0 in contingent payments, provided for an additional $20.0 in upfront funding, which we accrued as of December 31, 2019 as well as funding of $60.0 in exchange for an additional equity interest at fair value upon achievement of a specific development-related milestone event. We paid the additional $20.0 in upfront funding and the initial $30.0 in contingent payments in 2020. The agreement with Caelum also provides for additional payments, in the event Alexion exercises the purchase option, for up to $500.0, which includes an upfront option exercise payment and potential regulatory and commercial milestone payments. A Phase II trial for CAEL-101 commenced during the first quarter of 2020 and met its primary objectives, supporting the safety and tolerability of CAEL-101 and confirmed the dose and regimen to be adopted for the Phase III studies. In September 2020, Alexion and Caelum announced the initiation of the Cardiac Amyloid Reaching for Extended Survival (CARES) program. This includes two parallel Phase III trials to evaluate the survival benefits of CAEL-101. In December 2020, in connection with entering into the Merger Agreement with AstraZeneca, we determined that the fair value of our option to acquire the remaining equity of Caelum decreased as a result of a change to the expected option exercise date. This resulted in a $49.0 impairment charge which we recorded to investment income, net (refer to Note 7, *Other Investments*).

In March 2019, we entered into an agreement with Zealand which provides us with exclusive worldwide licenses, as well as development and commercial rights, for subcutaneously delivered preclinical peptide therapies directed at up to four complement pathway targets. Pursuant to the agreement, Zealand will lead joint discovery and research efforts through the preclinical stage, and Alexion will lead development efforts beginning with the investigational new drug filing and Phase I studies. In addition to the agreement, we made an equity investment in Zealand (refer to Note 7, *Other Investments*). Under the terms of the agreement, we made an upfront payment of $40.0 for an exclusive license to the lead target and the equity investment, as well as for preclinical research services to be performed by Zealand in relation to the lead target. The market value of the equity investment was $13.8 as of the date of acquisition, which we recorded in other assets in our consolidated balance sheets. We also recognized prepaid research and development expense of $5.0 within the consolidated balance sheets associated with the research activities to be performed by Zealand. Due to the early stage of the asset we are licensing, we recorded the upfront license payment of $21.2 as research and development expense during the first quarter 2019. As of December 31, 2020, we could be required to pay up to $610.0, for the lead target, upon the achievement of specified development, regulatory and commercial milestones, as well as royalties on commercial sales. In addition, we could be required to pay up to an additional $115.0 in development and regulatory milestones if both a long-acting and short-acting product are developed with respect to the lead target. Each of the three subsequent targets can be selected for an option fee of $15.0 and has the potential for additional development, regulatory and commercial milestones, as well as royalty payments, at a reduced price to the lead target.

In April 2019, we entered into an agreement with Affibody AB (Affibody), through which Alexion obtained an exclusive worldwide license, as well as development and commercial rights, to ABY-039, a bivalent antibody-mimetic that targets the neonatal Fc receptor (FcRn). Under the terms of the agreement, we made an upfront payment of $25.0 for the exclusive license to ABY-039. Due to the early stage of the asset we licensed, we recorded the upfront license payment as research and development expense during the second quarter 2019. In February 2020, based on data from our Phase I study, we terminated the agreement to co-develop ABY-039 with Affibody.

In September 2019, we entered into an agreement with Eidos through which Alexion obtained an exclusive license to develop and commercialize AG10 in Japan. AG10 is a small molecule designed to treat the root cause of transthyretin amyloidosis (ATTR) and is currently in a Phase III study in the U.S., Europe, and Japan for ATTR cardiomyopathy (ATTR-CM). In addition, we made an equity investment in Eidos (refer to Note 7, *Other Investments*). Under the terms of the agreement, we made an upfront payment of $50.0 for the exclusive license to AG10 in Japan and the equity investment. The market value of the equity investment was $19.9 as of the date of acquisition, which we recorded in other assets in our consolidated balance sheets. Due to the early stage of the asset we are licensing, we recorded the upfront license payment of $30.1 as research and development expense during the third

quarter 2019. As of December 31, 2020, we could also be required to pay $30.0 upon achievement of a Japanese-based regulatory milestone as well as royalties on commercial sales.

In October 2019, we entered into an option agreement with Stealth BioTherapeutics Corp. (Stealth), a clinical-stage biotechnology company whose lead product candidate, elamipretide, was being investigated in late-stage clinical studies in three primary mitochondrial diseases - primary mitochondrial myopathy (PMM), Barth syndrome and Leber's hereditary optic neuropathy. Under the terms of the agreement, we made an upfront payment of $30.0 for an equity investment in Stealth and an exclusive option to partner with Stealth in the development of subcutaneous elamipretide based on final results from the Phase III study in PMM. The market value of the equity investment was $9.6 as of the date of acquisition, which we recorded in other assets in our consolidated balance sheets. Due to the early stage of the asset for which we have an option to license, we recorded the upfront option payment of $20.4 as research and development expense during the fourth quarter 2019. In December 2019, Stealth announced that based on top-line data from the Phase 3 study in PMM, the study did not meet its primary endpoints. Following review of the Phase 3 data released in December 2019, we notified Stealth that we will not exercise the co-development option agreement.

In October 2018, we entered into a collaboration agreement with 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 the upfront license payment of $26.7 as research and development expense during the fourth quarter 2018. In December 2019, we exercised our option for exclusive rights to two additional targets within the complement pathway under an existing agreement with Dicerna, which expands our existing research collaboration and license agreement with Dicerna to include a total of four targets within the complement pathway. In connection with the option exercise, we paid Dicerna $20.0, which we recorded as research and development expense in the fourth quarter 2019. As of December 31, 2020, excluding accrued milestones, we could be required to pay up to $604.1 for amounts due upon the achievement of specified research, development, regulatory and commercial milestones on the four licensed targets, 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. Under the terms of the agreement, we made an upfront payment of $40.0 for an exclusive license to two of the four potential targets and due to the early stage of the assets we are licensing, we recorded an expense for the upfront payment during the fourth quarter 2017. During the second quarter 2020, we forfeited our rights to one of the two targets we initially licensed. As of December 31, 2020, we could be required to pay up to $155.0 for the remaining licensed target upon achievement of specified development, regulatory and sales-based milestones, as well as royalties on commercial sales. Each of the two subsequent targets can be licensed for an option fee of $8.0, with contingent payments of up to $160.0 per target, subject to development, regulatory and commercial milestones, as well as royalties on commercial sales.

In connection with our prior acquisition of Syntimmune, Inc., a clinical-stage biotechnology company developing an antibody therapy targeting the FcRn, we could be required to pay up to $800.0 upon the achievement of specified development, regulatory and commercial milestones, of which $130.0 is specific to the subcutaneous formulation. We are currently subject to a claim in litigation in connection with the Syntimmune acquisition alleging that Alexion failed to meet its obligations under the merger agreement to use commercially reasonable efforts to achieve the milestones and plaintiff has requested payment of the full earn-out amount.

In addition, excluding accrued milestones, as of December 31, 2020, we have other license agreements under which we may be required to pay up to an additional $114.0 for currently licensed targets, if certain development, regulatory and commercial milestones are met, including up to $71.5 for the development of cerdulatinib in multiple indications pursuant to an in-licensing agreement with Astellas Pharma, Inc. which was assumed through the acquisition of Portola in the third quarter 2020. Additional amounts may be payable if we elect to acquire licenses to additional targets, as applicable, under the terms of these agreements.

During the next 12 months, we may make milestone payments related to our asset acquisitions, option and in-license agreements of approximately $71.1, excluding milestones accrued as of December 31, 2020.

Asset Sale and Out-License Arrangements

In connection with prior asset sale and out-license arrangements, including those assumed by Alexion through the acquisition of Portola in the third quarter 2020, Alexion is entitled to receive contingent payments upon the achievement of various regulatory and commercial milestones and other events, as well as royalties on commercial sales. The amount of contingent consideration related to these agreements is fully constrained and therefore has not been recognized as of December 31, 2020.

Manufacturing Agreements

We have various manufacturing development and license agreements to support our clinical and commercial product needs.

We rely on Lonza, a third party manufacturer, to produce a portion of commercial and clinical quantities of our commercial products and product candidates. We have various manufacturing and license agreements with Lonza, with remaining total non-cancellable future commitments of approximately $1,137.8 through 2030. This amount includes $100.5 of undiscounted, fixed payments applicable to our Contract Manufacturing Organization (CMO) embedded lease arrangement with Lonza. 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 pay Lonza a royalty on the sales of SOLIRIS and ULTOMIRIS manufactured at Lonza facilities.

In addition to our commitments with Lonza, as of December 31, 2020 we have non-cancellable commitments of approximately $175.6 through 2023 with other third party manufacturers.

Contingent Liabilities

We are currently involved in various claims, disputes, lawsuits, investigations, administrative proceedings and legal proceedings. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. In accordance with generally accepted accounting principles, 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, proceedings and litigation, accruals are based on our best estimates based on information available at the time of the assessment. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation, court decisions or settlement of claims (and offers of settlement), we may reassess the potential liability related to these matters and may revise these estimates, which could result in a material adverse adjustment to our operating results. Costs associated with our involvement in legal proceedings are expensed as incurred. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. If we were unable to prevail in any such proceedings, our consolidated financial position, results of operations, and future cash flows may be materially impacted.

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

In May 2015, we received a subpoena in connection with an investigation by the Enforcement Division of the Securities and Exchange Commission (SEC) requesting information related to our grant-making activities and compliance with the Foreign Corrupt Practices Act (FCPA) in various countries. In addition, in October 2015, we received a request from the Department of Justice (DOJ) for the voluntary production of documents and other information pertaining to Alexion’s compliance with the FCPA. The SEC and DOJ also sought information related to Alexion’s recalls of specific lots of SOLIRIS and related securities disclosures.

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

In May 2020, DOJ informed us that it has closed its inquiry into these matters.

On July 2, 2020, we reached a civil settlement with the SEC fully resolving the SEC's investigation into possible violations of the FCPA. Alexion neither admitted nor denied any wrongdoing in connection with the settlement but agreed to pay $21.5 to the SEC, consisting of amounts attributable to disgorgement, civil penalties, and pre-judgment interest. In connection with this settlement, in July 2020, we paid $21.5 to the SEC.

Following the settlement with the SEC, the Ministry of Health in Turkey initiated an investigation regarding the matters referenced in the SEC Order as they relate to the Company's operations in Turkey between 2010 and 2015. We are cooperating with this investigation.

Alexion is committed to continually focusing on its compliance program and continues to enhance its comprehensive company-wide program that is designed to enhance our business processes, structures, controls, training, talent, and systems across Alexion's global operations.

As previously reported, on December 29, 2016, a shareholder filed a putative class action against the Company and certain former employees in the U.S. District Court for the District of Connecticut, alleging that defendants made misrepresentations and omissions about SOLIRIS. On April 12, 2017, the court appointed a lead plaintiff. On July 14, 2017, the lead plaintiff filed an amended putative class action complaint against the Company and seven current or former employees. Defendants moved to dismiss the amended complaint on September 12, 2017. Plaintiffs filed an opposition to defendants' motion to dismiss on November 13, 2017, and defendants filed a reply brief in further support of their motion on December 28, 2017. On March 26, 2019, the court held a telephonic status conference. During that conference, the court informed counsel that it was preparing a ruling granting the defendants' pending motion to dismiss. The court inquired of plaintiffs' counsel whether they intended to seek leave to amend their complaint, and indicated that if they wished to file a second amended complaint, they would be allowed to do so. On April 2, 2019, the court granted plaintiffs until May 31, 2019 to file a second amended complaint, thereby rendering moot defendants' pending motion to dismiss. On June 2, 2019, plaintiffs filed a second amended complaint against the same defendants. The complaint alleges that defendants engaged in securities fraud, including by making misrepresentations and omissions in its public disclosures concerning the Company's SOLIRIS sales practices, management changes, and related investigations, between January 30, 2014 and May 26, 2017, and that the Company's stock price dropped upon the purported disclosure of the alleged fraud. The plaintiffs seek to recover unspecified monetary relief, unspecified equitable and injunctive relief, interest, and attorneys' fees and costs. Defendants' filed a motion to dismiss the amended complaint on August 2, 2019; plaintiffs' filed their opposition to that motion on October 2, 2019; and defendants' filed their reply in further support of their motion on November 15, 2019. Given the early stage of these proceedings, we cannot presently predict the likelihood of obtaining dismissal of the case (or the ultimate outcome of the case if the motion to dismiss is denied by the court), nor can we estimate the possible loss or range of loss at this time.

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 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; Alexion's provision of free drug to Medicare patients; and Alexion compliance policies and training materials concerning the anti-kickback statute and information on donations to PSI and NORD from 2010 through 2016. In April 2019, we entered into a civil settlement agreement with the DOJ and the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services to resolve this matter. As part of the settlement agreement, Alexion paid $13.1 to the DOJ and OIG. OIG did not require a Corporate Integrity Agreement with Alexion because it made fundamental organizational changes, including hiring a new executive leadership team, replacing half of the members of its Board of Directors, and effecting a significant change in the workforce.

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

In June 2017, we received a demand to inspect certain of our books and records pursuant to Section 220 of the General Corporation Law of the State of Delaware on behalf of a purported stockholder. Among other things, the demand sought to determine whether to institute a derivative lawsuit against certain of the Company's directors and officers in relation to the investigation by our Audit and Finance Committee announced in November 2016 and the investigations instituted by the SEC, DOJ, U.S. Attorney's Office for the District of Massachusetts, and Brazilian law enforcement officials that are described above. We have responded to the demand. Given the early stages of this matter, an estimate of the possible loss or range of loss cannot be made at this time.

On September 27, 2017, a hearing panel of the Canadian Patented Medicine Prices Review Board (PMPRB) issued a decision in a previously pending administrative pricing matter that we had excessively priced SOLIRIS in a

manner inconsistent with the Canadian pricing rules and guidelines. In its decision, the PMPRB ordered Alexion to decrease the price of SOLIRIS to an upper limit based upon pricing in certain other countries, and to forfeit excess revenues for the period between 2009 and 2017. The amount of excess revenues for the period between 2009 and 2017 was determined not to be a material amount and was paid in 2018. In October 2017, Alexion filed an application for judicial review of the PMPRB's decision in the Federal Court of Canada. On May 23, 2019, the Federal Court of Canada dismissed Alexion's application for judicial review and, as a consequence, affirmed the decision of the PMPRB that we had excessively priced SOLIRIS. On June 21, 2019, Alexion filed a notice of appeal of the Federal Court of Canada's ruling, and, on October 17, 2019, Alexion filed a memorandum of fact and law in support of the appeal. On December 3, 2019, the Attorney General of Canada filed its memorandum of fact and law in support of the Federal Court of Canada's dismissal of Alexion's appeal of the PMPRB's decision. On December 19, 2019, the intervenor, the Minister of Health for the Province of British Columbia, filed a separate memorandum of fact and law in support of the Federal Court of Canada's decision. The Canadian Federal Court of Appeal heard the appeal on October 21 and 22, 2020, but has not issued a decision as of the date of this filing. Pursuant to an order made by the Federal Court of Canada, as of February 4, 2021, we have placed approximately $70.7 in escrow to secure our obligations pending the final resolution of all appeals in this matter. This amount reflects the difference between the list price for SOLIRIS and the price determined by the PMPRB to be non-excessive for sales of SOLIRIS in Canada for the period beginning September 2017 through December 31, 2020. In addition, on a quarterly basis, until the appeals process has concluded, Alexion will be required to place amounts into escrow for each vial of SOLIRIS sold in the applicable quarter equal to the difference between the list price for SOLIRIS and the price determined by the PMPRB to be non-excessive. Our revenues in Canada have been reduced by $49.2 cumulatively to date, which is our current best estimate of our liability through December 31, 2020 if we lose the appeal of this matter (the amount of our ultimate liability, however, may be greater than this estimate when the appeal process for this matter is concluded).

Chugai Pharmaceutical Co., Ltd. has filed three lawsuits against Alexion. The first was filed in November 2018 in the United States District Court for the District of Delaware against Alexion Pharmaceuticals, Inc. alleging that ULTOMIRIS infringes one U.S. patent held by Chugai Pharmaceutical Co., Ltd. Upon issuance of a new U.S. patent on November 12, 2019, Chugai filed a second lawsuit in the United States alleging that ULTOMIRIS infringes the new patent. The parties have agreed to consolidate the November 2018 and November 2019 lawsuits. Chugai filed a third lawsuit in December 2018 in the Tokyo District Court against Alexion Pharma GK (a wholly-owned subsidiary of Alexion) in Japan, and alleges that ULTOMIRIS infringes two Japanese patents held by Chugai Pharmaceutical Co., Ltd. Chugai's complaints seek unspecified damages and certain injunctive relief. On March 5, 2020, the Supreme Court of Japan dismissed Chugai's appeal against an earlier IP High Court of Japan decision which held that one of the Chugai patents-in-suit is invalid. Subsequently Chugai filed a correction to the claims of this patents-in-suit and Alexion has countered that the corrected claims are still invalid and not infringed. In all cases, Alexion has denied the charges and countered that the patents are neither valid nor infringed. A trial date for the U.S. case which was initially set for July 2021 has been re-scheduled for January 2022. The case is still at the briefing stage in Japan. Given the early stages of these litigations, an estimate of the possible loss or range of loss cannot be made at this time.

On February 28, 2019, Amgen Inc. (Amgen) petitioned the U.S. Patent and Trademark Office (PTO) to institute Inter Partes Review (IPR) of three patents owned by Alexion that relate to SOLIRIS: U.S. Patent Nos. 9,725,504; 9,718,880; and 9,732,149. In each case, Amgen alleged the patented subject matter was anticipated and/or obvious in view of prior art, and that the patent claims are therefore invalid. On August 30, 2019, the PTO instituted IPRs of each of the three patents. On May 28, 2020, we entered into a Confidential Settlement and License Agreement (the "Settlement Agreement") with Amgen to settle the three IPRs at the Patent Trial and Appeal Board ("PTAB") of the PTO. Pursuant to the Settlement Agreement, Alexion and Amgen have terminated each of the pending IPRs. In addition, effective March 1, 2025 (or an earlier date in certain circumstances), the Company grants to Amgen (and its affiliates and certain partners) a non-exclusive, royalty-free, license under U.S. patents and patent applications related to eculizumab and various aspects of the eculizumab product that Alexion currently markets and sells under the tradename SOLIRIS. This license will allow Amgen (and its affiliates and certain partners), effective March 1, 2025, the right to make, have made, use, import, have imported, sell, have sold, offer for sale, have offered for sale, distribute, and have distributed in, or for, the U.S., an eculizumab product.

In connection with an ongoing matter, in August 2019, the Brazilian Federal Revenue Service provided a Notice of Tax and Description of the Facts (the "Tax Assessment") to two Alexion subsidiaries (the "Brazil Subsidiaries"), as well as to two additional entities, a logistics provider utilized by Alexion and a distributor. The Tax Assessment

focuses on the importation of SOLIRIS vials pursuant to Alexion's free drug supply to patients program (referred to as Global Access to Medicines, or GATM) in Brazil. In September 2019, the Brazil Subsidiaries filed defenses to the Tax Assessment disputing the basis for liability under the Tax Assessment, based on, among others, the following: in connection with the operation of GATM, during the period from September 2014 to June 2019: (i) the importers responsible for the importation of the GATM SOLIRIS vials into Brazil were correctly identified and (ii) the correct customs value was utilized for the purpose of importing the GATM SOLIRIS vials provided to the patients free of charge. The defenses filed by Alexion are pending judgment at the first level of administrative appeals within the Brazilian federal administrative proceeding system. There are three separate levels of administrative appeals within the Brazilian federal administrative proceeding system and, if the outcome of these administrative appeals is unfavorable, the final decision of the federal administrative proceeding system can be disputed to the federal court systems in Brazil (at this time, Alexion intends to appeal the Tax Assessment if it is not overturned in the course of administrative appeals). Given the early stage of these proceedings, Alexion is unable to predict the duration, scope or outcome of this matter, but we expect that a final resolution will take three years or more. While it is possible that a loss related to the Tax Assessment may be incurred, given its ongoing nature, we cannot reasonably estimate the potential magnitude of any such possible loss or range of loss, or the cost of the ongoing administrative appeals (and potential appeals to the federal court system) of the Tax Assessment. Any determination that any aspects of the importation of free of charge medications into Brazil as set forth in the Tax Assessment are not, or were not, in compliance with existing laws or regulations could result in the imposition of fines, civil penalties and, potentially criminal penalties, and/or other sanctions against us, and could have an adverse impact on our Brazilian operations.

In connection with Alexion's acquisition of Portola, we have assumed litigation to which Portola was a party. Among the litigation assumed is a securities fraud class action filed against Portola and certain of its officers, directors and underwriters ("Defendants") under the Securities Act of 1933 and the Securities Exchange Act of 1934. Specifically, on January 16, 2020, February 7, 2020, and February 28, 2020, stockholders filed three putative class actions in the U.S. District Court for the Northern District of California, captioned *Hayden v. Portola Pharmaceuticals, Inc., et al., No. 3:20-cv-00367-VC (N.D. Cal.); McCutcheon v. Portola Pharmaceuticals, Inc., et al.,* No. 3:20-cv-00949 (N.D. Cal.)*; and Southeastern Pennsylvania Transportation Authority v. Portola Pharmaceuticals, Inc., et al.*, No. 3:20-cv-01501 (N.D. Cal.). These cases have since been consolidated, and on April 22, 2020, the Court issued an Order appointing the Alameda County Employees' Retirement Association ("ACERA") as Lead Plaintiff in the litigation. ACERA filed its amended consolidated complaint on May 20, 2020, asserting that Defendants made misrepresentations and omissions in public disclosures (including in materials issued in connection with the August 7, 2019 securities offering) concerning Portola's sales of andexanet alfa, marketed as ANDEXXA in the United States and ONDEXXYA in Europe, between January 8, 2019 and February 26, 2020. Specifically, plaintiffs allege that Defendants made materially false and/or misleading statements about the demand for ANDEXXA, usage of ANDEXXA by hospitals and healthcare organizations, and about Portola's accounting for its return reserves. Plaintiffs contend that the alleged fraud was revealed on January 9, 2020, when Portola announced its preliminary unaudited financial results for the fourth quarter of 2019, and again on February 26, 2020, when Portola issued its fourth quarter 2019 financial results. In July 2020, Portola and the Portola Defendants filed a motion to dismiss with the Court. The court heard oral argument on September 24, 2020 and granted defendants' pending motion to dismiss, but with leave for plaintiffs to amend further their complaint. Plaintiffs filed an amended complaint on November 5, 2020. In December 2020, Portola and Portola Defendants filed a motion to dismiss with the Court. Oral argument is scheduled for February 25, 2021. Plaintiffs seek to recover unspecified monetary relief, interest, and attorneys' fees and costs. Given the early stage of these proceedings, we cannot presently predict the likelihood of obtaining dismissal of the case (or the ultimate outcome of the case if that motion to dismiss is denied by the court), nor can we estimate the possible loss or range of loss at this time.

(amounts in millions except per share amounts)

12. Income Taxes

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

	Year Ended December 31,		
	2020	2019	2018
U.S.	$ (1,098.5)	$ 2.0	$ (451.4)
Non-U.S.	1,667.5	2,176.8	693.6
	$ 569.0	$ 2,178.8	$ 242.2

During the fourth quarter of 2013, in connection with the centralization of our global supply chain and technical operations in Ireland, our U.S. parent company became a direct partner in a captive foreign partnership. The partnership income, which is derived in foreign jurisdictions, is classified as “non-U.S. income” for purposes of financial reporting. Substantially all non-U.S. income relates to income from our captive foreign partnership.

The components of income tax expense are as follows:

	Year Ended December 31,		
	2020	2019	2018
Domestic			
Current	$ 3.1	$ 71.8	$ 57.0
Deferred	(382.1)	1,731.0	49.5
	(379.0)	1,802.8	106.5
Foreign			
Current	245.9	158.2	74.7
Deferred	98.7	(2,186.5)	(16.6)
	344.6	(2,028.3)	58.1
Total			
Current	249.0	230.0	131.7
Deferred	(283.4)	(455.5)	32.9
	$ (34.4)	$ (225.5)	$ 164.6

We continue to pay cash taxes in U.S. federal, various U.S. state, and foreign jurisdictions where we have utilized all of our tax attributes or have met the applicable limitation for attribute utilization.

Effective Tax Rate

The provision (benefit) for income taxes differs from the U.S. federal statutory tax rate. The reconciliation of the statutory U.S. federal income tax rate to our effective income tax rate is as follows:

	Year Ended December 31,		
	2020	2019	2018
U.S. federal statutory tax rate	21.0 %	21.0 %	21.0 %
Benefit of foreign earnings	(15.5)%	(12.6)%	(71.2)%
Tax credits	(7.3)%	(0.7)%	(17.0)%
Tax reserves	(0.6)%	(0.1)%	12.1 %
Acquired in-process research & development	— %	— %	102.6 %
Intra-entity asset transfer of intellectual property	0.4 %	(17.5)%	— %
Foreign-derived intangible income	(10.0)%	(1.6)%	(4.5)%
U.S. state taxes	(1.6)%	0.7 %	14.2 %
IRC 162(m) executive compensation	4.1 %	0.2 %	2.2 %
Other permanent differences	3.5 %	0.3 %	8.6 %
Effective Income Tax Rate	(6.0)%	(10.3)%	68.0 %

In our reconciliation of our statutory U.S. federal income tax rate to our effective tax rate above, we have included a benefit of foreign earnings amount which encapsulates the various tax impacts that result from our non-U.S. income. As a result of the Tax Cuts and Jobs Act of 2017 (Tax Act), a substantial portion of our foreign earnings are subject to the GILTI minimum tax at an effective rate which is lower than the U.S. statutory tax rate of 21.0%. While we are also subject to tax in foreign jurisdictions locally, the majority of these taxes are creditable against U.S. taxes imposed on foreign earnings. As a result, the effective tax rate on our foreign earnings is lower than the U.S. statutory rate.

In the year ended December 31, 2020, the benefit of foreign earnings includes foreign local tax expense of $270.8, which is offset by the benefit from U.S. foreign tax credits of $240.6, resulting in a net increase to the effective tax rate of 5.3%. We incurred U.S. tax expense on our foreign earnings of $201.5, which includes GILTI minimum tax. The U.S. tax on our foreign earnings reflects a benefit of $148.7, or 26.1%, primarily related to the Section 250(a) deduction, compared to the U.S. statutory rate. The benefit from foreign earnings also includes the impact of certain current year events as described below.

In the year ended December 31, 2020, other permanent differences includes an increase to the effective tax rate of 1.5%, or $8.5, associated with nondeductible contingent consideration in the form of non-tradeable contingent value rights (CVRs) relating to the Achillion acquisition. Also included in other permanent differences is a decrease to the effective tax rate of 1.1%, or $6.2, associated with a nontaxable gain from our Portola equity investment which was included in the fair value of consideration transferred in connection with the Portola acquisition.

During the second quarter 2020, we recognized an impairment charge of $2,042.3 related to the KANUMA intangible asset, resulting in a deferred tax benefit of $377.3. Refer to Note 4, *Intangible Assets and Goodwill*, for additional information on the impairment charge. These deferred tax benefits decreased the effective tax rate for the year ended December 31, 2020 by approximately 19.2%.

In August 2020, we received a notice of examination from the Dutch Tax Authorities (“DTA”) regarding certain matters relating to our 2014 through 2017 tax years. We entered into an agreement with the DTA in December 2020 and have agreed to pay approximately $73.8 in connection with the settlement, inclusive of the 2018 and 2019 tax years. After taking into account the $56.1 U.S. foreign tax credit claimed on the settlement, the net cash outflow was $17.7, representing a 3.1% net increase to the effective tax rate. This net tax expense is reflected within benefit from foreign earnings.

In April 2020 we became aware of a European withholding tax regulation that could be interpreted to apply to certain of our previous intra-group transactions. We continue to evaluate whether the interpretation of this regulation applies to our facts and circumstances, and, based on our preliminary analysis, we recorded an immaterial reserve related to this matter during the second quarter of 2020.

In the year ended December 31, 2019, the benefit of foreign earnings includes foreign local tax expense of $193.2, which is offset by the benefit from U.S. foreign tax credits of $196.1, resulting in a net decrease to the effective tax rate of 0.1%. We incurred U.S. tax expense on our foreign earnings of $187.6, which includes GILTI minimum tax. The U.S. tax on our foreign earnings reflects a benefit of $269.5, or 12.4%, primarily related to the Section 250(a) deduction, compared to the U.S. statutory rate. The benefit from foreign earnings also includes certain one-time tax benefits associated with the intellectual property of Wilson Therapeutics. The deferred tax benefits include $95.7 and $30.3 associated with a tax election made with respect to intellectual property of Wilson Therapeutics and a valuation allowance release and corresponding recognition of net operating losses, respectively. On July 1, 2019, the Wilson Therapeutics intellectual property was integrated into the Alexion corporate structure, resulting in income tax expense of approximately $10.2.

A comprehensive analysis of our prior year estimate related to our foreign-derived intangible income (“FDII”) was completed during the third quarter 2019 based on additional guidance provided in the proposed regulations issued by the U.S. Treasury Department in 2019. The analysis resulted in income tax benefit of $17.0 related to prior year, which was recorded as a change in estimate in income tax expense in our consolidated statements of operations, resulting in a decrease of approximately 0.8% to our effective tax rate.

In the year ended December 31, 2019, the Company completed an intra-entity asset transfer of certain intellectual property to an Irish subsidiary within our captive foreign partnership. The Company recognized deferred tax benefits of $2,221.5 which represents the difference between the basis of the intellectual property for financial statement purposes and the basis of the intellectual property for tax purposes, applying the appropriate enacted

statutory tax rates. The Company will receive future tax deductions associated with amortization of the intellectual property, and any amortization not deducted for tax purposes will be carried forward indefinitely under Irish tax law. An offsetting deferred tax expense of $1,839.3 has been recognized to reflect the reduction of future foreign tax credits associated with the foreign local tax amortization deductions. These net deferred tax benefits resulted in a decrease of approximately 17.5% to our effective tax rate.

In the year ended December 31, 2018, the benefit of foreign earnings includes foreign local tax expense of $58.1, substantially all of which is offset by the benefit from U.S. foreign tax credits of $54.2, resulting in a net increase to the effective tax rate of 1.6%. We incurred U.S. tax expense on our foreign earnings of $206.1, which includes GILTI minimum tax. The U.S. tax on our foreign earnings reflects a benefit of $108.7, or 44.8%, primarily related to the Section 250(a) deduction, compared to the U.S. statutory rate. Also included in this component is a benefit of $67.7 from adjustments to 2018 provisional accounting for the Tax Act, which resulted in a decrease to our effective tax rate of approximately 28.0%.

The effective tax rate reconciliation includes the tax impact of acquisitions of IPR&D assets. Absent successful clinical results and regulatory approval, there is no alternative use for certain acquired IPR&D assets. An increase to the effective tax rate results when the value of such assets are expensed, and no tax benefit is recognized. In the year ended December 31, 2018, this component of the effective tax rate includes an increase to tax expense of $248.4 related to the acquired IPR&D costs for the acquisitions of Wilson Therapeutics and Syntimmune, which increased our effective tax rate by 69.7% and 32.9%, respectively.

In the year ended December 31, 2018, other permanent differences include tax expense of $15.8 or 6.5% related to other nondeductible compensation.

The Tax Act

In December 2017, the Tax Act was enacted into law. The Tax Act decreased the US federal corporate tax rate to 21.0%, imposed a minimum tax on foreign earnings related to intangible assets (GILTI), a one-time transition tax on previously unremitted foreign earnings, and modified the taxation of other income and expense items. With regard to the GILTI minimum tax, foreign earnings are reduced by the profit attributable to tangible assets and a deductible allowance of up to 50.0%, subject to annual limitations. We have elected to account for the impact of the minimum tax in deferred taxes.

We calculated provisional amounts for the tax effects of the Tax Act that could be reasonably estimated, but not completed, in our results for the year ended December 31, 2017. As of the fourth quarter 2018 we had completed our analysis of all provisional estimates, and concluded as follows:

(a) We calculated a reasonable estimate of the one-time transition tax on previously unremitted earnings, which resulted in an increase to U.S. Federal tax expense of $177.9 and an increase to taxes payable, net of tax credits, of $28.0 in the period ended December 31, 2017. Our initial accounting for the transition tax was not complete as of December 31, 2017 because there was uncertainty regarding the calculation of the amounts subject to the tax. We completed our analysis of the transition tax and related interpretive guidance during the third quarter 2018. No significant measurement period adjustment to our initial accounting was required.

(b) We calculated a reasonable estimate of the impact of the GILTI minimum tax on deferred taxes, which resulted in an increase to U.S. Federal tax expense and the deferred tax liability of $236.9 in the period ended December 31, 2017. Our initial accounting for the minimum tax was incomplete because there was uncertainty regarding the calculation of the temporary differences subject to the minimum tax. We completed our analyses of these temporary differences and the expected timing and manner of their reversal during the fourth quarter 2018. We recorded measurement period adjustments during 2018 which resulted in a decrease to U.S. federal tax expense of $67.7.

(c) We calculated a reasonable estimate of the Tax Act's limits on deductions for employee remuneration, including remuneration in kind, which resulted in an insignificant impact to tax expense, taxes payable, and deferred taxes in the period ended December 31, 2017. Our initial accounting for these limits was incomplete because there was uncertainty regarding the value of the deduction-limited remuneration. We completed our analysis of the relevant employee remuneration arrangements during the third quarter 2018. No measurement period adjustment to our initial accounting was required.

(amounts in millions except per share amounts)

(d) We calculated a reasonable estimate of the impact of the Tax Act to U.S. state income taxes, which resulted in an increase to tax expense, taxes payable, and deferred taxes of $2.9, $2.2, and $0.7, respectively, in the period ended December 31, 2017. We interpreted the effect of the Tax Act's changes to federal law on each U.S. state's system of taxation as of the date of enactment. We completed additional analysis of the effect of modifications to federal deductions and income inclusions on U.S. state tax systems in the fourth quarter 2018. No measurement period adjustment to our initial accounting was required.

(e) We calculated the deferred tax liability related to our foreign captive partnership in the period ended December 31, 2017 consistent with our calculation in periods prior to enactment of the Tax Act. As a result, the deferred tax liability we recorded as of December 31, 2017 of $533.4 related to our foreign captive partnership was provisional. We completed additional analysis of the direct and indirect effects of the Tax Act during the fourth quarter 2018. We recorded measurement period adjustments during 2018 which resulted in an increase to U.S. state income tax expense and deferred taxes of $11.1.

Deferred Taxes

Provisions have been made for deferred taxes based on the differences between the basis of the assets and liabilities for financial statement purposes and the basis of the assets and liabilities for tax purposes using currently enacted tax rates and regulations that will be in effect when the differences are expected to be recovered or settled. The components of the deferred tax assets and liabilities are as follows:

	December 31, 2020	December 31, 2019
Deferred tax assets:		
Net operating losses	$ 318.1	$ 102.9
Income tax credits	465.1	328.1
Stock compensation	58.6	57.1
Accruals and allowances	138.8	65.2
Unrealized losses	25.4	18.8
Research and development expenses	1.9	3.5
Accrued royalties	1.2	0.8
ROU leases	45.8	46.2
Intangible assets	1,892.0	1,967.3
	2,946.9	2,589.9
Valuation allowance	(276.0)	(72.6)
Total deferred tax assets	2,670.9	2,517.3
Deferred tax liabilities:		
Depreciable assets	(5.6)	(5.1)
Inventory fair value step-up	(53.5)	—
Investment in foreign partnership	(1,992.7)	(2,249.5)
ROU leases	(51.9)	(53.9)
Total deferred tax liabilities	(2,103.7)	(2,308.5)
Net deferred tax (liability) asset	$ 567.2	$ 208.8

(amounts in millions except per share amounts)

As of December 31, 2020, we have tax effected federal and state net operating loss carryforwards of $210.4 and $108.1, respectively. Our net operating losses expire between 2022 and 2043, with the exception of $112.8 of federal and $1.9 state net operating losses that can be carried forward indefinitely. We also have federal and state income tax credit carryforwards of $417.0 and $83.5, respectively. The federal income tax credits expire between 2033 and 2040, whereas $51.6 of state income tax credit carryforwards expire between 2021 and 2035. The remaining $31.9 of state income tax credits can be carried forward indefinitely.

Included in the year ended December 31, 2020 are $75.7 of Connecticut state net operating loss carryforwards and $53.7 of Connecticut state income tax credit carryforwards. A change in the Connecticut state tax regime signed into law during 2019 phases out the capital-based component of the business tax. Once fully phased out in 2024, the Company will be subject to income-based taxes in the state of Connecticut. The Company anticipates generating tax credits in future years that exceed the amount that can otherwise be utilized. As a result, a full valuation allowance has been established against these carryforward attributes.

The increase in our net operating losses, income tax credits and valuation allowance primarily relates to the Achillion and Portola acquisitions. Refer to Note 2, *Acquisitions*, for additional information. We continue to maintain a valuation allowance against other certain deferred tax assets where realization is not certain. The following table represents a roll-forward of our valuation allowance on deferred tax assets:

	Valuation Allowance on Deferred Tax Assets
Balances, December 31, 2017	$ (3.4)
Additions charged to income tax expense	—
Additions charged to acquired in-process research and development	(17.1)
Reductions credited to income tax expense	0.9
Balances, December 31, 2018	$ (19.6)
Additions charged to income tax expense	(68.6)
Reductions credited to income tax expense	15.6
Balances, December 31, 2019	$ (72.6)
Additions charged to income tax expense	(18.8)
Additions charged to goodwill	(184.6)
Reductions credited to income tax expense	—
Balances, December 31, 2020	$ (276.0)

Included in our investment in foreign partnership above is a deferred tax liability of $1,194.3 associated with GILTI minimum tax.

Unrecognized Tax Benefits

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

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

	2020	2019	2018
Beginning of period balance	$ 133.8	$ 92.7	$ 60.9
Increases for tax positions taken during a prior period	27.6	3.4	9.1
Decreases for tax positions taken during a prior period	(10.0)	(4.9)	(5.8)
Increases for tax positions taken during the current period	28.0	43.8	28.8
Decreases for tax positions related to settlements	(13.9)	—	—
Decreases for tax positions related to lapse of statute	(2.1)	(1.2)	(0.3)
	$ 163.4	$ 133.8	$ 92.7

The total amount of accrued interest and penalties were not significant as of December 31, 2020. The total amount of tax benefit recorded during 2020, 2019, and 2018 which related to unrecognized tax benefits was $21.4,

$4.6 and $35.4, respectively. All of our unrecognized tax benefits, if recognized, would have a favorable impact on the effective tax rate.

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

Tax Audits

We file federal and state income tax returns in the U.S. and in numerous foreign jurisdictions. The U.S. and foreign jurisdictions have statutes of limitations ranging from 3 to 6 years. However, the limitation period could be extended due to our tax attribute carryforward position in a number of our jurisdictions. The tax authorities generally have the ability to review income tax returns for periods where the limitation period has previously expired and can subsequently adjust tax attribute values.

In 2017, the Internal Revenue Service (IRS) commenced an examination of our U.S. income tax returns for 2015. During the second quarter of 2020 we received a Revenue Agent Report (RAR) and held discussions with the IRS regarding a proposed adjustment related to the valuation of certain intellectual property that was contributed into our captive partnership during 2015. The Company agreed with the adjustment outlined in the RAR and recognized a previously unrecognized tax benefit in the second quarter of 2020 that did not result in a significant impact to the financial statements. The IRS concluded its examination during the third quarter 2020 without additional adjustments.

As described above, we entered into an agreement with the DTA in December 2020 and have agreed to pay approximately $73.8 in connection with a settlement regarding certain matters relating to our 2014 through 2019 tax years.

Undistributed Earnings

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.

Coronavirus Aid, Relief and Economic Security Act

In response to the market volatility and instability resulting from the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed into law on March 27, 2020. The CARES Act lifts certain deduction limitations originally imposed by the Tax Act. Under the Tax Act, federal net operating losses (NOLs) generated after 2017 could not be carried back and utilization was limited to 80% of taxable income. The CARES Act allows for a five-year carryback of federal NOLs generated in 2018 through 2020 and eliminates the 80% taxable income limitation by allowing corporate entities to fully utilize NOL carryforwards to offset taxable income in 2018 through 2020. In addition, the CARES Act generally allows taxpayers to deduct interest up to 50% of adjusted taxable income (30% limit under the Tax Act) for tax years 2019 and 2020. The CARES Act also allows taxpayers with prior year alternative minimum tax (repealed by the Tax Act) (AMT) credits to accelerate refund claims to tax years beginning in 2018 and 2019 instead of recovering the credits over a period of years, as originally enacted by the Tax Act.

Additionally, the CARES Act raises the corporate charitable deduction limit to 25% of taxable income and provides a technical correction to the Tax Act to generally provide qualified improvement property a 15-year cost-recovery period and allow 100% bonus depreciation. The enactment of the CARES Act did not result in any material adjustments to our income tax provision for the year ended December 31, 2020, or to our U.S. federal and state net deferred tax liabilities as of December 31, 2020.

(amounts in millions except per share amounts)

13. Share-based Compensation

2017 Incentive Plan

The 2017 Plan was approved by our stockholders in May 2017 and replaced the 2004 Plan effective May 10, 2017. The 2017 Plan is a broad based plan that provides for the grant of equity awards including restricted stock and restricted stock units (collectively referred to as Restricted Stock), incentive and non-qualified stock options, and other stock-related awards to our directors, officers, key employees and consultants, for up to a maximum of 18.2 shares in addition to awards outstanding under the 2004 Incentive Plan on or after March 14, 2017 that are subsequently canceled, cash settled, expired, forfeited, or otherwise terminated without the delivery of such shares, subject to the limitations in the 2017 Plan. Stock options granted under the 2017 Plan have a maximum contractual term of ten years from the date of grant, have an exercise price not less than the fair value of the stock on the grant date and generally vest over four years. Restricted Stock awards also generally vest over four years, with performance-based restricted stock units having a three-year vesting period.

Stock Options

A summary of the status of our stock options as of December 31, 2020, and changes during the year then ended is presented in the table and narrative below:

	Number of shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2019	3.0	$ 119.51		
Granted	—	75.10		
Exercised	(0.7)	64.79		
Forfeited and canceled	(0.1)	146.19		
Outstanding as of December 31, 2020	2.2	$ 134.15	3.52	$ 67.3
Vested and unvested expected to vest as of December 31, 2020	2.2	$ 134.15	3.52	$ 67.2
Exercisable as of December 31, 2020	2.2	$ 134.35	3.49	$ 66.3

Total intrinsic value of stock options exercised during the years ended December 31, 2020, 2019 and 2018 was $39.3, $14.7 and $27.5, respectively. We primarily utilize newly issued shares to satisfy the exercise of stock options. The total fair value of options vested during the years ended December 31, 2020, 2019 and 2018 was $4.8, $10.1 and $27.2, respectively.

We did not grant any stock options during the years ended December 31, 2020, 2019 and 2018.

Restricted Stock

A summary of the status of our nonvested Restricted Stock as of December 31, 2020 and changes during the year then ended is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested Restricted Stock as of December 31, 2019	4.3	$ 128.24
Shares granted	3.9	100.95
Shares forfeited	(0.6)	119.07
Shares vested	(2.2)	122.86
Nonvested Restricted Stock as of December 31, 2020	5.4	$ 111.54

The fair value of Restricted Stock at the date of grant is based on the fair market value of the shares of common stock underlying the awards on the date of grant. The weighted average fair value at the date of grant for Restricted Stock awards granted during the years ended December 31, 2020, 2019 and 2018, including restricted stock units with performance conditions, was $100.95, $133.89 and $119.27 per share, respectively. Included in

(amounts in millions except per share amounts)

the number of shares granted during 2020 is 0.4 shares of replacement awards related to our acquisition of Portola and 0.3 shares relating to incremental shares earned for performance-based awards granted in prior years.

The total fair value of Restricted Stock vested during the years ended December 31, 2020, 2019 and 2018 was $271.3, $161.3 and $181.7, respectively. Restricted Stock vested during 2020 includes 0.6 shares with a total fair value of $71.8 due to accelerated vesting of Restricted Stock and performance-based awards.

During 2020, we granted 0.5 shares to senior management that include both market-based and non-market-based performance conditions which provide the recipient the right to receive restricted stock at the end of a three year performance period. We used payout simulation models to estimate the grant date fair value of these awards. The grant date fair value of these awards was estimated to be $94.03 based on the probable achievement of the performance targets. The expense recognized for performance-based awards during the years ended December 31, 2020, 2019 and 2018 was $66.6, $46.3 and $14.9, respectively.

Employee Stock Purchase Plan

During 2015, the Company adopted the ESPP under which employees can purchase shares of our common stock based on a percentage of their compensation subject to certain limits. The purchase price per share is equal to the lower of 85.0% of the fair market value of our common stock on the offering date or the purchase date with a six month look-back feature. Under the ESPP, up to 1.0 shares of common stock may be issued to eligible employees who elect to participate in the purchase plan. Shares issued and compensation expense recognized under the ESPP for the years ended December 31, 2020, 2019 and 2018 was not material.

Share-Based Compensation Expense

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

	Year Ended December 31,		
	2020	2019	2018
Cost of sales (exclusive of amortization of purchased intangible assets)	$ 12.4	$ 14.1	$ 16.0
Research and development	68.6	61.8	57.5
Selling, general and administrative	179.7	161.1	129.5
Acquisition-related costs	20.4	—	—
Total share-based compensation expense	281.1	237.0	203.0
Income tax effect	(65.3)	(55.0)	(46.5)
Total share-based compensation expense, net of tax	$ 215.8	$ 182.0	$ 156.5

Share-based compensation expense capitalized to inventory during the years ended December 31, 2020, 2019 and 2018 was $11.9, $12.9, and $14.5, respectively.

As of December 31, 2020, there was $366.3 of total unrecognized share-based compensation expense related to non-vested share-based compensation arrangements granted under our share-based compensation plans. The expense is expected to be recognized over a weighted-average period of 1.68 years.

(amounts in millions except per share amounts)

14. Stockholders' Equity

Share Repurchases

In November 2012, our Board of Directors authorized a share repurchase program. In February 2017, our Board of Directors increased the amount that we are authorized to expend on future repurchases to $1,000.0 under our repurchase program, which superseded all prior repurchase programs. The entire amount authorized pursuant to this February 2017 Board approval has been utilized. On October 22, 2019, the Board of Directors approved a share repurchase authorization of up to $1,000.0. On July 28, 2020, the Board of Directors approved a new share repurchase authorization of up to an additional $1,500.0. 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 our discretion. Under the program, we repurchased 4.9 and 3.8 shares of our common stock at a cost of $510.8 and $416.0 during the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, there is a total of $2,024.7 remaining for repurchases under the repurchase programs.

15. Other Comprehensive Income and Accumulated Other Comprehensive Income

The following table summarizes the changes in AOCI, by component, for the years ended December 31, 2020, 2019 and 2018:

	Defined Benefit Pension Plans	Unrealized Gains (Losses) from Debt Securities	Unrealized Gains (Losses) from Hedging Activities	Foreign Currency Translation Adjustment	Total Accumulated Other Comprehensive Income (Loss)
Balances, December 31, 2017	$ (4.8)	$ 0.2	$ (13.9)	$ (15.9)	$ (34.4)
Other comprehensive income (loss) before reclassifications	1.5	0.1	32.9	(0.5)	34.0
Amounts reclassified from other comprehensive income	0.7	(0.6)	(9.4)	—	(9.3)
Net other comprehensive income (loss)	2.2	(0.5)	23.5	(0.5)	24.7
Balances, December 31, 2018	$ (2.6)	$ (0.3)	$ 9.6	$ (16.4)	$ (9.7)
Other comprehensive income (loss) before reclassifications	(6.6)	0.2	(11.1)	(1.0)	(18.5)
Amounts reclassified from other comprehensive income	—	—	(38.6)	—	(38.6)
Net other comprehensive income (loss)	(6.6)	0.2	(49.7)	(1.0)	(57.1)
Balances, December 31, 2019	$ (9.2)	$ (0.1)	$ (40.1)	$ (17.4)	$ (66.8)
Other comprehensive income (loss) before reclassifications	(1.5)	0.1	(88.1)	5.7	(83.8)
Amounts reclassified from other comprehensive income	0.5	—	25.5	—	26.0
Net other comprehensive income (loss)	(1.0)	0.1	(62.6)	5.7	(57.8)
Balances, December 31, 2020	$ (10.2)	$ —	$ (102.7)	$ (11.7)	$ (124.6)

The table below provides details regarding significant reclassifications from AOCI during the years ended December 31, 2020, 2019 and 2018:

(amounts in millions except per share amounts)

Details about Accumulated Other Comprehensive Income Components	Amount Reclassified From Accumulated Other Comprehensive Income during the year ended December 31, 2020	2019	2018	Affected Line Item in the Consolidated Statements of Operations
Unrealized Gains (Losses) on Hedging Activity				
Forward exchange forward contracts	$ 4.7	$ 36.8	$ (1.8)	Net product sales
Interest rate swap contracts	(37.5)	13.3	13.6	Interest expense
	(32.8)	50.1	11.8	
	7.3	(11.5)	(2.4)	Income tax (benefit) expense
	$ (25.5)	$ 38.6	$ 9.4	
Defined Benefit Pension Items				
Amortization of prior service costs and actuarial losses	$ (0.7)	$ —	$ (0.3)	
Curtailment	—	—	(0.6)	
	(0.7)	—	(0.9)	
	0.2	—	0.2	Income tax (benefit) expense
	$ (0.5)	$ —	$ (0.7)	

16. Fair Value Measurement

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

The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2020 and 2019, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

(amounts in millions except per share amounts)

Balance Sheet Classification	Type of Instrument	Fair Value Measurement at December 31, 2020 Total	Level 1	Level 2	Level 3
Cash equivalents	Money market funds	$ 833.7	$ —	$ 833.7	$ —
Marketable securities	Mutual funds	$ 34.9	$ 34.9	$ —	$ —
Other assets	Equity securities	$ 143.2	$ 122.7	$ 20.5	$ —
Prepaid expenses and other current assets	Foreign exchange forward contracts	$ 26.1	$ —	$ 26.1	$ —
Other current liabilities	Foreign exchange forward contracts	$ 80.1	$ —	$ 80.1	$ —
Other liabilities	Foreign exchange forward contracts	$ 1.2	$ —	$ 1.2	$ —
Other current liabilities	Interest rate contracts	$ 45.9	$ —	$ 45.9	$ —
Other liabilities	Interest rate contracts	$ 45.4	$ —	$ 45.4	$ —
Current portion of contingent consideration	Acquisition-related contingent consideration	$ 114.9	$ —	$ —	$ 114.9
Contingent consideration	Acquisition-related contingent consideration	$ 299.4	$ —	$ —	$ 299.4

Balance Sheet Classification	Type of Instrument	Fair Value Measurement at December 31, 2019 Total	Level 1	Level 2	Level 3
Cash equivalents	Money market funds	$ 635.9	$ —	$ 635.9	$ —
Cash equivalents	Commercial paper	$ 227.9	$ —	$ 227.9	$ —
Cash equivalents	Corporate bonds	$ 20.6	$ —	$ 20.6	$ —
Cash equivalents	Bank certificates of deposit	$ 19.2	$ —	$ 19.2	$ —
Cash equivalents	Other government-related obligations	$ 60.4	$ —	$ 60.4	$ —
Marketable securities	Mutual funds	$ 23.1	$ 23.1	$ —	$ —
Marketable securities	Commercial paper	$ 19.0	$ —	$ 19.0	$ —
Marketable securities	Corporate bonds	$ 3.7	$ —	$ 3.7	$ —
Marketable securities	Other government-related obligations	$ 10.0	$ —	$ 10.0	$ —
Marketable securities	Bank certificates of deposit	$ 8.2	$ —	$ 8.2	$ —
Other assets	Equity securities	$ 79.0	$ 51.2	$ 27.8	$ —
Prepaid expenses and other current assets	Foreign exchange forward contracts	$ 29.9	$ —	$ 29.9	$ —
Other assets	Foreign exchange forward contracts	$ 0.6	$ —	$ 0.6	$ —
Other current liabilities	Foreign exchange forward contracts	$ 26.6	$ —	$ 26.6	$ —
Other liabilities	Foreign exchange forward contracts	$ 1.1	$ —	$ 1.1	$ —
Other current liabilities	Interest rate contracts	$ 19.5	$ —	$ 19.5	$ —
Other liabilities	Interest rate contracts	$ 41.9	$ —	$ 41.9	$ —
Contingent consideration	Acquisition-related contingent consideration	$ 192.4	$ —	$ —	$ 192.4
Other current liabilities	Other contingent payments	$ 24.0	$ —	$ —	$ 24.0

There were no securities transferred between Level 1, 2 and 3 during the year ended December 31, 2020.

Valuation Techniques

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

Cash equivalents and marketable securities classified as Level 2 within the valuation hierarchy include money market funds, commercial paper, U.S. and foreign government-related debt, corporate debt securities and certificates

(amounts in millions except per share amounts)

of deposit. We estimate the fair values of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include market pricing based on real-time trade data for similar securities, issuer credit spreads, benchmark yields, and other observable inputs. We validate the prices provided by our third-party pricing sources by understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances.

Other investments in equity securities of publicly traded companies which are subject to holding period restrictions are carried at fair value using an option pricing valuation model and classified as Level 2 equity securities within the fair value hierarchy. The most significant assumptions within the option pricing valuation model are the term of the restrictions and the stock price volatility, which is based upon the historical volatility of the applicable company or similar companies. We also use a constant maturity risk-free interest rate to match the remaining term of the restrictions on such investments.

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

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

As of December 31, 2020, there has not been any impact to the fair value of our derivative liabilities due to our own credit risk. Similarly, there has not been any significant adverse impact to our derivative assets based on our evaluation of our counterparties' credit risks.

Acquisition-Related Contingent Consideration

In connection with prior business combinations, we may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approvals or sales-based milestone events. We determine the fair value of these obligations using various estimates that are not observable in the market and represent a Level 3 measurement within the fair value hierarchy. As of December 31, 2020, the resulting probability-weighted cash flows were discounted using a cost of debt ranging from 2.8% to 3.3% for developmental and regulatory milestones and a weighted average cost of capital of 9.0% for sales-based milestones.

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

As of December 31, 2020, estimated future contingent milestone payments related to prior business combinations range from zero if no milestone events are achieved, to a maximum of $905.6 if all development, regulatory and sales-based milestones are reached. As of December 31, 2020, the fair value of acquisition-related contingent consideration was $414.3. During the next 12 months, we expect to make milestone payments of $120.0 associated with our prior business combinations. The following table represents a roll-forward of our acquisition-related contingent consideration:

	Year ended December 31, 2020
Balance as of December 31, 2019	$ 192.4
Amounts issued	160.7
Changes in fair value	61.2
Balance as of December 31, 2020	$ 414.3

Other Contingent Payments

In January 2019, we entered into an agreement with Caelum, a biotechnology company that is developing CAEL-101 for light chain (AL) amyloidosis. Under the terms of the agreement, we acquired a minority equity interest

in preferred stock of Caelum and an exclusive option to acquire the remaining equity in Caelum based on Phase II data, for pre-negotiated economics. We paid $30.0 during the first quarter 2019 and agreed to pay up to an additional $30.0 in contingent development milestones prior to our exercise of the option to acquire the remaining equity in Caelum. These contingent payments met the definition of a derivative liability and were initially recorded at fair value of $27.1, based on the probability-weighted cash flows, discounted using a cost of debt ranging from 3.3% to 3.5%.

In December 2019, following FDA feedback which resulted in the redesign and expansion of Caelum's planned clinical development program for CAEL-101, we amended the terms of our existing option agreement with Caelum. The amendment modified the terms of the option to acquire the remaining equity in Caelum based on data from the expanded Phase II/III trials. The amendment also modified the development-related milestone events associated with the initial $30.0 in contingent payments, provided for an additional $20.0 in upfront funding, as well as funding of $60.0 in exchange for an additional equity interest at fair value upon achievement of a specific development-related milestone event. As of December 31, 2019 and in connection with the amendment, we remeasured the derivative liability related to the initial $30.0 in contingent payments to its fair value, or $24.0, based on the probability-weighted cash flows, discounted using a cost of debt of 2.1% and accrued for the additional $20.0 in upfront funding. We paid the additional $20.0 in upfront funding and the initial $30.0 in contingent payments in 2020.

Each reporting period, we adjust the derivative liability associated with the contingent payments to fair value with changes in fair value recognized in other income and (expense). Changes in fair values reflect new information about the probability and anticipated timing of meeting the conditions of the milestone payments. In the absence of new information, changes in fair value will only reflect the interest component of the liability related to the passage of time. The aggregate $30.0 milestone payments made during 2020 settled the derivative liability and reduced the derivative liability balance to zero. We recorded $6.0 of expense in other income and (expense) during the year ended December 31, 2020. We recorded $3.1 of income in other income and (expense) during the year ended December 31, 2019, including $4.1 as a result of the amendment to our agreement with Caelum.

17. Restructuring and Related Expenses

During the third quarter 2020, we initiated restructuring activities primarily within our commercial organization as part of an initiative intended to redefine our operating model. The actions are intended to reallocate resources necessary to align our organization with our diversifying portfolio of new products and strategic objectives, and will include investments in digital capabilities, technologies and solutions to support a more virtual and digital customer experience and tailored to the markets in which we operate.

The actions are expected to be substantially completed during 2021, with the cumulative pretax costs to be incurred by the Company to implement the program estimated to be approximately $10.0, which has primarily been recognized during the year ended December 31, 2020. We expect that the pretax costs will primarily result in cash outlays, as the costs primarily relate to employee separation expenses.

In the first quarter 2019, we initiated corporate restructuring activities to re-align our international commercial organization through re-prioritization of certain geographical markets and to implement operational excellence through strategic reallocation of resources. Actions under the first quarter 2019 restructuring program have been completed.

In the first quarter 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. In September 2017, we committed to an operational plan to re-align the global organization with its refocused corporate strategy. The re-alignment included the relocation of the Company's headquarters to Boston, Massachusetts and a reduction of the Company's global workforce. The restructuring was designed to result in cost savings by focusing the development portfolio, simplifying business structures and process across the Company's global operations, and closing multiple Alexion sites. Costs incurred during 2018 relate to the 2017 restructuring plan. Actions under the 2017 restructuring programs have been completed.

(amounts in millions except per share amounts)

The following table summarizes the total expenses recorded related to the restructuring activities by type of activity and the locations recognized within the consolidated statements of operations:

	December 31, 2020				December 31, 2019				December 31, 2018			
	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total
Cost of sales (exclusive of amortization of purchased intangible assets)	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ 5.8	$ —	$ 5.8
Research and development	—	—	—	—	—	—	—	—	—	0.1	—	0.1
Selling, general and administrative	—	—	—	—	—	—	—	—	—	19.4	—	19.4
Restructuring expenses	8.4	—	1.9	10.3	8.4	—	3.6	12.0	4.6	—	20.9	25.5
Other income and (expense)	—	—	—	—	—	—	—	—	—		(0.1)	(0.1)
	$ 8.4	$ —	$ 1.9	$ 10.3	$ 8.4	$ —	$ 3.6	$ 12.0	$ 4.6	$ 25.3	$ 20.8	$ 50.7

Employee separation costs are associated with headcount reductions.

Asset-related charges consist of accelerated depreciation costs and asset impairment charges. Accelerated depreciation costs primarily relates to site closures, including ARIMF (which was sold to a third-party in 2018). Accelerated depreciation costs represent the difference between the depreciation expense recognized over the revised useful life of the asset, based upon the anticipated date the site closure, and the depreciation expense as determined using the useful life prior to the restructuring activities. Asset impairment charges primarily related to manufacturing assets that will no longer be utilized due to the 2017 restructuring activities.

Other costs consist of contract termination expenses, relocation costs, and other costs incurred as a direct result of an exit plan.

The following table presents a reconciliation of the restructuring reserve recorded within accounts payable and accrued expenses on the Company's consolidated balance sheets for the years ended December 31, 2020 and 2019:

	December 31, 2020			December 31, 2019		
	Employee Separation Costs	Other	Total	Employee Separation Costs	Other	Total
Liability, beginning of year	$ 3.3	$ 3.5	$ 6.8	$ 4.2	$ —	$ 4.2
Charges	14.3	2.4	16.7	14.2	3.0	17.2
Settlements	(3.5)	(5.4)	(8.9)	(9.3)	(0.1)	(9.4)
Adjustments to previous estimates	(5.9)	(0.5)	(6.4)	(5.8)	0.6	(5.2)
Liability, end of year	$ 8.2	$ —	$ 8.2	$ 3.3	$ 3.5	$ 6.8

The restructuring reserve of $8.2 and $6.8 is recorded in accounts payable and accrued expenses on the Company's consolidated balance sheet as of December 31, 2020 and 2019, respectively. The accrued amounts are expected to be paid in the next twelve months. We currently estimate incurring an immaterial amount of restructuring expenses in 2021 related to the third quarter 2020 action.

(amounts in millions except per share amounts)

18. Segment Information

We operate in a single segment, focusing on serving patients affected by rare diseases and devastating conditions through the discovery, development and commercialization of life-changing therapies. Consistent with our operational structure, our chief operating decision maker manages and allocates resources at a global, consolidated level. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with our management reporting. Disclosures about net product sales and long-lived assets by geographic area are presented below.

Net Product Sales

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

	Year Ended December 31,			% Change	
	2020	2019	2018	2020 compared to 2019	2019 compared to 2018
SOLIRIS					
United States	$ 2,259.7	$ 2,014.0	$ 1,588.4	12.2 %	26.8 %
Europe	1,033.3	1,049.8	1,036.7	(1.6)%	1.3 %
Asia Pacific	343.0	423.5	382.0	(19.0)%	10.9 %
Rest of World	428.2	459.1	555.9	(6.7)%	(17.4)%
	$ 4,064.2	$ 3,946.4	$ 3,563.0	3.0 %	10.8 %
ULTOMIRIS					
United States	$ 646.0	$ 236.8	$ —	172.8 %	**
Europe	170.4	52.2	—	226.4 %	**
Asia Pacific	255.3	49.9	—	411.6 %	**
Rest of World	5.0	—	—	**	**
	$ 1,076.7	$ 338.9	$ —	**	**
STRENSIQ					
United States	$ 562.9	$ 451.7	$ 374.3	24.6 %	20.7 %
Europe	80.8	77.0	61.7	4.9 %	24.8 %
Asia Pacific	61.0	50.4	27.9	21.0 %	80.6 %
Rest of World	27.1	13.4	11.2	102.2 %	19.6 %
	$ 731.8	$ 592.5	$ 475.1	23.5 %	24.7 %
ANDEXXA					
United States	$ 71.7	$ —	$ —	**	**
Europe	6.8	—	—	**	**
Asia Pacific	—	—	—	**	**
Rest of World	—	—	—	**	**
	$ 78.5	$ —	$ —	**	**
KANUMA					
United States	$ 63.7	$ 60.0	$ 51.3	6.2 %	17.0 %
Europe	35.6	27.1	21.6	31.4 %	25.5 %
Asia Pacific	4.3	4.6	3.7	(6.5)%	24.3 %
Rest of World	14.3	20.5	15.4	(30.2)%	33.1 %
	$ 117.9	$ 112.2	$ 92.0	5.1 %	22.0 %
Total Net Product Sales	$ 6,069.1	$ 4,990.0	$ 4,130.1	21.6 %	20.8 %

** Percentages not meaningful

(amounts in millions except per share amounts)

Long-Lived Assets

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

	December 31, 2020	2019
United States	$ 261.0	$ 272.8
Europe	976.2	889.6
Other	1.6	0.9
	$ 1,238.8	$ 1,163.3

19. Quarterly Financial Information (unaudited)

The following condensed quarterly financial information is for the years ended December 31, 2020 and 2019:

2020	March 31	June 30	September 30	December 31
Total revenues	$ 1,444.8	$ 1,444.6	$ 1,588.7	$ 1,591.8
Cost of sales (exclusive of amortization of purchased intangible assets) [A]	111.7	144.9	144.7	152.2
Gross profit	1,333.1	1,299.7	1,444.0	1,439.6
Operating expenses	637.6	2,669.9 [1]	759.1	817.5
Operating income (loss)	695.5	(1,370.2) [1]	684.9	622.1
Net income (loss)	$ 557.6	$ (1,068.1) [1]	$ 578.1	$ 535.8
Earnings (loss) per common share:				
Basic	$ 2.52	$ (4.84)	$ 2.64	$ 2.45
Diluted	$ 2.50	$ (4.84)	$ 2.62	$ 2.42

2019	March 31	June 30	September 30	December 31
Total revenues	$ 1,140.4	$ 1,203.3	$ 1,263.1	$ 1,384.3
Cost of sales (exclusive of amortization of purchased intangible assets) [A]	85.8	99.2	95.2	114.3
Gross profit	1,054.6	1,104.1	1,167.9	1,270.0
Operating expenses	537.8	571.5	637.9	729.0
Operating income	516.8	532.6	530.0	541.0
Net income	$ 587.9 [2]	$ 459.8	$ 467.6	$ 889.0 [3]
Earnings per common share:				
Basic	$ 2.63	$ 2.05	$ 2.09	$ 4.02
Diluted	$ 2.61	$ 2.04	$ 2.08	$ 4.00

(A) Gross profit is calculated as total revenues less cost of sales

[1] Included within operating expenses for the second quarter 2020, we recorded an impairment charge of $2,042.3 to write-down the KANUMA intangible asset to fair value. The KANUMA intangible asset impairment resulted in a deferred tax benefit of $377.3. Refer to Note 4, *Intangible Assets and Goodwill* for additional information.

[2] During the first quarter 2019, we recognized one-time tax benefits of $95.7 and $30.3 associated with a tax election made with respect to intellectual property of Wilson Therapeutics AB and a release of an existing valuation allowance, respectively. Refer to Note 12, *Income Taxes* for additional information.

[3] During the fourth quarter 2019, we recognized a one-time tax benefit of $382.2 related to an intra-entity asset transfer of certain intellectual property within our captive foreign partnership. Refer to Note 12, *Income Taxes* for additional information.

20. Subsequent Events

In January 2021, Alexion entered into a definitive asset purchase agreement with Rhythm Pharmaceuticals, Inc. (“Rhythm”) to acquire its Rare Pediatric Disease Priority Review Voucher (PRV) for $100.0. Alexion’s acquisition of Rhythm’s PRV is subject to the satisfaction of customary closing conditions and approval from relevant regulatory agencies, including the expiration or early termination of the applicable waiting period under the Hart-Scott Rodino Antitrust Improvements Act. Upon closing, we will make a $100.0 cash payment and we expect to capitalize the PRV as an acquired IPR&D intangible asset.

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

The following summary describes the material terms of the common stock Alexion Pharmaceuticals, Inc., which is listed on the Nasdaq Global Select Market under the symbol "ALXN". This description of our common stock is qualified by reference to our certificate of incorporation, as amended, and our bylaws, both of which are incorporated by reference as exhibits to the Annual Report on Form 10-K of which this Exhibit 4.2 is a part.

Authorized Capital Shares. Our certificate of incorporation, as amended, authorizes us to issue 290,000,000 shares of common stock, par value $0.0001 per share. The shares of common stock currently outstanding are fully paid and nonassessable.

*Voting***.** Holders of our common stock are entitled to one vote per share for the election of directors and on all other matters that require stockholder approval. There is no cumulative voting.

Dividends and Other Distributions. Subject to any preferences that may apply to any shares of preferred stock outstanding at the time, holders of our common stock are entitled to share in an equal amount per share any dividends declared by our board of directors on the common stock and paid out of legally available assets.

Distribution on Dissolution. Subject to any preferential rights of any outstanding preferred stock, in the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in the assets remaining after payment of liabilities and the liquidation preferences of any outstanding preferred stock.

Other Rights. Our common stock does not carry any preemptive rights enabling a holder to subscribe for, or receive shares of, any class of our common stock or any other securities convertible into shares of any class of our common stock, and is not subject to any redemption or sinking fund provisions.

Anti-Takeover Provisions of our Certificate of Incorporation, Bylaws, and Delaware Law. Provisions in our certificate of incorporation, as amended, and bylaws may discourage certain types of transactions involving an actual or potential change of control of Alexion. 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% 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. Under our certificate of incorporation, 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 Corporation Laws, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15.0% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Exhibit 21.1

SUBSIDIARIES OF ALEXION PHARMACEUTICALS, INC.

Alexion Delaware Holding LLC is organized in Delaware

Alexion Services Latin America, Inc. is organized in Delaware

Alexion US Holdings LLC is organized in Delaware

Alexion US1 LLC is organized in Delaware

Alexion Pharma LLC is organized in Delaware

Alexion Holding LLC is organized in Delaware

Savoy Therapeutics Corp. is organized in Delaware

Wilson Therapeutics USA, Inc. is organized in Delaware

Syntimmune, Inc. is organized in Delaware

Achillion Pharmaceuticals, Inc. is organized in Delaware

Portola Pharmaceuticals, LLC is organized in Delaware

Portola USA Inc. is organized in Delaware

Alexion Pharma Argentina SRL is organized in Argentina

Alexion Pharmaceuticals Australasia PTY LTD is organized in Australia

Alexion Pharma Austria GmbH is organized in Austria

Portola Österreich GmbH is organized in Austria

Alexion Pharma Belgium Sprl is organized in Belgium

Alexion Services Europe Sprl is organized in Belgium

Alexion Bermuda L.P. is organized in Bermuda

Alexion Bermuda II L.P. is organized in Bermuda

Alexion Bermuda Holding ULC is organized in Bermuda

Alexion 1609 Partners, LP is organized in Bermuda

Alexion Bermuda Partners L.P. is organized in Bermuda

Alexion Bermuda Limited is organized in Bermuda

Alexion Farmacêutica Brasil Importação e Distribuição de Produtos e Serviços de Administração de Vendas Ltda. (doing business as Alexion Brasil) is organized in Brazil

Alexion Farmacêutica América Latina Serviços de Administração de Vendas Ltda. (doing business as Alexion Latina America) is organized in Brazil

Alexion Pharma Canada Corp. is organized in Canada

Alexion Pharmaceuticals (Shanghai) Company Limited is organized in Shanghai

Alexion Pharma Colombia SAS is organized in Colombia

Alexion Pharma Czech s.r.o is organized in the Czech Republic

Alexion Pharma Middle East FZ-LLC is organized in Dubai

Alexion Europe SAS is organized in France

Alexion Pharma France SAS is organized in France

Alexion Pharma Germany GmbH is organized in Germany

Portola Deutschland GmbH is organized in Germany

Portola FRG GmbH is organized in Germany

Alexion Business Services Private Limited is organized in India

Alexion Pharma International Operations Unlimited Company is organized in Ireland
Alexion Pharma Holding Unlimited Company is organized in Ireland
Alexion Pharma Development Unlimited Company is organized in Ireland
Alexion Pharma Israel Ltd. is organized in Israel
Alexion Pharma Italy Sarl is organized in Italy
Portola Italia S.r.l. is organized in Italy
Alexion Pharma GK is organized in Japan
Alexion Pharma Mexico, S. de R.L. de C.V. is organized in Mexico
Alexion Holding B.V. is organized in the Netherlands
Alexion Pharma Foreign Holdings B.V. is organized in the Netherlands
Alexion Pharma Netherlands B.V. is organized in the Netherlands
Portola Netherlands B.V. is organized in the Netherlands
Alexion Pharma OOO LLC is organized in Russia
Alexion Pharma Korea LLC is organized in South Korea
Alexion Pharma Spain S.L. is organized in Spain
Portola Pharmaceuticals Espana S.L. is organized in Spain
Alexion Pharma Nordics AB is organized in Sweden
Alexion Pharma Nordics Holding AB is organized in Sweden
Wilson Therapeutics Incentive AB is organized in Sweden
TTM Europe Development AB is organized in Sweden
Wilson Therapeutics AB is organized in Sweden
Alexion Pharma GmbH is organized in Switzerland
Portola Schweiz GmbH is organized in Switzerland
Alexion Pharma Taiwan LTD is organized in Taiwan
Alexion Ilaç Ticaret Limited Þirketi is organized in Turkey
Alexion Pharma UK Ltd. is organized in the United Kingdom
Portola Pharma UK Ltd. is organized in the United Kingdom
Syntimmune, Ltd. is organized in the United Kingdom

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-240210, 333-217905, 333-205379, 333-146319, 333-139600, 333-123212, and 333-153612) and Form S-3 (No. 333-226838) of Alexion Pharmaceuticals, Inc. of our report dated February 8, 2021 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
February 8, 2021

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ludwig Hantson, certify that:

1 I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2020 of Alexion Pharmaceuticals, Inc.;

2 Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3 Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4 The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5 The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 8, 2021

/s/ LUDWIG N. HANTSON, Ph.D.
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Aradhana Sarin, certify that:

1 I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2020 of Alexion Pharmaceuticals, Inc.;

2 Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3 Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4 The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5 The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 8, 2021

/s/ ARADHANA SARIN, M.D.
Executive Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Alexion Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2020 as filed with the Securities and Exchange Commission (the "Report"), I, Ludwig N. Hantson, Ph.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to my knowledge, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 8, 2021

/s/ LUDWIG N. HANTSON, Ph.D.
Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Alexion Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2020 as filed with the Securities and Exchange Commission (the "Report"), I, Aradhana Sarin, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to my knowledge, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 8, 2021

/s/ ARADHANA SARIN, M.D.
Executive Vice President and Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.