UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2019

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)

N/A
(Former name, former address, and former fiscal year, if changed since last report)

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 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 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 ☒ Accelerated filer ☐ Non-accelerated filer ☐
Smaller reporting company ☐ Emerging growth company ☐

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Common Stock $0.0001 par value	221,290,691
Class	**Outstanding as of October 21, 2019**

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Alexion Pharmaceuticals, Inc.

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

	September 30, 2019	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 2,171.3	$ 1,365.5
Marketable securities	44.4	198.3
Trade accounts receivable, net	1,116.3	922.3
Inventories	576.7	472.5
Prepaid expenses and other current assets	432.5	426.4
Total current assets	4,341.2	3,385.0
Property, plant and equipment, net	1,148.0	1,471.5
Intangible assets, net	3,410.1	3,641.3
Goodwill	5,037.4	5,037.4
Right of use operating assets	206.9	—
Other assets	671.4	396.7
Total assets	$ 14,815.0	$ 13,931.9
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 868.2	$ 698.2
Revolving credit facility	—	250.0
Current portion of long-term debt	126.6	93.8
Current portion of contingent consideration	—	97.6
Other current liabilities	96.4	34.4
Total current liabilities	1,091.2	1,174.0
Long-term debt, less current portion	2,406.7	2,501.7
Contingent consideration	188.0	183.2
Facility lease obligation	—	361.0
Deferred tax liabilities	314.7	391.1
Noncurrent operating lease liabilities	166.8	—
Other liabilities	280.4	155.6
Total liabilities	4,447.8	4,766.6
Commitments and contingencies (Note 18)		
Stockholders' Equity:		
Common stock, $0.0001 par value; 290 shares authorized; 237.5 and 236.2 shares issued at September 30, 2019 and December 31, 2018, respectively	—	—
Additional paid-in capital	8,738.0	8,539.1
Treasury stock, at cost, 16.2 and 12.7 shares at September 30, 2019 and December 31, 2018, respectively	(2,073.4)	(1,689.9)
Accumulated other comprehensive loss	(48.2)	(9.7)
Retained earnings	3,750.8	2,325.8
Total stockholders' equity	10,367.2	9,165.3
Total liabilities and stockholders' equity	$ 14,815.0	$ 13,931.9

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

Alexion Pharmaceuticals, Inc.

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

	Three months ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net product sales	$ 1,263.1	$ 1,026.5	$ 3,605.8	$ 3,001.6
Other revenue	—	—	1.0	0.8
Total revenues	1,263.1	1,026.5	3,606.8	3,002.4
Cost of sales	95.2	90.6	280.2	277.5
Operating expenses:				
Research and development	232.9	174.8	616.4	524.8
Selling, general and administrative	299.3	258.7	880.1	793.1
Acquired in-process research and development	—	—	(4.1)	803.7
Amortization of purchased intangible assets	75.6	80.0	235.7	240.1
Change in fair value of contingent consideration	29.8	53.5	7.2	110.9
Restructuring expenses	0.3	10.3	11.9	26.4
Total operating expenses	637.9	577.3	1,747.2	2,499.0
Operating income	530.0	358.6	1,579.4	225.9
Other income and expense:				
Investment income	23.0	5.9	50.6	119.4
Interest expense	(17.9)	(24.6)	(56.1)	(73.7)
Other income and (expense)	0.4	2.2	2.9	3.5
Income before income taxes	535.5	342.1	1,576.8	275.1
Income tax expense	67.9	11.2	61.5	152.5
Net income	$ 467.6	$ 330.9	$ 1,515.3	$ 122.6
Earnings per common share				
Basic	$ 2.09	$ 1.48	$ 6.77	$ 0.55
Diluted	$ 2.08	$ 1.47	$ 6.72	$ 0.55
Shares used in computing earnings per common share				
Basic	223.3	222.9	223.8	222.5
Diluted	224.5	224.6	225.4	224.2

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

Alexion Pharmaceuticals, Inc.

Condensed Consolidated Statements of Comprehensive Income (Loss)
(unaudited)
(amounts in millions)

	Three months ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net income	$ 467.6	$ 330.9	$ 1,515.3	$ 122.6
Other comprehensive income (loss), net of tax:				
Foreign currency translation	(2.5)	(1.7)	(3.0)	(6.0)
Unrealized gains (losses) on debt securities	—	0.1	0.2	(0.3)
Unrealized gains on pension obligation	—	—	—	0.7
Unrealized gains (losses) on hedging activities, net of tax of $3.5, $2.9, $(10.8) and $13.4, respectively	12.2	11.4	(35.7)	46.9
Other comprehensive income (loss), net of tax	9.7	9.8	(38.5)	41.3
Comprehensive income	$ 477.3	$ 340.7	$ 1,476.8	$ 163.9

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

Alexion Pharmaceuticals, Inc.

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

Three months ended September 30, 2019	Common Stock Shares Issued	Common Stock Amount	Additional Paid-In Capital	Treasury Stock at Cost Shares	Treasury Stock at Cost Amount	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
Balances, June 30, 2019	237.3	$ —	$ 8,677.0	13.1	$ (1,738.8)	$ (57.9)	$ 3,283.2	$10,163.5
Repurchase of common stock	—	—	—	3.1	(334.6)	—	—	(334.6)
Issuance of common stock under stock option and stock purchase plans	0.1	—	1.9	—	—	—	—	1.9
Issuance of restricted common stock	0.1	—	—	—	—	—	—	—
Share-based compensation expense	—	—	59.1	—	—	—	—	59.1
Net income	—	—	—	—	—	—	467.6	467.6
Other comprehensive income	—	—	—	—	—	9.7	—	9.7
Balances, September 30, 2019	237.5	$ —	$ 8,738.0	16.2	$ (2,073.4)	$ (48.2)	$ 3,750.8	$10,367.2

Three months ended September 30, 2018	Common Stock Shares Issued	Common Stock Amount	Additional Paid-In Capital	Treasury Stock at Cost Shares	Treasury Stock at Cost Amount	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
Balances, June 30, 2018	235.5	$ —	$ 8,420.2	12.7	$ (1,689.9)	$ (2.9)	$ 2,040.0	$ 8,767.4
Repurchase of common stock	—	—	—	—	—	—	—	—
Issuance of common stock under stock option and stock purchase plans	0.2	—	16.8	—	—	—	—	16.8
Issuance of restricted common stock	0.1	—	—	—	—	—	—	—
Share-based compensation expense	—	—	44.8	—	—	—	—	44.8
Net income	—	—	—	—	—	—	330.9	330.9
Other comprehensive income	—	—	—	—	—	9.8	—	9.8
Balances, September 30, 2018	235.8	$ —	$ 8,481.8	12.7	$ (1,689.9)	$ 6.9	$ 2,370.9	$ 9,169.7

Nine Months Ended September 30, 2019	Common Stock Shares Issued	Common Stock Amount	Additional Paid-In Capital	Treasury Stock at Cost Shares	Treasury Stock at Cost Amount	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
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	—	—	—	3.5	(383.5)	—	—	(383.5)
Issuance of common stock under stock option and stock purchase plans	0.3	—	23.2	—	—	—	—	23.2
Issuance of restricted common stock	1.0	—	—	—	—	—	—	—
Share-based compensation expense	—	—	175.7	—	—	—	—	175.7
Net income	—	—	—	—	—	—	1,515.3	1,515.3
Other comprehensive loss	—	—	—	—	—	(38.5)	—	(38.5)
Adoption of new accounting standards (see Note 2)	—	—	—	—	—	—	(90.3)	(90.3)
Balances, September 30, 2019	237.5	$ —	$ 8,738.0	16.2	$ (2,073.4)	$ (48.2)	$ 3,750.8	$10,367.2

Nine Months Ended September 30, 2018	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	0.5	—	41.4	—	—	—	—	41.4
Issuance of restricted common stock	1.0	—	—	—	—	—	—	—
Share-based compensation expense	—	—	150.1	—	—	—	—	150.1
Net income	—	—	—	—	—	—	122.6	122.6
Other comprehensive income	—	—	—	—	—	41.3	—	41.3
Adoption of new accounting standards	—	—	—	—	—	—	6.2	6.2
Balances, September 30, 2018	235.8	$ —	$ 8,481.8	12.7	$ (1,689.9)	$ 6.9	$ 2,370.9	$ 9,169.7

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

Alexion Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows
(unaudited)
(amounts in millions)

	Nine months ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net income	$ 1,515.3	$ 122.6
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	286.2	306.9
Impairment of assets	—	13.5
Change in fair value of contingent consideration	7.2	110.9
Payments of contingent consideration	(100.0)	—
Share-based compensation expense	176.8	150.9
Non-cash expense for acquired IPR&D	—	86.6
Deferred taxes (benefit)	(136.1)	79.1
Unrealized foreign currency loss (gain)	(3.3)	8.6
Unrealized loss (gain) on forward contracts	(15.3)	(9.9)
Unrealized gain on strategic equity investments	(20.6)	(100.5)
Other	(2.3)	(3.0)
Changes in operating assets and liabilities:		
Accounts receivable	(199.1)	(197.4)
Inventories	(105.9)	26.7
Prepaid expenses, right of use operating assets and other assets	(42.2)	(85.1)
Accounts payable, accrued expenses, lease liabilities and other liabilities	207.1	(167.3)
Net cash provided by operating activities	1,567.8	342.6
Cash flows from investing activities:		
Purchases of available-for-sale debt securities	(51.2)	(771.4)
Proceeds from maturity or sale of available-for-sale debt securities	211.0	1,356.4
Purchases of mutual funds related to nonqualified deferred compensation plan	(13.4)	(9.0)
Proceeds from sale of mutual funds related to nonqualified deferred compensation plan	11.4	9.3
Purchases of property, plant and equipment	(124.7)	(170.6)
Purchases of strategic investments	(63.7)	—
Purchase of intangible assets	(16.0)	—
Other	—	3.6
Net cash provided by (used in) investing activities	(46.6)	418.3
Cash flows from financing activities:		
Debt issuance costs	—	(7.6)
Proceeds from revolving credit facility	—	250.0
Payments on term loan facility	(65.4)	(293.8)
Payments on revolving credit facility	(250.0)	—
Repurchases of common stock	(383.5)	(85.0)
Net proceeds from issuance of common stock under share-based compensation arrangements	23.2	41.4
Other	(3.7)	(10.5)
Net cash used in financing activities	(679.4)	(105.5)
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(6.1)	(10.6)
Net change in cash and cash equivalents and restricted cash	835.7	644.8
Cash and cash equivalents and restricted cash at beginning of period	1,367.4	586.3
Cash and cash equivalents and restricted cash at end of period	$ 2,203.1	$ 1,231.1

	Nine months ended September 30,	
	2019	2018
Supplemental cash flow disclosures from investing and financing activities:		
Fair value of contingent liability related to strategic investment and purchase option	$ 27.6	$ —
Operating ROU lease assets obtained in exchange for operating lease liabilities	$ 23.9	$ —
Capitalization of construction costs related to facility lease obligations	$ —	$ 44.3
Accounts payable and accrued expenses for purchases of property, plant and equipment and intangible assets	$ 3.1	$ 10.2

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

	Nine months ended September 30,	
	2019	2018
Cash and cash equivalents	$ 2,171.3	$ 1,228.9
Restricted cash included in other current assets	$ 31.5	$ 0.1
Restricted cash included in other noncurrent assets	$ 0.3	$ 2.1
Total cash and cash equivalents and restricted cash reported in the condensed consolidated statement of cash flows	$ 2,203.1	$ 1,231.1

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 18).

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

1. 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 through the innovation, development and commercialization of life-changing therapies.

We are the global leader in complement inhibition and have developed and commercialize two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), as well as the first approved complement inhibitor to treat anti-acetylcholine receptor (AChR) antibody-positive generalized myasthenia gravis (gMG) and anti-AQP4 antibody-positive neuromyelitis optica spectrum disorder (NMOSD). In addition, Alexion 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).

In addition to our marketed therapies, we have a diverse pipeline resulting from internal innovation and business development with strategic focus in hematology and nephrology, neurology, metabolics and neonatal Fc receptor (FcRn). We were incorporated in 1992 under the laws of the State of Delaware.

2. Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. These accounting principles were applied on a basis consistent with those of the consolidated financial statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2018. In our opinion, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of our financial statements for interim periods presented in accordance with accounting principles generally accepted in the United States. The condensed consolidated balance sheet as of December 31, 2018 was derived from audited annual financial statements but does not include all disclosures required by accounting principles generally accepted in the United States. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2018 included in our Annual Report on Form 10-K for the year ended December 31, 2018. The results of operations for the three and nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the full year or any other future periods.

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.

The accompanying unaudited condensed consolidated financial statements include the accounts of Alexion Pharmaceuticals, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Our significant accounting policies are described in Note 1 of the notes to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018. Updates to our accounting policies, including impacts from the adoption of new accounting standards, are discussed below in this Note 2 and within Note 17, *Leases.*

Reclassifications

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

New Accounting Pronouncements

Accounting Standards Update (ASU) 2016-13, "Measurement of Credit Losses on Financial Instruments": In June 2016, the Financial Accounting Standards Board (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 do not expect the adoption of this standard to have a significant impact on our financial statements; however, the impact will depend on the composition of the Company's portfolio of financial instruments, and the current and forecasted economic conditions as of the adoption date.

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, including adoption in any interim period and can be adopted prospectively or retrospectively. We intend to adopt this new guidance on a prospective basis. We do not expect the adoption of this standard to have a significant impact on our financial statements; however, the adoption of this standard will result in an increase in capitalized assets related to qualifying CCA implementation costs incurred after the adoption date.

Recently Adopted Accounting Pronouncements

ASU 2016-02, "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. The new standard establishes a right of use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as financing or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations.

We adopted the new standard on January 1, 2019 using the modified retrospective approach. We have elected to apply the transition method that allows companies to continue applying the guidance under the lease standard in effect at that time in the comparative periods presented in the consolidated financial statements and recognize a cumulative-effect adjustment to the opening balance of retained earnings on the date of adoption. We also elected the “package of practical expedients”, which permits us not to reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs.

Results for reporting periods beginning after January 1, 2019 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. 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 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 condensed 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.

ASU 2018-02, "Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income": In February 2018, the FASB issued a new standard that permits entities to make a one-time reclassification from accumulated other comprehensive income (AOCI) to retained earnings for the stranded tax effects resulting from the newly enacted corporate tax rates under the Tax Cuts and Jobs Act (the Tax Act), that was effective for the year ended December 31, 2017. We adopted the new standard on January 1, 2019 and elected not to reclassify the income tax effects of the Tax Act from AOCI to retained earnings. We continue to release disproportionate income tax effects from AOCI based on the aggregate portfolio approach. The adoption of this standard did not have an impact on our condensed consolidated financial statements.

3. 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.

(amounts in millions, except per share amounts)

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.

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

(amounts in millions, except per share amounts)

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.

4. Inventories

The components of inventory are as follows:

	September 30, 2019		December 31, 2018	
Raw materials	$	36.0	$	31.4
Work-in-process		180.4		90.4
Finished goods		360.3		350.7
	$	576.7	$	472.5

5. Intangible Assets and Goodwill

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

		September 30, 2019						December 31, 2018					
	Estimated Life (years)	Cost		Accumulated Amortization		Net		Cost		Accumulated Amortization		Net	
Licensing rights	5-8	$	47.0	$	(32.8)	$	14.2	$	39.0	$	(29.3)	$	9.7
Patents	7		10.5		(10.5)		—		10.5		(10.5)		—
Purchased technology	6-16		4,710.5		(1,314.8)		3,395.7		4,710.5		(1,079.1)		3,631.4
Other intangibles	5		0.4		(0.2)		0.2		0.4		(0.2)		0.2
Total		$	4,768.4	$	(1,358.3)	$	3,410.1	$	4,760.4	$	(1,119.1)	$	3,641.3
Goodwill	Indefinite	$	5,040.3	$	(2.9)	$	5,037.4	$	5,040.3	$	(2.9)	$	5,037.4

Amortization expense for the three months ended September 30, 2019 and 2018 was $77.5 and $80.2, respectively. Amortization expense for the nine months ended September 30, 2019 and 2018 was $239.2 and $240.8, respectively. As of September 30, 2019, assuming no changes in the gross cost basis of intangible assets, the total estimated amortization expense for finite-lived intangible assets is $74.0 for the three months ending December 31, 2019, and approximately $296.0 for each of the years ending December 31, 2020 through December 31, 2024.

As of September 30, 2019, the net book value of our purchased technology includes $3,057.5 associated with the KANUMA intangible asset, which we acquired in the acquisition of Synageva BioPharma Corp. As part of our standard quarterly procedures, we reviewed the KANUMA asset as of September 30, 2019 and determined that there were no indicators of impairment. Cash flow models used in our assessments are based on our commercial experience to date with KANUMA and require the use of significant estimates, which include, but are not limited to, long-range pricing expectations and patient-related assumptions, including patient identification, conversion and retention rates. We will continue to review the related valuation and accounting of this asset as new information becomes available to us.

6. 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 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 ending June 30, 2019, we are required to make payments of 5.00% of the original principal amount of the term loan facility annually, payable in equal quarterly installments.

In connection with entering into the Credit Agreement and the Prior Credit Agreement, we paid an aggregate of $53.1 in financing costs. Financing costs are amortized as interest expense over the life of the debt. Amortization expense associated with deferred financing costs for the three months ended September 30, 2019 and 2018 was $1.3 and amortization expense associated with deferred financing costs for the nine months ended September 30, 2019 and 2018 was $3.8 and $6.7, respectively. Remaining unamortized deferred financing costs as of September 30, 2019 and December 31, 2018 were $17.0 and $20.8, respectively.

We made principal payments of $32.7 and $65.4 on the term loan during the three and nine months ended September 30, 2019, respectively, and as of September 30, 2019, we had $2,547.1 outstanding on the term loan. In January 2019, we paid the outstanding balance on the revolving credit facility of $250.0 in full and we had no outstanding borrowings under the revolving credit facility as of September 30, 2019. As of September 30, 2019, we had open letters of credit of $1.0 that offset our availability in the revolving facility.

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

7. 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 during the applicable period. 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.

(amounts in millions, except per share amounts)

The following table summarizes the calculation of basic and diluted EPS for the three and nine months ended September 30, 2019 and 2018:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Net income used for basic and diluted calculation	$ 467.6	$ 330.9	$ 1,515.3	$ 122.6
Shares used in computing earnings per common share—basic	223.3	222.9	223.8	222.5
Weighted-average effect of dilutive securities:				
Stock awards	1.2	1.7	1.6	1.7
Shares used in computing earnings per common share—diluted	224.5	224.6	225.4	224.2
Earnings per common share:				
Basic	$ 2.09	$ 1.48	$ 6.77	$ 0.55
Diluted	$ 2.08	$ 1.47	$ 6.72	$ 0.55

We exclude from diluted EPS the weighted-average number of securities whose effect is anti-dilutive. Excluded from the calculation of diluted EPS for the three months ended September 30, 2019 and 2018 were 3.3 and 2.5 shares of common stock, respectively, because their effect was anti-dilutive. Similarly, we excluded 3.1 and 2.9 shares of common stock from the calculation of EPS for the nine months ended September 30, 2019 and 2018, respectively, because their effect was anti-dilutive.

8. Marketable Securities

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 September 30, 2019 and December 31, 2018 were as follows:

	September 30, 2019			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Commercial paper	$ 287.3	$ —	$ —	$ 287.3
Corporate bonds	4.6	—	—	4.6
Other government-related obligations:				
U.S.	130.5	—	—	130.5
Foreign	8.8	—	—	8.8
Bank certificates of deposit	15.6	—	—	15.6
Total available-for-sale debt securities	$ 446.8	$ —	$ —	$ 446.8

	December 31, 2018			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Commercial paper	$ 52.1	$ —	$ —	$ 52.1
Corporate bonds	122.9	—	(0.1)	122.8
Other government-related obligations:				
U.S.	17.5	—	—	17.5
Bank certificates of deposit	33.2	—	—	33.2
Total available-for-sale debt securities	$ 225.7	$ —	$ (0.1)	$ 225.6

The aggregate fair value of available-for-sale debt securities in an unrealized loss position as of September 30, 2019 and December 31, 2018 was $0.7 and $128.7, respectively. We did not have any investments in a continuous unrealized loss position for more than twelve months as of September 30, 2019 and December 31, 2018. As of September 30, 2019, we believe that the cost basis of our available-for-sale debt securities is recoverable.

(amounts in millions, except per share amounts)

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

	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 423.2	$ 43.8
Marketable securities	23.6	181.8
	$ 446.8	$ 225.6

The fair values of available-for-sale debt securities at September 30, 2019, by contractual maturity, are summarized as follows:

	September 30, 2019
Due in one year or less	$ 443.2
Due after one year through three years	3.6
	$ 446.8

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. As of September 30, 2019 and December 31, 2018, the fair value of these investments was $20.8 and $16.5, respectively.

We utilize the specific identification method in computing realized gains and losses. Realized gains and losses on our marketable securities were not material for the three and nine months ended September 30, 2019 and 2018.

9. 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, with durations of up to 60 months, 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. 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 September 30, 2019, we had open revenue related foreign exchange forward contracts with notional amounts totaling $1,211.9 that qualified for hedge accounting with current contract maturities through May 2021. As of September 30, 2019, we had open expense related foreign exchange forward contracts with notional amounts totaling $15.6 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 September 30, 2019:

(amounts in millions, except per share amounts)

Type of Interest Rate Swap Contract	Notional Amount	Effective Date	Termination Date	Fixed Interest Rate or Rate Range
Floating to Fixed	1,531.3	December 2016 - January 2018	December 2019	0.98% - 1.62%
Floating to Fixed	450.0	December 2018	December 2022	2.60% - 2.79%
Floating to Fixed	300.0	January 2019	December 2019	2.08%
Floating to Fixed	1,300.0	December 2019	December 2022	2.37% - 2.83%

The amount of gains and (losses) recognized in the condensed consolidated statements of operations for the three and nine months ended September 30, 2019 and 2018 from foreign exchange and interest rate swap contracts that qualified as cash flow hedges were as follows:

	Three months ended September 30, 2019		Three months ended September 30, 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
Total amount presented in the Condensed Consolidated Statements of Operations	$ 1,263.1	$ (17.9)	$ 1,026.5	$ (24.6)
Impact of cash flow hedging relationships:				
Foreign exchange forward contracts	$ 11.0	$ —	$ 3.3	$ —
Interest rate swap contracts	$ —	$ 3.4	$ —	$ 4.0

	Nine months ended September 30, 2019		Nine months ended September 30, 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
Total amount presented in the Condensed Consolidated Statements of Operations	$ 3,605.8	$ (56.1)	$ 3,001.6	$ (73.7)
Impact of cash flow hedging relationships:				
Foreign exchange forward contracts	$ 27.1	$ —	$ (11.5)	$ —
Interest rate swap contracts	$ —	$ 12.5	$ —	$ 8.5

The impact on AOCI from foreign exchange and interest rate swap contracts that qualified as cash flow hedges, for the three and nine months ended September 30, 2019 and 2018 were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Foreign Exchange Forward Contracts:				
Gain (loss) recognized in AOCI, net of tax	$ 30.5	$ 9.8	$ 40.8	$ 26.3
Gain (loss) reclassified from AOCI to net product sales, net of tax	$ 8.6	$ 2.5	$ 21.0	$ (8.9)
Interest Rate Swap Contracts:				
Gain (loss) recognized in AOCI, net of tax	$ (7.1)	$ 7.2	$ (45.9)	$ 18.4
Gain (loss) reclassified from AOCI to interest expense, net of tax	$ 2.6	$ 3.1	$ 9.6	$ 6.7

Assuming no change in foreign exchange rates from market rates at September 30, 2019, $29.1 of gains 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 September 30, 2019, $14.0 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 at September 30, 2019.

(amounts in millions, except per share amounts)

We enter into foreign exchange forward contracts, with durations of up to 8 months, designed to limit the balance sheet exposure of monetary assets and liabilities. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results. Hedge accounting is not applied to these derivative instruments as gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. As of September 30, 2019, the notional amount of foreign exchange contracts where hedge accounting is not applied was $1,103.2.

We recognized a gain (loss) of $1.4 and $6.8, in other income and (expense) for the three months ended September 30, 2019 and 2018, respectively, associated with the foreign exchange contracts not designated as hedging instruments. We recognized a gain (loss) of $(1.2) and $17.1, in other income and (expense) for the nine months ended September 30, 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 September 30, 2019 and December 31, 2018:

	September 30, 2019			
	Derivative Assets		Derivative Liabilities	
	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	$ 32.5	Other current liabilities	$ 3.6
Foreign exchange forward contracts	Other assets	4.1	Other liabilities	0.8
Interest rate swap contracts	Prepaid expenses and other current assets	2.4	Other current liabilities	16.4
Interest rate swap contracts	Other assets	—	Other liabilities	55.7
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	10.3	Other current liabilities	13.5
Total fair value of derivative instruments		**$ 49.3**		**$ 90.0**

(amounts in millions, except per share amounts)

	December 31, 2018			
	Derivative Assets		Derivative Liabilities	
	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	$ 16.9	Other current liabilities	$ 7.3
Foreign exchange forward contracts	Other assets	0.3	Other liabilities	3.1
Interest rate swap contracts	Prepaid expenses and other current assets	20.1	Other current liabilities	0.8
Interest rate swap contracts	Other assets	—	Other liabilities	17.3
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	23.6	Other current liabilities	11.5
Total fair value of derivative instruments		**$ 60.9**		**$ 40.0**

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

	September 30, 2019					
				Gross Amounts Not Offset in the Condensed Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Condensed Consolidated Balance Sheet	Net Amounts of Assets/Liabilities Presented in the Condensed Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 49.3	$ —	$ 49.3	$ (11.8)	$ —	$ 37.5
Derivative liabilities	(90.0)	—	(90.0)	11.8	—	(78.2)

	December 31, 2018					
				Gross Amounts Not Offset in the Condensed Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Condensed Consolidated Balance Sheet	Net Amounts of Assets/Liabilities Presented in the Condensed Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 60.9	$ —	$ 60.9	$ (30.2)	$ —	$ 30.7
Derivative liabilities	(40.0)	—	(40.0)	30.2	—	(9.8)

10. Other Investments

Other investments include strategic investments in equity securities of certain biotechnology companies which we acquired in connection with license and option agreements. These investments are included in other assets in our condensed 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. As a result, we recognized an unrealized gain of $100.8 in investment income during the first quarter 2018 to adjust our 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. There were no observable price changes during the second and third quarters of 2018.

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 has a readily determinable fair value, we are recording the investment at fair value, with the effects of the holding period restriction estimated using an option pricing valuation model. During the three and nine months ended September 30, 2019, we recognized an unrealized gain of $12.3 and $13.1, respectively, in investment income to adjust our investment in Moderna to fair value as of September 30, 2019.

The fair value of this investment was $95.0 and $81.9 as of September 30, 2019 and December 31, 2018, respectively.

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 three and nine months ended September 30, 2019, we recognized an unrealized (loss) gain of $(1.1) and $3.1, respectively, in investment income to adjust our equity investment in Dicerna to fair value as of September 30, 2019.

The fair value of this investment was $12.0 and $8.9 as of September 30, 2019 and December 31, 2018, respectively.

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 in connection with an agreement that we entered into with Caelum, see Note 18, *“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 do not have a readily determinable fair value, we are recording the assets at cost, less impairment, and adjusted for 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 three and nine months ended September 30, 2019. The carrying value of the investment and option of $41.0 and $16.1, respectively, were not impaired as of September 30, 2019.

Zealand

In March 2019, we purchased $13.8 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, see Note 18, *“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 three and nine months ended September 30, 2019, we recognized an unrealized gain of $3.7 and $7.3, respectively, in investment income to adjust our equity investment in Zealand to fair value as of September 30, 2019.

(amounts in millions, except per share amounts)

The fair value of this investment was $20.4 as of September 30, 2019.

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., see Note 18, *"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, with the effects of a one year holding period restriction estimated using an option pricing valuation model. During the three and nine months ended September 30, 2019, we recognized an unrealized loss of $2.9 in investment income to adjust our equity investment in Eidos to fair value as of September 30, 2019.

The fair value of this investment was $17.0 as of September 30, 2019.

11. Stockholders' Equity

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 the repurchase program, which superseded all prior repurchase programs. The repurchase program does not have an expiration date and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at our discretion. Under the program, we repurchased 3.1 shares of our common stock at a cost of $334.6 during the three months ended September 30, 2019. The Company did not repurchase any shares during the three months ended September 30, 2018. During the nine months ended September 30, 2019 and 2018, we repurchased 3.5 and 0.7 shares of our common stock at a cost of $383.5 and $85.0, respectively.

Subsequent to September 30, 2019, we repurchased 0.1 shares of common stock under our repurchase program at a cost of $7.0. As of October 21, 2019, there is a total of $60.9 remaining for repurchases under the repurchase program.

12. Other Comprehensive Income and Accumulated Other Comprehensive Income

The following tables summarize the changes in AOCI, by component, for the nine months ended September 30, 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, 2018	$ (2.6)	$ (0.3)	$ 9.6	$ (16.4)	$ (9.7)
Other comprehensive income (loss) before reclassifications	—	0.2	(5.1)	(3.0)	(7.9)
Amounts reclassified from other comprehensive income	—	—	(30.6)	—	(30.6)
Net other comprehensive income (loss)	—	0.2	(35.7)	(3.0)	(38.5)
Balances, September 30, 2019	$ (2.6)	$ (0.1)	$ (26.1)	$ (19.4)	$ (48.2)

(amounts in millions, except per share amounts)

	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	1.2	0.2	44.7	(6.0)	40.1
Amounts reclassified from other comprehensive income	(0.5)	(0.5)	2.2	—	1.2
Net other comprehensive income (loss)	0.7	(0.3)	46.9	(6.0)	41.3
Balances, September 30, 2018	$ (4.1)	$ (0.1)	$ 33.0	$ (21.9)	$ 6.9

The table below provides details regarding significant reclassifications from AOCI during the three and nine months ended September 30, 2019 and 2018:

Details about Accumulated Other Comprehensive Income Components	Amount Reclassified From Accumulated Other Comprehensive Income during the three months ended September 30, 2019	2018	Amount Reclassified From Accumulated Other Comprehensive Income during the nine months ended September 30, 2019	2018	Affected Line Item in the Condensed Consolidated Statements of Operations
Unrealized Gains (Losses) on Hedging Activity					
Foreign exchange forward contracts	$ 11.0	$ 3.3	$ 27.1	$ (11.5)	Net product sales
Interest rate swap contracts	3.4	4.0	12.5	8.5	Interest expense
	14.4	7.3	39.6	(3.0)	
	(3.2)	(1.7)	(9.0)	0.8	Income tax (benefit) expense
	$ 11.2	$ 5.6	$ 30.6	$ (2.2)	

13. 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 September 30, 2019 and December 31, 2018, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

(amounts in millions, except per share amounts)

		Fair Value Measurement at September 30, 2019			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Money market funds	$ 529.1	$ —	$ 529.1	$ —
Cash equivalents	Commercial paper	$ 287.3	$ —	$ 287.3	$ —
Cash equivalents	Bank certificates of deposit	$ 7.1	$ —	$ 7.1	$ —
Cash equivalents	Other government-related obligations	$ 128.8	$ —	$ 128.8	$ —
Marketable securities	Mutual funds	$ 20.8	$ 20.8	$ —	$ —
Marketable securities	Commercial paper	$ —	$ —	$ —	$ —
Marketable securities	Corporate bonds	$ 4.6	$ —	$ 4.6	$ —
Marketable securities	Other government-related obligations	$ 10.5	$ —	$ 10.5	$ —
Marketable securities	Bank certificates of deposit	$ 8.5	$ —	$ 8.5	$ —
Other assets	Equity securities	$ 144.4	$ 32.4	$ 112.0	$ —
Prepaid expenses and other current assets	Foreign exchange forward contracts	$ 42.8	$ —	$ 42.8	$ —
Other assets	Foreign exchange forward contracts	$ 4.1	$ —	$ 4.1	$ —
Other current liabilities	Foreign exchange forward contracts	$ 17.1	$ —	$ 17.1	$ —
Other liabilities	Foreign exchange forward contracts	$ 0.8	$ —	$ 0.8	$ —
Prepaid expenses and other current assets	Interest rate contracts	$ 2.4	$ —	$ 2.4	$ —
Other current liabilities	Interest rate contracts	$ 16.4	$ —	$ 16.4	$ —
Other liabilities	Interest rate contracts	$ 55.7	$ —	$ 55.7	$ —
Current portion of contingent consideration	Acquisition-related contingent consideration	$ —	$ —	$ —	$ —
Contingent consideration	Acquisition-related contingent consideration	$ 188.0	$ —	$ —	$ 188.0
Other current liabilities	Other contingent payments	$ 14.0	$ —	$ —	$ 14.0
Other liabilities	Other contingent payments	$ 13.6	$ —	$ —	$ 13.6

(amounts in millions, except per share amounts)

Balance Sheet Classification	Type of Instrument	Fair Value Measurement at December 31, 2018			
		Total	Level 1	Level 2	Level 3
Cash equivalents	Money market funds	$ 569.4	$ —	$ 569.4	$ —
Cash equivalents	Commercial paper	$ 35.4	$ —	$ 35.4	$ —
Cash equivalents	Corporate bonds	$ 0.2	$ —	$ 0.2	$ —
Cash equivalents	Other government-related obligations	$ 8.2	$ —	$ 8.2	$ —
Marketable securities	Mutual funds	$ 16.5	$ 16.5	$ —	$ —
Marketable securities	Commercial paper	$ 16.7	$ —	$ 16.7	$ —
Marketable securities	Corporate bonds	$ 122.6	$ —	$ 122.6	$ —
Marketable securities	Other government-related obligations	$ 9.3	$ —	$ 9.3	$ —
Marketable securities	Bank certificates of deposit	$ 33.2	$ —	$ 33.2	$ —
Other assets	Equity securities	$ 90.8	$ 8.9	$ 81.9	$ —
Prepaid expenses and other current assets	Foreign exchange forward contracts	$ 40.5	$ —	$ 40.5	$ —
Other assets	Foreign exchange forward contracts	$ 0.3	$ —	$ 0.3	$ —
Other current liabilities	Foreign exchange forward contracts	$ 18.8	$ —	$ 18.8	$ —
Other liabilities	Foreign exchange forward contracts	$ 3.1	$ —	$ 3.1	$ —
Prepaid expenses and other current assets	Interest rate contracts	$ 20.1	$ —	$ 20.1	$ —
Other current liabilities	Interest rate contracts	$ 0.8	$ —	$ 0.8	$ —
Other liabilities	Interest rate contracts	$ 17.3	$ —	$ 17.3	$ —
Current portion of contingent consideration	Acquisition-related contingent consideration	$ 97.6	$ —	$ —	$ 97.6
Contingent consideration	Acquisition-related contingent consideration	$ 183.2	$ —	$ —	$ 183.2

There were no securities transferred between Level 1, 2 and 3 during the nine months ended September 30, 2019.

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 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 similar companies. We also use a constant maturity risk-free interest rate to match the remaining term of the restrictions on such investments.

(amounts in millions, except per share amounts)

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 September 30, 2019, 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. The resulting probability-weighted cash flows were discounted using a cost of debt of 5.1% for developmental and regulatory milestones and a weighted average cost of capital of 10.0% 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 September 30, 2019, estimated future contingent milestone payments related to prior business combinations range from zero if no milestone events are achieved, to a maximum of $602.0 if all development, regulatory and sales-based milestones are reached. In the second quarter 2019, a sales-based milestone associated with our acquisition of Enobia Pharma Corp. was achieved. In connection with such achievement, we made a $100.0 milestone payment in the third quarter 2019.

As of September 30, 2019, the fair value of acquisition-related contingent consideration was $188.0. The following table represents a roll-forward of our acquisition-related contingent consideration:

	Nine months ended September 30, 2019
Balance at beginning of period	$ 280.8
Milestone payments	(100.0)
Changes in fair value	7.2
Balance at end of period	$ 188.0

Other Contingent Payments

In January 2019, we entered into an agreement with Caelum, a biotechnology company that is developing CAEL101 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 could be required to pay up to an additional $30.0 in contingent milestone-dependent fees. These contingent payments meet 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%.

Each reporting period, we adjust the derivative liability associated with the contingent fees 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 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. As of September 30, 2019, the fair value of our contingent fees was $27.6. We recorded $(0.2) and $(0.5) in other income and (expense) during the three and nine months ended September 30, 2019, respectively, related to the change in the fair value of the liability.

(amounts in millions, except per share amounts)

14. Revenue Recognition

Disaggregation of Revenue

The Company disaggregates revenue from contracts with customers into product and geographical regions as summarized below.

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
SOLIRIS				
United States	$ 496.8	$ 404.5	$ 1,456.8	$ 1,136.3
Europe	255.5	262.1	800.2	766.3
Asia Pacific	118.0	98.2	329.2	277.3
Rest of World	120.2	123.2	347.1	406.4
Total	$ 990.5	$ 888.0	$ 2,933.3	$ 2,586.3
ULTOMIRIS				
United States	$ 65.1	$ —	$ 143.9	$ —
Europe	21.1	—	21.1	—
Asia Pacific	3.7	—	3.7	—
Rest of World	—	—	—	—
Total	$ 89.9	$ —	$ 168.7	$ —
STRENSIQ				
United States	$ 118.0	$ 86.6	$ 323.7	$ 275.7
Europe	19.0	16.6	56.0	47.0
Asia Pacific	14.0	7.2	36.0	19.2
Rest of World	3.3	2.8	10.0	7.1
Total	$ 154.3	$ 113.2	$ 425.7	$ 349.0
KANUMA				
United States	$ 16.0	$ 13.7	$ 45.1	$ 38.6
Europe	6.3	4.7	19.4	16.4
Asia Pacific	1.3	0.8	3.4	2.9
Rest of World	4.8	6.1	10.2	8.4
Total	$ 28.4	$ 25.3	$ 78.1	$ 66.3
Total Net Product Sales	$ 1,263.1	$ 1,026.5	$ 3,605.8	$ 3,001.6

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 condensed consolidated balance sheets.

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

(amounts in millions, except per share amounts)

	September 30, 2019	December 31, 2018
Receivables, which are included in "Trade accounts receivable, net"	$ 1,116.3	$ 922.3
Contract liabilities, which are included in "Other current liabilities"	$ 26.3	$ 3.4

15. Income Taxes

The following table provides a comparative summary of our income tax expense and effective income tax rate for the three and nine months ended September 30, 2019 and 2018:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Income tax expense	$ 67.9	$ 11.2	$ 61.5	$ 152.5
Effective income tax rate	12.7%	3.3%	3.9%	55.4%

Income tax expense is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. During the first quarter 2019, in connection with the future integration of intellectual property of Wilson Therapeutics into the Alexion corporate structure, we recognized certain one-time tax benefits. 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. These deferred tax benefits decreased the effective tax rate for the nine months ended September 30, 2019 by approximately 8.0%. Future changes to our intellectual property integration planning could materially impact our effective tax rate in subsequent periods.

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.

During the third quarter 2019, we completed a comprehensive analysis of our current and prior year estimates related to our foreign-derived intangible income (“FDII”) based on additional guidance provided in the proposed regulations issued by the U.S. Treasury Department in 2019. The analysis resulted in income tax benefits of approximately $29.9, including $17.0 million related to prior year estimated tax benefits, which were recorded as a change in estimate in income tax expense in our consolidated statements of operations during the three and nine months ended September 30, 2019. These tax benefits decreased the effective tax rate for the three and nine months ended September 30, 2019 by approximately 5.6% and 1.9%, respectively.

The income tax expense for the three months ended September 30, 2018 includes a U.S. tax reform measurement period adjustment to deferred taxes of $(53.1). This deferred tax benefit decreased the effective tax rate by approximately 15.5%. The income tax expense for the nine months ended September 30, 2018 includes an increase in the effective tax rate of approximately 41.3% attributable to the acquisition of Wilson Therapeutics. Absent successful clinical results and regulatory approval, there is no alternative future use of the WTX101 asset acquired. Accordingly, the value of the asset of $803.7 was expensed as in-process research and development costs during the nine month period, for which no tax benefit has been recognized. Also included in the nine months ended September 30, 2018 is a U.S. tax reform measurement period adjustment to deferred taxes of $(14.7). This deferred tax benefit decreased the effective tax rate by approximately 1.4%.

In 2017, the Internal Revenue Service (IRS) commenced an examination of our U.S. income tax returns for 2015. We anticipate this audit will conclude within the next twelve months. We have not been notified of any significant adjustments proposed by the IRS. It is reasonably possible that previously unrecognized tax benefits could be recognized upon the conclusion of the IRS examination. At this time, an estimate of the change in unrecognized tax benefits cannot be made.

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.

We continue to maintain a valuation allowance against certain deferred tax assets where realization is not certain.

(amounts in millions, except per share amounts)

16. Defined Benefit Plans

We maintain defined benefit plans for employees in certain countries outside the U.S., including retirement benefit plans required by applicable local law. The plans are valued by independent actuaries using the projected unit credit method. The liabilities correspond to the projected benefit obligations of which the discounted net present value is calculated based on years of employment, expected salary increases, and pension adjustments. The total net periodic benefit cost for the three and nine months ended September 30, 2019 and 2018 was not material.

17. Leases

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 condensed consolidated statements of operations. Financing lease ROU asset amortization and interest costs are recorded within operating expenses and interest expense, respectively, within our condensed 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 condensed consolidated balance sheet as of September 30, 2019. Financing leases are included in property, plant and equipment, other current liabilities, and other liabilities in our condensed consolidated balance sheet as of September 30, 2019.

The following table summarizes our lease assets and liabilities as of September 30, 2019:

ROU Assets and Liabilities

	Balance Sheet Location	Financing	Operating
ROU - Asset	*Right of use operating assets*	$ —	$ 206.9
ROU - Asset	*Property, plant, and equipment*	119.1	—
Lease liabilities (current)	*Other current liabilities*	5.1	17.4
Lease liabilities (noncurrent)	*Noncurrent operating lease liabilities*	—	166.8
Lease liabilities (noncurrent)	*Other liabilities*	74.2	—

(amounts in millions, except per share amounts)

The following table summarizes our lease related costs for the three and nine months ended September 30, 2019:

Lease Cost

	Statement of Operations Location	Three months ended September 30, 2019	Nine months ended September 30, 2019
Financing Lease Cost		$ 3.7	$ 11.2
Amortization of ROU Assets	*Operating Expenses*	2.7	8.2
Interest on Lease Liabilities	*Interest Expense*	1.0	3.0
Operating Lease Cost	*Operating Expenses*	8.5	26.1
Variable Lease Cost	*Operating Expenses*	4.8	9.1
Total Lease Cost		$ 17.0	$ 46.4

Amounts above include $5.3 and $11.6 of lease costs associated with our CMO embedded lease arrangement for the three and nine months ended September 30, 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 three and nine months ended September 30, 2019:

Other Information	Three months ended September 30, 2019	Nine months ended September 30, 2019
Cash Paid For Amounts Included In Measurement of Liabilities	$ 9.0	$ 25.5
Operating Cash Flows From Financing Leases	1.0	3.0
Operating Cash Flows From Operating Leases	6.8	18.8
Financing Cash Flows From Financing Leases	1.2	3.7
ROU Assets Obtained In Exchange For New Financing Liabilities (1)	—	—
ROU Assets Obtained In Exchange For New Operating Liabilities (2)	4.3	25.0

(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 nine months ended September 30, 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 nine months ended September 30, 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 September 30, 2019:

Lease Liability Maturity Summary

Year	Financing	Operating	Total
2019 (remaining)	$ 2.2	$ 5.7	$ 7.9
2020	8.8	24.7	33.5
2021	9.0	22.0	31.0
2022	9.2	20.8	30.0
2023	9.2	20.5	29.7
2024	9.4	20.1	29.5
Thereafter	54.6	112.1	166.7

Reconciliation of Lease Liabilities	Financing	Operating	Total
Weighted-average Remaining Lease Term *(years)*	10.92	10.47	10.61
Weighted-average Discount Rate	4.85%	4.11%	4.34%
Total Undiscounted Lease Liability	$ 102.4	$ 225.9	$ 328.3
Imputed Interest	23.0	41.8	64.8
Total Discounted Lease Liability	79.3	184.2	263.5

(amounts in millions, except per share amounts)

For comparable purposes, our aggregate future minimum non-cancellable commitments under operating leases as of December 31, 2018 were as follows:

Year	
2019	$ 27.8
2020	24.7
2021	21.3
2022	19.9
2023	19.7
Thereafter	132.2

Excluded from the table above are commitments with Lonza Group AG and its affiliates (Lonza), a third party manufacturer that produces a portion of commercial and clinical quantities of our commercial products and product candidates. During the third quarter 2015, we entered into an agreement with Lonza whereby Lonza constructed a facility to be used to manufacture product under a supply agreement for Alexion at one of its existing facilities, resulting in the determination that the CMO arrangement contained a lease. This agreement requires us to make certain payments during the construction of the manufacturing facility and annual payments for ten years thereafter. As the arrangement contains both a lease and non-lease component, related to the supply of product, the consideration paid to Lonza is allocated between these components. As of December 31, 2018, we had various manufacturing and licensing agreements with Lonza, with remaining total non-cancellable future commitments of approximately $1,084.6. This amount included $88.7 of undiscounted, fixed payments applicable to our CMO embedded lease arrangement with Lonza, based on the relative standalone price of the lease and non-lease components of the arrangement at that time.

18. 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 CAEL101 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 could be required to pay up to an additional $30.0 in contingent milestone-dependent fees. 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 contingent milestone-dependent fees, 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. 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 1 studies. In addition to the agreement, we made an equity investment in Zealand (see Note 10). 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 condensed consolidated balance sheets. We also recognized prepaid research and development expense of $5.0 within the condensed 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 September 30, 2019, 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. 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 March 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 FcRn and is currently in Phase 1 development. The agreement with Affibody was subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act and, following receipt of such approval, the transaction closed in April 2019. Pursuant to the agreement, Alexion will lead the clinical development and commercial activities for ABY-039 in rare Immunoglobulin G (IgG)-mediated autoimmune diseases. Affibody has the option to co-promote ABY-039 in the U.S. and will lead clinical development of ABY-039 in an undisclosed indication. 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 are licensing, we recorded the upfront license payment as research and development expense during the second quarter 2019. As of September 30, 2019, we could also be required to pay up to $625.0 for amounts due upon achievement of specific development, regulatory, and commercial milestones, as well as royalties on commercial sales.

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 3 study in the U.S. and Europe for ATTR cardiomyopathy (ATTR-CM). In addition, we made an equity investment in Eidos (see Note 10). 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 condensed 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 September 30, 2019, 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 connection with our prior acquisition of Syntimmune (see Note 3), we could be required to pay up to $800.0 upon the achievement of specified development, regulatory and commercial milestones.

In addition, as of September 30, 2019, we have other license agreements under which we may be required to pay up to an additional $834.6 for currently licensed targets, if certain development, regulatory and commercial milestones are met. Additional amounts may be payable if we elect to acquire licenses to additional targets, as applicable, under the terms of these agreements.

Asset Sale and Out-License Arrangements

In connection with prior asset sale and out-license arrangements, 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 September 30, 2019.

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 $1,062.2. This amount includes $102.3 of undiscounted, fixed payments applicable to our 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 also pay Lonza a royalty on sales of SOLIRIS that was manufactured at the Alexion Rhode Island Manufacturing Facility (ARIMF facility) prior to the sale of the facility and a payment with respect to sales of SOLIRIS manufactured at Lonza facilities. We also pay Lonza a royalty on the sales of ULTOMIRIS.

In addition to our commitments with Lonza, as of September 30, 2019 we have non-cancellable commitments of approximately $63.2 through 2020 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 FCPA. The SEC and DOJ also seek information related to Alexion's recalls of specific lots of SOLIRIS and related securities disclosures. Alexion is cooperating with these investigations.

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

At this time, Alexion is unable to predict the duration, scope or outcome of these investigations. While it is possible that a loss related to these matters may be incurred, given the ongoing nature of these investigations, management cannot reasonably estimate the potential magnitude of any such loss or range of loss, or the cost of the ongoing investigation. Any determination that our operations or activities are not or were not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief, and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Alexion is committed to strengthening its compliance program and is currently implementing a comprehensive company-wide transformation plan that is designed to enhance and remediate its 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 May 31, 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' reply in further support of their motion is due November 16, 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 Sao Paulo, Brazil offices as part of an investigation being conducted into Alexion's Brazilian operations. We are cooperating with this inquiry.

In June 2017, we received a demand to inspect certain 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 not determined 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. Pursuant to an order made by the Federal Court of Canada, as of October 23, 2019, we have placed approximately $37.0 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 September 30, 2019. 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 list price for SOLIRIS and the price determined by the PMPRB to be non-excessive. Our revenues in Canada recognized in the quarter ended September 30, 2019 were reduced by $3.9 and we have accrued an aggregate of $24.3, which is our current best estimate of our liability through September 30, 2019 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).

In October 2018, the Japanese Ministry of Health, Labour and Welfare (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.

Chugai Pharmaceutical Co., Ltd. has filed two 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. The second lawsuit was filed 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. In both cases, Alexion has denied the charges and countered that the patents are neither valid nor infringed. A trial date for the U.S. case has been set for May 2021. 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 alleges 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. We expect the PTO to review written submissions by both parties, hold an oral argument, and issue decisions on the three IPRs by August 30, 2020. At this time we cannot determine what decision the PTO will make.

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. 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.

19. Restructuring and Related Expenses

In the first quarter 2019, we initiated corporate restructuring activities to re-align our commercial organization through re-prioritization of certain geographical markets and to implement operational excellence through strategic reallocation of resources.

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.

(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:

	Three months ended September 30, 2019				Three months ended September 30, 2018			
	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total
Cost of sales	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Research and development	—	—	—	—	—	—	—	—
Selling, general and administrative	—	—	—	—	—	7.9	—	7.9
Restructuring expense	(2.8)	—	3.1	0.3	2.8	—	7.5	10.3
Other (income) expense	—	—	—	—	—	—	—	—
	$ (2.8)	$ —	$ 3.1	$ 0.3	$ 2.8	$ 7.9	$ 7.5	$ 18.2

	Nine months ended September 30, 2019				Nine months ended September 30, 2018			
	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total
Cost of sales	$ —	$ —	$ —	$ —	$ —	$ 5.8	$ —	$ 5.8
Research and development	—	—	—	—	—	0.1	—	0.1
Selling, general and administrative	—	—	—	—	—	18.0	—	18.0
Restructuring expense	8.7	—	3.2	11.9	6.9	—	19.5	26.4
Other (income) expense	—	—	—	—	—	—	(0.1)	(0.1)
	$ 8.7	$ —	$ 3.2	$ 11.9	$ 6.9	$ 23.9	$ 19.4	$ 50.2

The following table presents a reconciliation of the restructuring reserve recorded within accounts payable and accrued expenses on the Company's condensed consolidated balance sheets as of September 30, 2019:

	Three months ended September 30, 2019				Nine months ended September 30, 2019			
	Employee Separation Costs	Asset Charges	Other Costs	Total	Employee Separation Costs	Asset Charges	Other Costs	Total
Liability, beginning of period	$ 9.5	$ —	$ —	$ 9.5	$ 4.2	$ —	$ —	$ 4.2
Restructuring and related expenses	—	—	3.1	3.1	14.2	—	3.1	17.3
Cash settlements	(2.3)	—	(0.1)	(2.4)	(8.6)	—	(0.1)	(8.7)
Adjustments to previous estimates	(2.8)	—	—	(2.8)	(5.4)	—	—	(5.4)
Asset impairments	—	—	—	—	—	—	—	—
Liability, end of period	$ 4.4	$ —	$ 3.0	$ 7.4	$ 4.4	$ —	$ 3.0	$ 7.4

The restructuring reserve of $7.4 and $4.2 is recorded in accounts payable and accrued expenses on the Company's condensed consolidated balance sheets as of September 30, 2019 and December 31, 2018, respectively. The accrued amounts are expected to be paid in the next twelve months. We currently estimate incurring up to an additional $8.0 in restructuring expenses related to the first quarter 2019 action.

20. Subsequent Events

On October 10, 2019, we entered into an option agreement with Stealth BioTherapeutics Corp. (Stealth), a clinical-stage biotechnology company whose lead product candidate, elamipretide, is being investigated in late-stage clinical studies in three primary mitochondrial diseases - primary mitochondrial myopathy (PMM), Barth syndrome and Leber's hereditary optic neuropathy (LHON). Under the terms of the option agreement, Alexion will receive an exclusive option to partner with Stealth in the development of subcutaneous elamipretide based on final results from the Phase 3 study currently underway in PMM. If we choose to exercise the option, the companies will co-develop subcutaneous elamipretide in the U.S. for PMM and Barth syndrome, as well as LHON. Upon commercialization, the agreement would provide for a 50-50 co-promote between the two companies in the U.S. and Alexion would receive exclusive rights to develop and commercialize subcutaneous elamipretide outside the U.S. Under the terms of the agreement, we made an upfront payment of $30.0 for the option and an equity investment in Stealth. The agreement also provides for additional payments, in the event Alexion exercises the option, of up to $440.0, which includes an upfront option exercise payment, an additional equity investment and potential regulatory and commercial milestone payments, as well as royalties on commercial sales outside the U.S.

On October 15, 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 is developing oral small molecule Factor D inhibitors to treat people with complement alternative pathway-mediated rare diseases, such as PNH and C3 glomerulopathy (C3G). The company currently has two clinical-stage medicines in development, including danicopan (ACH-4471) in Phase 2 and ACH-5228 in Phase 1. Alexion's acquisition of Achillion is subject to the approval of Achillion shareholders and satisfaction of customary closing conditions and approval from relevant regulatory agencies, including clearance under the Hart-Scott Rodino Antitrust Improvements Act. Under the terms of the definitive acquisition agreement, we will pay $6.30 per share of Achillion common stock, or an estimated $930.0, with the final purchase price to be determined upon closing. The acquisition will be funded with cash on hand. The transaction includes the potential for additional consideration in the form of non-tradeable contingent value rights (CVRs), which may 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. FDA approval of danicopan and $1.00 per share for the initiation of Phase 3 in ACH-5228.

On October 22, 2019, the Board of Directors approved a new share repurchase authorization of up to $1,000.0. The repurchase program does not have an expiration date and we are not obligated to acquire a particular number of shares of common stock. The repurchase program may be discontinued at any time at our discretion.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Note Regarding Forward-Looking Statements

This quarterly report on Form 10-Q 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 potential benefits and commercial potential of ULTOMIRIS®, SOLIRIS®, STRENSIQ® and KANUMA® for approved indications and any expanded uses;
- sales of our products in various markets worldwide, pricing for our products, level of insurance coverage and reimbursement for our products, timing regarding development and regulatory approvals for 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 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 regarding pricing (and discounts) and the adoption, implementation and interpretation of healthcare laws and regulations (and the impact on our business);
- plans and prospects for future regulatory approval of products and product candidates;
- competitors, potential competitors and future competitive products (including biosimilars);
- plans to grow our product pipeline (and diversify our business, including through acquisitions) and anticipated benefits to the Company;
- future objective to expand business and sales;
- future plans to retain earnings and not pay dividends;
- expected decisions to appeal certain litigation and intellectual property decisions;
- expectations to realize the carrying value of product inventory;
- impact of accounting standards;
- future costs, operating expenses (including research and development, sales, general and administrative and restructuring expenses) and capital requirements, capital investment, sufficiency of cash to fund operations for at least the next 12 months, ability to fund operations and make payment on 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);
- 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 derivative 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 and anticipated regulatory approval 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;
- estimates of the capacity of manufacturing and other service facilities to support our business operations, products and product candidates.

Such risks and uncertainties include, but are not limited to, increased competition, actions by regulatory agencies, product candidates not receiving regulatory approvals, the possibility that expected tax benefits will not be realized, assessment of impact of recent accounting pronouncements, potential declines in sovereign credit ratings or sovereign defaults in countries where we sell our products, delay of collection or reduction in reimbursement due to adverse economic conditions or changes in government and private insurer regulations and approaches to reimbursement, uncertainties surrounding legal proceedings, company investigations and government investigations and assessments, including our Securities and Exchange Commission (SEC) and U.S. Department of Justice (DOJ) investigations, the securities class action litigation filed in December 2016, the investigation of our Brazilian operations by Brazilian authorities, the tax assessment by the Brazilian Federal Revenue Service, risks related to the short and long-term effects of other government healthcare measures, intellectual property lawsuits and the institution of Inter Partes Reviews, 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.

Overview

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

We are the global leader in complement inhibition and have developed and commercialize two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), as well as the first approved complement inhibitor to treat anti-acetylcholine receptor (AChR) antibody-positive generalized myasthenia gravis (gMG) and anti-AQP4 antibody-positive neuromyelitis optica spectrum disorder (NMOSD). In addition, Alexion 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).

In addition to our marketed therapies, we have a diverse pipeline resulting from internal innovation and business development with strategic focus in hematology and nephrology, neurology, metabolics and neonatal Fc receptor (FcRn).

Recent Developments

In August 2019, the European Commission (EC) approved SOLIRIS as the first treatment for NMOSD in adults who are anti-aquaporin-4 (AQP4) antibody-positive with a relapsing course of the disease.

In August 2019, the European Medicines Agency accepted a Type 2 variation application for the use of ULTOMIRIS as a potential treatment for patients with aHUS.

In September 2019, Alexion submitted an application to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for the use of ULTOMIRIS as a potential treatment for patients with aHUS.

In September 2019, we entered into an agreement with Eidos Therapeutics, Inc. (Eidos), a subsidiary of BridgeBio Pharma, Inc., which provides us with 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. In addition, we made an equity investment in Eidos. Under the terms of the agreement, we made an upfront payment of $50.0 for an exclusive license to AG10 in Japan and the equity investment. We could also be required to pay $30.0 upon achievement of a Japanese-based regulatory milestone as well as royalties on commercial sales.

On October 10, 2019, we entered into an option agreement with Stealth BioTherapeutics Corp. (Stealth), a clinical-stage biotechnology company whose lead product candidate, elamipretide, is being investigated in late-stage clinical studies in three primary mitochondrial diseases - primary mitochondrial myopathy (PMM), Barth syndrome and Leber's hereditary optic neuropathy (LHON). Under the terms of the option agreement, Alexion will receive an exclusive option to partner with Stealth in the development of subcutaneous elamipretide based on final results from the Phase 3 study currently underway in PMM. If we choose to exercise the option, the companies will co-develop subcutaneous elamipretide in the U.S. for PMM and Barth syndrome, as well as LHON. Upon commercialization, the agreement would provide for a 50-50 co-promote between the two companies in the U.S. and Alexion would receive exclusive rights to develop and commercialize subcutaneous elamipretide outside the U.S. Under the terms of the agreement, we made an upfront payment of $30.0 for the option and an equity investment in Stealth. The agreement also provides for additional payments, in the event Alexion exercises the option, of up to $440.0, which includes an upfront option exercise payment, an additional equity investment and potential regulatory and commercial milestone payments, as well as royalties on commercial sales outside the U.S.

On October 15, 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 is developing oral small molecule Factor D inhibitors to treat people with complement alternative pathway-mediated rare diseases, such as PNH and C3 glomerulopathy (C3G). The company currently has two clinical-stage medicines in development, including danicopan (ACH-4471) in Phase 2 and ACH-5228 in Phase 1. Alexion's acquisition of Achillion is subject to the approval of Achillion shareholders and satisfaction of customary closing conditions and approval from relevant regulatory agencies, including clearance under the Hart-Scott Rodino Antitrust Improvements Act. Under the terms of the definitive acquisition agreement, we will pay $6.30 per share of Achillion common stock, or an estimated

$930.0, with the final purchase price to be determined upon closing. The acquisition will be funded with cash on hand. The transaction includes the potential for additional consideration in the form of non-tradeable contingent value rights (CVRs), which may 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. FDA approval of danicopan and $1.00 per share for the initiation of Phase 3 in ACH-5228.

In October 2019, the U.S. Food and Drug Administration (FDA) approved ULTOMIRIS as a treatment for patients with aHUS to inhibit complement-mediated thrombotic microangiopathy (TMA).

On October 22, 2019, the Board of Directors approved a new share repurchase authorization of up to $1,000.0. The repurchase program does not have an expiration date and we are not obligated to acquire a particular number of shares of common stock. The repurchase program may be discontinued at any time at our discretion.

Products and Development Programs

We focus our product development programs on life-transforming therapeutics for rare diseases for which current treatments are either non-existent or inadequate. 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. Chronic hemolysis in patients with PNH may be associated with life-threatening thromboses, recurrent pain, kidney disease, disabling fatigue, impaired quality of life, severe anemia, pulmonary hypertension, shortness of breath and intermittent episodes of dark-colored urine (hemoglobinuria).
Atypical Hemolytic Uremic Syndrome (aHUS)	aHUS is a severe and life-threatening, ultra-rare genetic disease characterized by chronic uncontrolled complement activation and thrombotic microangiopathy (TMA), the formation of blood clots in small blood vessels throughout the body, causing a reduction in platelet count (thrombocytopenia) and life-threatening damage to the kidney, brain, heart and other vital organs.
Generalized Myasthenia Gravis (gMG)	Myasthenia Gravis (MG) is a debilitating, complement-mediated neuromuscular disease in which patients suffer profound muscle weakness throughout the body, resulting in slurred speech, impaired swallowing and choking, double vision, upper and lower extremity weakness, disabling fatigue, shortness of breath due to respiratory muscle weakness and episodes of respiratory failure.
Hypophosphatasia (HPP)	HPP is an ultra-rare genetic and progressive metabolic disease in which patients experience devastating effects on multiple systems of the body, leading to debilitating or life-threatening complications. HPP is characterized by defective bone mineralization that can lead to deformity of bones and other skeletal abnormalities, as well as systemic complications such as profound muscle weakness, seizures, pain, and respiratory failure leading to premature death in infants.
Lysosomal Acid Lipase Deficiency (LAL Deficiency or LAL-D)	LAL-D is a serious, life-threatening ultra-rare disease associated with premature mortality and significant morbidity. LAL-D is a chronic disease in which genetic mutations result in decreased activity of the LAL enzyme that leads to marked accumulation of lipids in vital organs, blood vessels, and other tissues, resulting in progressive and systemic organ damage including hepatic fibrosis, cirrhosis, liver failure, accelerated atherosclerosis, cardiovascular disease, and other devastating consequences.
Relapsing Neuromyelitis Optica Spectrum Disorder (NMOSD)	Relapsing NMOSD is a severe and ultra-rare autoimmune disease of the central nervous system that primarily affects the optic nerves and the spinal cord. Each relapse of the 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 in these patients.
Wilson Disease	Wilson disease is a rare disorder that can lead to severe liver disease, including cirrhosis and acute liver failure, as well as debilitating neurological morbidities such as impaired movement, gait, speech, swallowing, and psychiatric disorders.
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).

Marketed Products

Our marketed products consist of the following:

(amounts in millions, except per share amounts)

Product	Therapeutic Area	Approved Indication
ULTOMIRIS® (ravulizumab-cwvz) injection for intravenous use	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH) Atypical Hemolytic Uremic Syndrome (aHUS)
SOLIRIS® (eculizumab) Injection for Intravenous Use	Hematology Hematology/Nephrology Neurology Neurology	Paroxysmal Nocturnal Hemoglobinuria (PNH) Atypical Hemolytic Uremic Syndrome (aHUS) Generalized Myasthenia Gravis (gMG) 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)

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 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 the Ministry of Health, Labour and Welfare (MHLW) in Japan in June 2019. ULTOMIRIS was also 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 August 2019, the European Medicines Agency accepted a Type 2 variation application for the use of ULTOMIRIS as a potential treatment for patients with aHUS.

In September 2019, Alexion submitted an application to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for use of ULTOMIRIS as a potential treatment for patients with aHUS.

In October 2019, the U.S. FDA approved the use of ULTOMIRIS as a treatment for adult and pediatric (one month of age or older) patients with aHUS in order to inhibit complement-mediated thrombotic microangiopathy (TMA).

SOLIRIS (eculizumab)

SOLIRIS is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation associated with chronic disorders in several therapeutic areas, including hematology, nephrology and neurology. SOLIRIS is a humanized monoclonal antibody that effectively blocks terminal complement activity at the doses currently prescribed.

SOLIRIS is approved for the treatment of PNH in adults and for the treatment of pediatric and adult patients with aHUS in the U.S., Europe, Japan and in several other countries. We are sponsoring a multinational registry to gather information regarding the natural history of patients with PNH and aHUS and the longer term outcomes during SOLIRIS treatment.

In 2017, the U.S. FDA and EC approved SOLIRIS for the treatment of refractory gMG in adults who are anti-acetylcholine receptor (AChR) antibody-positive. Additionally, in 2017 the Ministry of Health, Labour and Welfare (MHLW) in Japan approved SOLIRIS as a treatment for patients with gMG who are AChR antibody-positive and whose symptoms are difficult to control with high-dose intravenous immunoglobulin therapy or plasmapheresis (PLEX).

In June 2019, SOLIRIS became the first U.S. FDA-approved treatment option for adult patients with Neuromyelitis Optica Spectrum Disorder (NMOSD) who are anti-aquaporin-4 (AQP4) auto antibody positive. In August 2019, the European Commission approved SOLIRIS as the first treatment in Europe for NMOSD in adults who are AQP4 antibody-positive with a relapsing course of the disease. Alexion submitted an application for SOLIRIS as a treatment for patients with NMOSD to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) in March 2019.

STRENSIQ (asfotase alfa)

STRENSIQ, a targeted enzyme replacement therapy, is the first and only approved therapy for patients with HPP and is designed to directly address underlying causes of HPP by aiming to restore the genetically defective metabolic process, thereby preventing or reversing the severe and potentially life-threatening complications in patients with HPP. STRENSIQ is approved in the U.S. for patients with perinatal-, infantile- and juvenile-onset HPP, Europe for the treatment of patients with pediatric-onset HPP, and Japan for the treatment of patients with HPP. We are sponsoring a multinational registry to gather information regarding the natural history of patients with HPP and the longer-term outcomes during STRENSIQ treatment.

KANUMA (sebelipase alfa)

KANUMA, a recombinant form of the human LAL enzyme, is the only enzyme-replacement therapy that is approved for the treatment for patients with LAL-D. KANUMA is approved in the U.S. for the treatment of patients with LAL-D, Europe for long-term enzyme replacement therapy in patients with LAL-D, and Japan for the treatment of patients with LAL-D. We are sponsoring a multinational registry to gather information regarding the natural history of patients with LAL-D and the longer-term outcomes during KANUMA treatment.

(amounts in millions, except per share amounts)

Clinical Development Programs

Our ongoing clinical development programs include the following:

Product	Development Area	Indication	Phase I	Phase II	Phase III	Filed
ULTOMIRIS (ALXN1210/ravulizumab-cwvz) (Intravenous)	Neurology	gMG			l	
ULTOMIRIS (ALXN1210/ravulizumab-cwvz) (Subcutaneous)	Hematology/Nephrology	PNH/aHUS			l	
ALXN1810 (Subcutaneous)	Next Generation Subcutaneous Complement Inhibitor		l			
ALXN1720 (Subcutaneous)	Next Generation Subcutaneous Complement Inhibitor		l			
ALXN1840 (WTX101)	Metabolic Disorders	Wilson disease			l	
ABY-039	FcRn		l			

In addition to our ongoing development programs, we hold a minority interest and option to acquire Caelum Biosciences (Caelum), a biotechnology company that is developing CAEL101 for light chain (AL) amyloidosis. CAEL-101 is a first-in-class 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 Phase 1a/1b study for CAEL-101 has been completed. A pivotal Phase 2/3 study investigating CAEL-101 as an add-on to current standard-of-care therapy is planned to begin in the first half of 2020.

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, we 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 thrombotic microangiopathy (TMA) response. A second Phase III, single arm, multicenter study to evaluate the safety, efficacy, pharmacokinetics (PK), and pharmacodynamics (PD) of ALXN1210 administered by IV infusion every 8 weeks in inhibitor-naïve pediatric patients (including adolescents) with aHUS is ongoing.

In August 2019, the European Medicines Agency accepted a Type 2 variation application for the use of ULTOMIRIS as a potential treatment for patients with aHUS. In September 2019, Alexion submitted an application to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for use of ULTOMIRIS as a potential treatment for patients with aHUS. In October 2019, the U.S. FDA approved ULTOMIRIS for the treatment of patients with aHUS in order to inhibit complement-mediated thrombotic microangiopathy (TMA).

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.

In addition to aHUS and gMG, Alexion plans to initiate: (i) a Phase III study of ALXN1210 in NMOSD; (ii) a Phase II/III study for ALXN1210 in Amyotrophic Lateral Sclerosis (ALS); (iii) an exploratory biomarker study for ALXN1210 in Primary Progressive Multiple Sclerosis (PPMS); and (iv) a Phase III study in hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA).

Subcutaneous (SC) Delivery

In March 2019, Alexion initiated a single, PK-based Phase III study of ALXN1210 delivered subcutaneously once per week to PNH patients to support regulatory approval submissions in both PNH and aHUS.

ALXN1810 Subcutaneous (SC) Delivery

ALXN1810 combines ALXN1210 with recombinant human hyaluronidase enzyme (rHuPH20) from Halozyme Therapeutics, Inc. to potentially further extend the dosing interval for ALXN1210 SC from once per week to once every two weeks or more. Alexion completed a SC healthy volunteer study with ALXN1810 in December 2018. Strategic planning for the best development path for ALXN1810 is ongoing.

ALXN1720 Subcutaneous (SC) Delivery

ALXN1720 is a novel humanized minibody antibody that binds selectively and with high affinity to human complement component 5 (C5). ALXN1720 is designed for subcutaneous (SC) 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 safety and tolerability.

ALXN1840 (WTX101)

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

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

ALXN1830 (SYNT001)

ALXN1830 (SYNT001) is a humanized monoclonal antibody that is designed to inhibit the interaction of the neonatal Fc receptor (FcRn) with IgG and IgG immune complexes and has the potential to improve treatment in a number of rare IgG-mediated diseases. Alexion plans to initiate Phase II trials in WAIHA and gMG. In addition, Alexion plans to initiate a Phase 1 study of a subcutaneous formulation of ALXN1830 in healthy volunteers.

ABY-039

In March 2019, we entered into an agreement with 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 FcRn. Following receipt of applicable antitrust approval, the transaction closed in April 2019. Pursuant to the agreement, Alexion is leading the clinical development and commercial activities for ABY-039 in rare IgG-mediated autoimmune diseases. A Phase I study of single ascending doses and multiple ascending doses is ongoing.

AG10

In September 2019, we entered into an agreement with 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 evaluating AG10 in a Phase III study in the United States and Europe for ATTR cardiomyopathy and plans to begin a Phase III study in ATTR polyneuropathy in the second half of 2019. Alexion plans to expand the AG10 program into Japan.

Manufacturing

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

We have various agreements with Lonza through 2030, with remaining total non-cancellable commitments of approximately $1,062.2. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangements. Under an existing arrangement, we pay Lonza a royalty on sales of SOLIRIS that was manufactured at the Alexion Rhode Island Manufacturing Facility (ARIMF) prior to the sale of the facility in 2018. We also pay Lonza a royalty on the sales of ULTOMIRIS and a payment with respect to sales of SOLIRIS manufactured at Lonza facilities. Lonza is in the process of qualifying a new manufacturing facility dedicated to Alexion products and commitments entered into under this arrangement are included in the non-cancellable commitments amount noted above.

In addition, we have non-cancellable commitments of approximately $63.2 through 2020 with other third party manufacturers.

In April 2014, we purchased a fill/finish facility in Athlone, Ireland, which has been refurbished to become our first company-owned fill/finish facility. We have also constructed a new biologics manufacturing facility at this site and we anticipate this facility will receive regulatory approval in 2020.

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

Critical Accounting Policies and the Use of Estimates

The significant accounting policies and basis of preparation of our consolidated financial statements are described in Note 1, *Business Overview and Summary of Significant Accounting Policies* of the Consolidated Financial Statements included in our Form 10-K for the year ended December 31, 2018. Under accounting principles generally accepted in the U.S., we are required to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingent assets and liabilities in our financial statements. 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 could differ materially from those estimates.

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

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

For a complete discussion of these critical accounting policies, refer to “Critical Accounting Policies and Use of Estimates” within “Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations” included within our Form 10-K for the year ended December 31, 2018.

New Accounting Pronouncements

For information on new accounting pronouncements adopted in the current period and recently issued standards, see Note 2, *“Basis of Presentation and Principles”* to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

(amounts in millions, except per share amounts)

Results of Operations

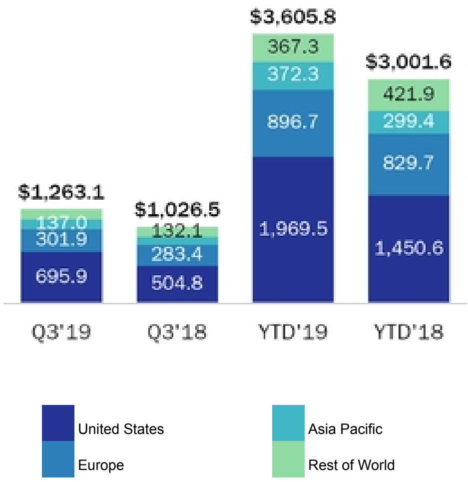
Net Product Sales

Net product sales by significant geographic region for the three and nine months ended September 30, 2019 and 2018 are as follows:

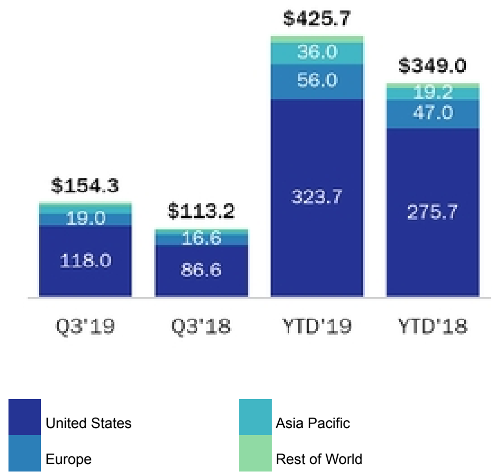
	Three months ended September 30,		%	Nine months ended September 30,		%
	2019	2018	Change	2019	2018	Change
SOLIRIS						
United States	$ 496.8	$ 404.5	22.8 %	$ 1,456.8	$ 1,136.3	28.2 %
Europe	255.5	262.1	(2.5)%	800.2	766.3	4.4 %
Asia Pacific	118.0	98.2	20.2 %	329.2	277.3	18.7 %
Rest of World	120.2	123.2	(2.4)%	347.1	406.4	(14.6)%
Total	$ 990.5	$ 888.0	11.5 %	$ 2,933.3	$ 2,586.3	13.4 %
ULTOMIRIS						
United States	$ 65.1	$ —	**	$ 143.9	$ —	**
Europe	21.1	—	**	21.1	—	**
Asia Pacific	3.7	—	**	3.7	—	**
Rest of World	—	—	**	—	—	**
Total	$ 89.9	$ —	**	$ 168.7	$ —	**
STRENSIQ						
United States	$ 118.0	$ 86.6	36.3 %	$ 323.7	$ 275.7	17.4 %
Europe	19.0	16.6	14.5 %	56.0	47.0	19.1 %
Asia Pacific	14.0	7.2	94.4 %	36.0	19.2	87.5 %
Rest of World	3.3	2.8	17.9 %	10.0	7.1	40.8 %
Total	$ 154.3	$ 113.2	36.3 %	$ 425.7	$ 349.0	22.0 %
KANUMA						
United States	$ 16.0	$ 13.7	16.8 %	$ 45.1	$ 38.6	16.8 %
Europe	6.3	4.7	34.0 %	19.4	16.4	18.3 %
Asia Pacific	1.3	0.8	62.5 %	3.4	2.9	17.2 %
Rest of World	4.8	6.1	(21.3)%	10.2	8.4	21.4 %
Total	$ 28.4	$ 25.3	12.3 %	$ 78.1	$ 66.3	17.8 %
Total Net Product Sales	$ 1,263.1	$ 1,026.5	23.0 %	$ 3,605.8	$ 3,001.6	20.1 %

** Percentages not meaningful

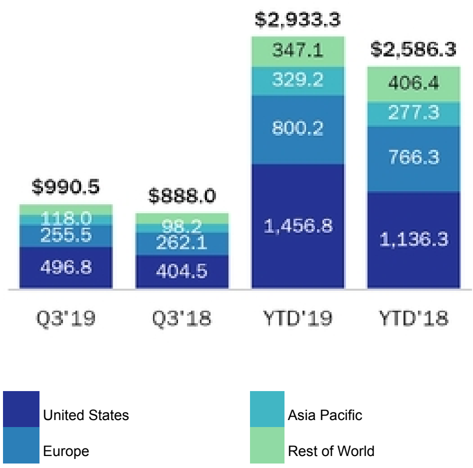
Net Product Sales



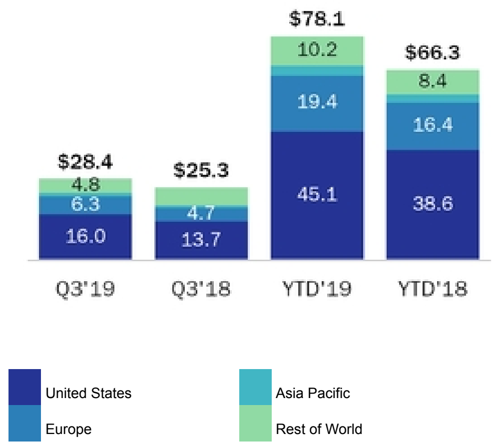
STRENSIQ net product sales



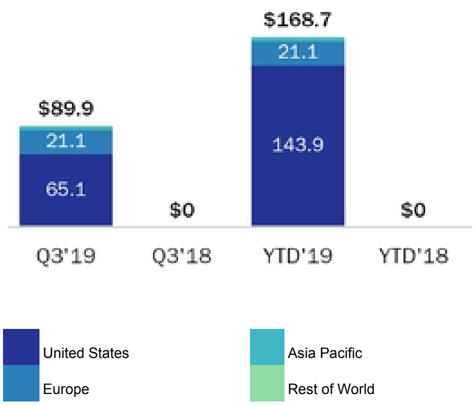
SOLIRIS net product sales



KANUMA net product sales

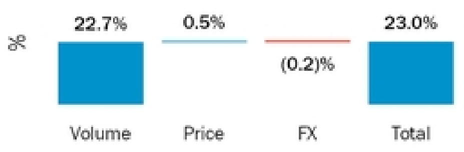


ULTOMIRIS net product sales



The components of the increase in net product sales are as follows:

Three Months Ended September 30, 2019 compared to 2018:



Nine Months Ended September 30, 2019 compared to 2018:

The increase in net product sales for the three and nine months ended September 30, 2019, as compared to the same periods in 2018, was primarily due to an increase in unit volumes of 22.7% in each period. This increase in unit volumes is primarily due to increased global demand for SOLIRIS therapy including sales to patients with gMG as well as ULTOMIRIS volumes due to the loading doses required in a patient's first year on therapy. Partially offsetting this increase is the conversion of PNH patients from SOLIRIS to ULTOMIRIS. While ULTOMIRIS contributed to the first nine months of 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 continuing efforts to identify and reach more patients with HPP and LAL-D globally.

The increase in net product sales for the nine months ended September 30, 2019, as compared to the same period in 2018 was partially offset by $24.3, or 0.9%, as a result of a judicial order issued in the second quarter 2019 related to SOLIRIS pricing in Canada (See Note 18). The decision led to a reduction of revenue in the second quarter of 2019 and will result in further reductions in all subsequent quarters until the appeals process has concluded. The reduction of revenue recorded for the nine months ended September 30, 2019 includes the impact for the period from September 2017 to September 2019.

As a result of strategic pricing decisions implemented for STRENSIQ in the U.S. that limits annual treatment costs given weight based dosing, we expect price to be unfavorably impacted for STRENSIQ in the U.S. in future periods as compared to prior periods.

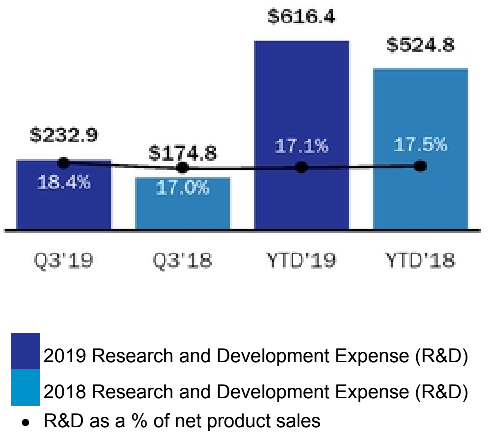
Cost of Sales

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

The following table summarizes cost of sales for the three and nine months ended September 30, 2019 and 2018:

The decrease in cost of sales as a percentage of net product sales for the three and nine months ended September 30, 2019, as compared to the same periods in 2018, was primarily due to decreases in royalty expenses due to a contract expiration that occurred during the fourth quarter 2018. Additionally, the nine months ended 2018 included asset related charges associated with the closure of the ARIMF facility as part of our 2017 restructuring activities (see Note 19).

Research and Development Expense

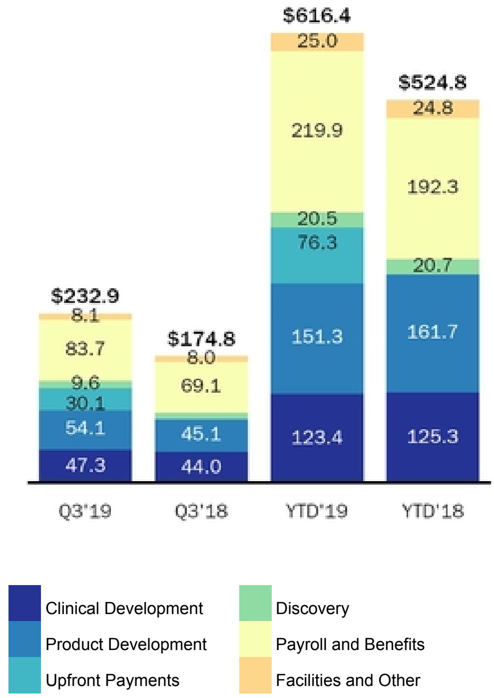


Our research and development expense includes personnel, facility and direct costs associated with the research and development (R&D) of our product candidates, as well as product development costs.

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 arrangements and R&D-related asset purchase agreements we have entered into with third parties. Clinical development costs are comprised of costs to conduct and manage clinical trials related to eculizumab, ALXN1210 and other product candidates. Product development costs are those incurred in performing duties related to manufacturing development and regulatory functions, including manufacturing of material for clinical and research activities and other administrative costs incurred during product development. Discovery research costs are incurred in conducting laboratory studies and performing preclinical research for other uses of our products and other product candidates. Upfront payments include upfront payments related to strategic licensing arrangements 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. Clinical development costs have been accumulated and allocated to each of our programs, while product development and discovery research costs have not been allocated.

Other R&D expenses consist of costs to compensate personnel, to maintain our facilities and equipment, and other occupancy costs associated with our research and development efforts. These costs relate to efforts on our clinical and preclinical products, our product development and our discovery research efforts. These costs have not been allocated directly to each program.

The following graph provides information regarding research and development expenses for the three and nine months ended September 30, 2019 and 2018:



For the three months ended September 30, 2019, the increase in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase of $30.1 in upfront payments relating to the license payment made during the third quarter 2019 in connection with the arrangement we entered into with Eidos. No upfront payments related to licensing arrangements were made for the three months ended September 30, 2018.
- Increase of $14.6 in payroll and benefits primarily related to headcount increases.
- Increase of $9.0 in product development expenses primarily related to ALXN 1830 (SYNT001), offset in part by a decrease in costs associated with milestone expenses related to our licensing agreements.

For the nine months ended September 30, 2019, the increase in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase of $76.3 in upfront payments relating to the license payments made in connection with the arrangements we entered into with Zealand, Affibody and Eidos during the nine months ended September 30, 2019. No upfront payments related to licensing arrangements were made for the nine months ended 2018.

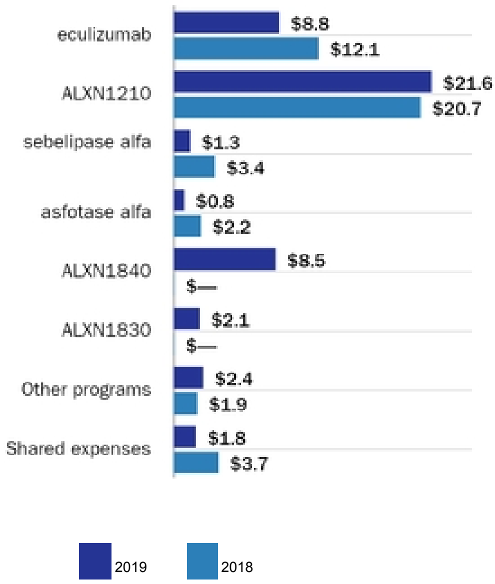
- Increase of $27.6 in payroll and benefits primarily related to headcount increases.

Partially offset by the following:

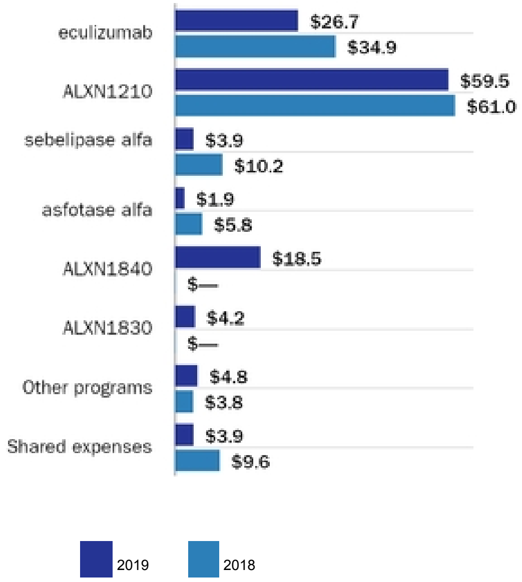
- Decrease of $10.4 in product development expenses primarily related to a decrease in costs associated with milestone expenses.

The following graph summarizes R&D expenses related to our clinical development programs. Please refer to "Clinical Development Programs" above for a description of certain of these programs:

Three months ended September, 2019 and 2018

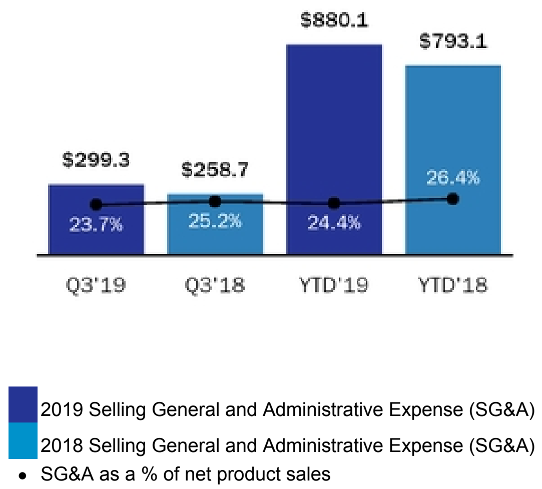


Nine months ended September, 2019 and 2018



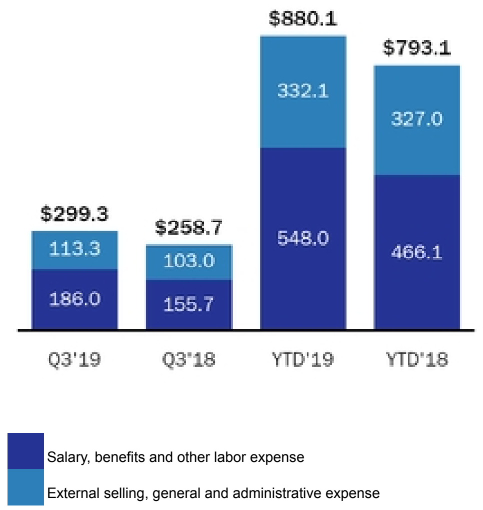
The successful development of our drug candidates is uncertain and subject to a number of risks. We cannot guarantee that results of clinical trials will be favorable or sufficient to support regulatory approvals for any of our product development programs. We could decide to abandon development or be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

Selling, General and Administrative Expense



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

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



For the three months ended September 30, 2019, the increase of $40.6 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase in salary, benefits and other labor expenses of $30.3. 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.
- Increase in external selling, general and administrative expenses of $10.3. The increase was primarily related to an increase in professional services, offset in part by a decrease in asset related charges recorded in the same period in 2018 associated with restructuring programs.

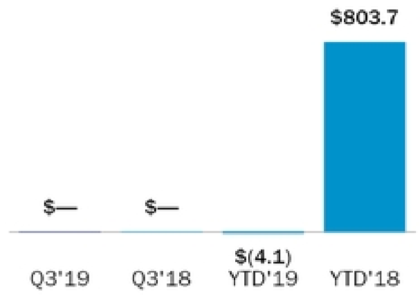
For the nine months ended September 30, 2019, the increase of $87.0 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase in salary, benefits and other labor expenses of $81.9. 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.

Acquired In-Process Research and Development

The nine months ended September 30, 2019 includes 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 nine months ended September 30, 2018 we recorded IPR&D expense of $803.7 related to the Wilson Therapeutics acquisition completed in the second quarter of 2018. The IPR&D asset associated with the Wilson Therapeutics acquisition has not reached technological feasibility and had no alternative future use as of the acquisition date and was therefore expensed during the second quarter 2018.



Amortization of Purchase Intangible Assets

For the three months ended September 30, 2019 and 2018, we recorded $75.6 and $80.0, respectively, and $235.7 and $240.1 for the nine months ended September 30, 2019 and 2018, respectively, in amortization expense related to purchased intangible assets. Amortization expense is primarily associated with intangible assets related to STRENSIQ and KANUMA, for which we received regulatory approval in the third quarter 2015.

During the third quarter 2019, the U.S. patent term extension to a composition of matter patent for STRENSIQ was granted, which resulted in a change in the estimated useful life of the STRENSIQ intangible asset and will result in lower amortization expense in future periods.

Change in Fair Value of Contingent Consideration

For the three and nine months ended September 30, 2019, the expense resulting from the change in fair value of contingent consideration associated with our prior business combinations was $29.8 and $7.2, respectively, as compared to $53.5 and $110.9 for the three and nine months ended September 30, 2018. The change in the fair value of contingent consideration will fluctuate based on the timing of recognition of changes in the probability of achieving and the expected timing of milestone payments in connection with previous acquisitions.

Changes in the fair value of contingent consideration expense for the three and nine months ended September 30, 2019 include the impact of changes in the expected timing of achieving contingent milestones, in addition to the interest component related to the passage of time.

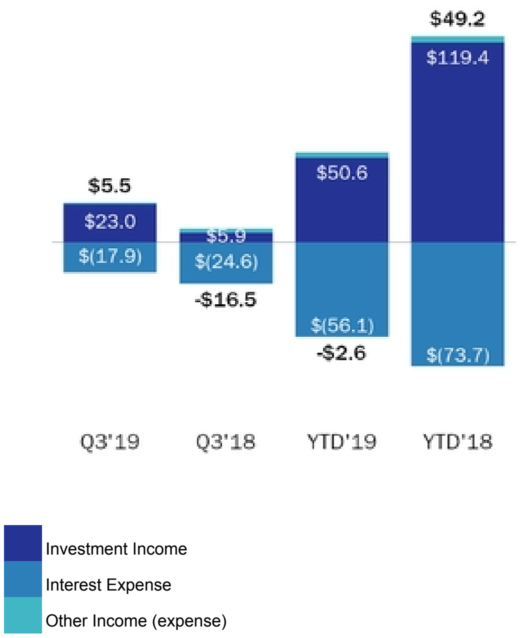
In September 2018, we amended the terms of certain contingent milestone payments due under our prior merger agreement with Enobia Pharma Corp., dated December 28, 2011. The amendment removed our obligations with respect to a regulatory milestone and redistributed the contingent payment associated with this milestone to various sales milestones. As a result of this amendment and the probability of achieving the various sales milestones, our contingent consideration liability increased by $48.7 in the third quarter 2018. The remaining change in the fair value of contingent consideration for the nine months ended September 30, 2018 was primarily due to increases in the likelihood and anticipated timing of payments for contingent consideration.

Restructuring Expenses

For the three months ended September 30, 2019 and 2018, we recorded $0.3 and $10.3, respectively, and $11.9 and $26.4 for the nine months ended September 30, 2019 and 2018, respectively, in restructuring expenses. The charges recorded during the three and nine months ended September 30, 2019 relate to restructuring activities initiated in the first quarter 2019 to re-align our commercial organization. The charges recorded during the three and nine months ended September 30, 2018 relate to a company-wide restructuring initiated in 2017 (see Note 19).

Other Income and (Expense)

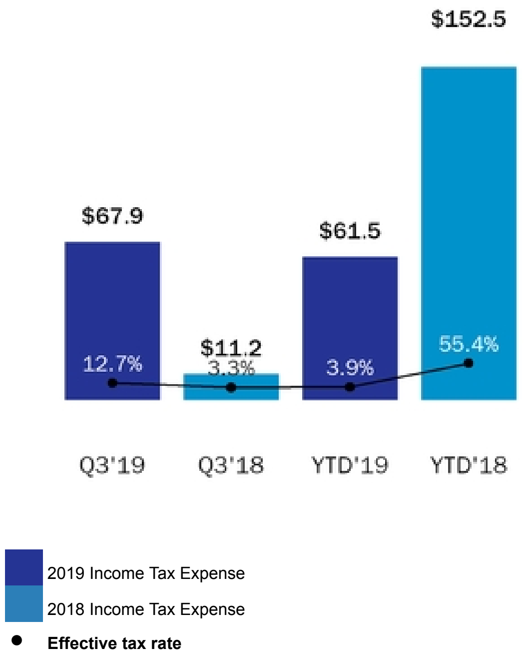
The following table provides information regarding other income and expense:



For the three and nine months ended September 30, 2019, we recognized investment income of $23.0 and $50.6, respectively, primarily related to the recognition of unrealized gains of $12.0 and $20.6, respectively, on our strategic equity investments recorded at fair value, with the largest component related to our Moderna Therapeutics Inc. equity investment. For the three and nine months ended September 30, 2018, we recognized investment income of $5.9 and $119.4, respectively. The nine months ended September 30, 2018 included the recognition of an unrealized gain of $100.8 on our investment in Moderna Therapeutics, Inc. following the completion of a new round of equity financing in the first quarter 2018.

For the three months ended September 30, 2019 and 2018, we recorded $17.9 and $24.6, respectively, and $56.1 and $73.7 for the nine months ended September 30, 2019 and 2018, respectively, in interest expense. The decrease in interest expense is driven by the derecognition of certain previously recorded build-to-suite arrangements in the first quarter 2019 due to the adoption of the new lease accounting standard.

Income Taxes



During the three and nine months ended September 30, 2019, we recorded income tax expense of $67.9 and $61.5 and an effective tax rate of 12.7% and 3.9%, respectively, compared to income tax expense of $11.2 and $152.5 and an effective tax rate of 3.3% and 55.4%, respectively, for three and nine months ended September 30, 2018.

Income tax expense is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. During the first quarter 2019, in connection with the future integration of intellectual property of Wilson Therapeutics into the Alexion corporate structure, we recognized certain one-time tax benefits. 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. These deferred tax benefits decreased the effective tax rate for the nine months ended September 30, 2019 by approximately 8.0%. Future changes to our intellectual property integration planning could materially impact our effective tax rate in subsequent periods.

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.

During the third quarter 2019, we completed a comprehensive analysis of our current and prior year estimates related to our foreign-derived intangible income ("FDII") based on additional guidance provided in the proposed regulations issued by the U.S. Treasury

Department in 2019. The analysis resulted in income tax benefits of approximately $29.9, including $17.0 million related to prior year estimated tax benefits, which were recorded as a change in estimate in income tax expense in our consolidated statements of operations during the three and nine months ended September 30, 2019. These tax benefits decreased the effective tax rate for the three and nine months ended September 30, 2019 by approximately 5.6% and 1.9%, respectively.

The income tax expense for the three months ended September 30, 2018 includes a U.S. tax reform measurement period adjustment to deferred taxes of $(53.1). This deferred tax benefit decreased the effective tax rate by approximately 15.5%. The income tax expense for the nine months ended September 30, 2018 includes an increase in the effective tax rate of approximately 41.3% attributable to the acquisition of Wilson Therapeutics. Absent successful clinical results and regulatory approval, there is no alternative future use of the WTX101 asset acquired. Accordingly, the value of the asset of $803.7 was expensed as in-process research and development costs during the nine month period, for which no tax benefit has been recognized. Also included in the nine months ended September 30, 2018 is a U.S. tax reform measurement period adjustment to deferred taxes of $(14.7). This deferred tax benefit decreased the effective tax rate by approximately 1.4%.

We continue to benefit from a reduced tax rate as a result of our centralized global supply chain and technical operations in Ireland.

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.

(amounts in millions, except per share amounts)

Financial Condition, Liquidity and Capital Resources

The following table summarizes the components of our financial condition as of September 30, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018	$ Change
Cash and cash equivalents	$ 2,171.3	$ 1,365.5	$ 805.8
Marketable securities	$ 44.4	198.3	(153.9)
Long-term debt (includes current portion & revolving credit facility)	$ 2,547.1	2,862.5	(315.4)
Current assets	$ 4,341.2	3,385.0	956.2
Current liabilities	$ 1,091.2	1,174.0	(82.8)
Working capital	$ 3,250.0	2,211.0	1,039.0

The aggregate increase in cash and cash equivalents and marketable securities of $651.9 at September 30, 2019 as compared to December 31, 2018 was primarily attributable to cash generated from operations and net proceeds from the issuance of common stock under share-based compensation arrangements. Partially offsetting these increases was cash utilized to repurchase shares of common stock, payments on our revolving credit facility and term loan facility, upfront payments related to agreements with Caelum, Zealand, Affibody and Eidos, payment of a sales-based milestone to Enobia Pharma Corp. and purchases of property, plant, and equipment.

Excluding the impact of any future acquisitions, we expect our annual operating expenses to decrease as a percentage of sales in 2019 as compared to 2018. We also expect reduced capital investment in 2019 as compared to 2018. We anticipate that cash generated from operations and our existing available cash, cash equivalents and marketable securities should provide us adequate resources to fund our operations as currently planned for at least the next twelve months.

We have financed our operations and capital expenditures primarily through positive cash flows from operations. We expect to continue to be able to fund our operations, including principal and interest payments on our Amended and Restated Credit Agreement and contingent payments 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) 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 September 30, 2019, four customers accounted for 65.7% of the accounts receivable balance, with these individual customers accounting for 10.6% to 19.8% of the accounts receivable balance. At December 31, 2018, three customers accounted for 48.7% of the accounts receivable balance, with these individual customers accounting for 14.0% to 19.1% of the accounts receivable balance.

For the three months ended September 30, 2019, three customers accounted for 46.6% of our net product sales with these individual customers accounting for 14.2% to 16.7%. For the nine months ended September 30, 2019 three customers accounted for 45.7% of our net product sales with these individual customers accounting for 13.8% to 16.9% of our net product sales. For the three months ended September 30, 2018, three customers accounted for 41.1% of our net product sales with these individual customers accounting for 11.3% to 16.7% of our net product sales. For the nine months ended September 30, 2018, four customers accounted for 49.9% of our net product sales with these individual customers accounting for 10.0% to 16.3% of our 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. Substantially all of our accounts receivable are due from wholesale distributors, public hospitals and other government entities. We monitor the financial performance of our customers so that we can appropriately respond to changes in their credit worthiness. We operate in certain jurisdictions where weakness in economic conditions can result in extended collection periods. We continue to monitor these conditions and assess their possible impact on our business. To date, we have not experienced any significant losses with respect to collection of our accounts receivable.

We manage our foreign currency transaction risk and interest rate risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. As of September 30, 2019, we had foreign exchange forward contracts with notional amounts totaling $2,330.7. These outstanding foreign exchange forward contracts had a net fair value of $29.0, of which $46.9 is included in other current assets and noncurrent assets and $17.9 is included in other current liabilities and noncurrent liabilities. As of September 30, 2019, we had interest rate swap contracts with notional amounts totaling $3,581.3. These outstanding interest rate swap contracts had a net fair value liability of $69.7 of which $2.4 is included in other current assets and $72.1 is included in other current liabilities and noncurrent liabilities. The counterparties to these contracts are large domestic and multinational commercial banks, and we believe the risk of nonperformance is not material.

As of September 30, 2019, 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, commercial paper, municipal bonds, U.S. and foreign government-related debt, corporate debt securities, certificates of deposit, equity securities subject to holding period restrictions and derivative contracts. Our Level 2 liabilities consist also of derivative contracts. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. Our Level 3 liabilities consist of contingent consideration related to business acquisitions and derivative liabilities associated with other contingent payments.

Business Combinations and Contingent Consideration Obligations

At September 30, 2019, the purchase agreements for our business combinations include contingent payments totaling up to $602.0 that will become payable if and when certain development and commercial milestones are achieved. Of these milestone amounts, $367.0 and $235.0 of the contingent payments relate to development and commercial milestones, respectively. We do not expect these amounts to have a significant impact on our liquidity in the near-term, and, during the next 12 months, we do not expect to make milestone payments associated with our prior business combinations.

As additional future payments become probable, we will evaluate methods of funding payments, which could be made from available cash and marketable securities, cash generated from operations or proceeds from 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 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 could be required to pay up to an additional $30.0 in contingent milestone-dependent fees. The agreement also provides for potential 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 that provides us with exclusive worldwide licenses, as well as development and commercial rights for preclinical peptide therapies subcutaneously delivered for up to four complement pathway targets. Zealand will lead the joint discovery and research efforts through the preclinical stage, and Alexion will lead development efforts beginning with investigational new drug filing and Phase 1 studies. In addition to the agreement, we made an equity investment in Zealand. 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. 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. 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 March 2019, we entered into an agreement with Affibody that provides us with 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) and is currently in Phase 1 development. The agreement with Affibody was subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act and, following receipt of such approval, closed in April 2019. Pursuant to the agreement, Alexion will lead the clinical development and commercial activities for ABY-039 in rare Immunoglobulin G (IgG)-mediated autoimmune diseases. Affibody has the option to co-promote ABY-039 in the U.S. and will lead clinical development of ABY-039 in an undisclosed indication. Under the terms of the agreement, we made an upfront payment of $25.0 for the exclusive license to ABY-039. As of September 30, 2019, we could also be required to pay up to $625.0 for amounts due upon achievement of specific development, regulatory, and commercial milestones, as well as royalties on commercial sales.

In September 2019, we entered into an agreement with Eidos that provides us with an exclusive license to develop and commercialize AG10 in Japan. AG10 is an orally administered small molecule designed to bind and stabilize TTR in the blood. In addition, we made an equity investment in Eidos. Under the terms of the agreement, we made an upfront payment of $50.0 for an exclusive license to AG10 in Japan and the equity investment. As of September 30, 2019, 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) under which Alexion will receive an exclusive option to co-develop subcutaneous elamipretide in the U.S. as well as exclusive rights to develop and commercialize subcutaneous elamipretide outside the U.S. Under the terms of the agreement, we made an upfront payment of $30.0 for the option and an equity investment in Stealth. The agreement also provides for additional payments, in the event Alexion exercises the option, of up to $430.0, which includes an upfront option exercise payment, an additional equity investment and potential regulatory and commercial milestone payments, as well as royalties on commercial sales outside the U.S.

In connection with our prior acquisition of Syntimmune, a clinical-stage biotechnology company developing an antibody therapy targeting the neonatal Fc receptor (FcRn), we could be required to pay up to $800.0 upon the achievement of specified development, regulatory and commercial milestones. In addition, as of September 30, 2019, we have other license and collaboration agreements under which we may be required to pay up to an additional $834.6 for currently licensed targets, if certain development, regulatory and commercial milestones are met. 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 and licensing agreements to have a significant impact on our liquidity in the near-term. During the next 12 months, we may make milestone payments related to these arrangements of approximately $225.1.

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 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.

At September 30, 2019, we have $263.5 of total financing and operating lease liabilities recorded on our condensed consolidated balance sheets. The total undiscounted lease commitments as of September 30, 2019 were $328.3, of which, $33.4 is payable during the next 12 months. Refer to Note 17 *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, Alexion 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 $2,612.5 term loan facility and a $1,000.0 revolving credit facility. Borrowings can be used for working capital requirements, acquisitions and other general corporate purposes. Beginning with the quarter ending June 30, 2019, we are required to make payments of 5.00% of the original principal amount of the term loan facility annually, payable in equal quarterly installments.

As of September 30, 2019, we had $2,547.1 outstanding on the term loan. As of September 30, 2019, we had open letters of credit of $1.0 that offset our availability in the revolving facility. In January 2019 we paid the outstanding balance on the revolving credit facility of $250.0 in full and we had no outstanding borrowings under the revolving credit facility as of September 30, 2019.

Manufacturing Obligations

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

We have various agreements with Lonza, with remaining total non-cancellable commitments of approximately $1,062.2 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 also pay Lonza a royalty on sales of SOLIRIS that was manufactured at Alexion Rhode Island Manufacturing Facility (ARIMF) prior to its sale and a payment with respect to sales of SOLIRIS manufactured at Lonza facilities. We also pay Lonza a royalty on the sales of ULTOMIRIS.

(amounts in millions, except per share amounts)

In addition to Lonza, we have non-cancellable commitments of approximately $63.2 through 2020 with other third party manufacturers.

Taxes

We have recorded tax on the undistributed earnings of our controlled foreign corporation (CFC) subsidiaries. To the extent CFC earnings may not be repatriated to the U.S. as a dividend distribution due to limitations imposed by law, we have not recorded the related potential withholding, foreign local, and U.S. state income taxes.

Common Stock Repurchase Program

In November 2012, our Board of Directors authorized a share repurchase program. In February 2017, our Board of Directors increased the amount that we are authorized to expend on future repurchases to $1,000.0 under the repurchase program, which superseded all prior repurchase programs. The repurchase program does not have an expiration date and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at our discretion. Under the program, we repurchased 3.1 shares of our common stock at a cost of $334.6, during the three months ended September 30, 2019. The Company did not repurchase any shares during the three months ended September 30, 2018. During the nine months ended September 30, 2019 and September 30, 2018, we repurchased 3.5 and 0.7 shares of our common stock at a cost of $383.5 and $85.0, respectively. Subsequent to September 30, 2019, we repurchased 0.1 shares of our common stock under our repurchase program at a cost of $7.0. As of October 21, 2019, there is a total of $60.9 remaining for repurchases under the repurchase program.

On October 22, 2019, the Board of Directors approved a new share repurchase authorization of up to $1,000.0. The repurchase program does not have an expiration date and we are not obligated to acquire a particular number of shares of common stock. The repurchase program may be discontinued at any time at our discretion.

Cash Flows

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

	Nine months ended September 30,		$
	2019	2018	Change
Net cash provided by operating activities	$ 1,567.8	$ 342.6	$ 1,225.2
Net cash provided by (used in) investing activities	(46.6)	418.3	(464.9)
Net cash used in financing activities	(679.4)	(105.5)	(573.9)
Effect of exchange rate changes on cash	(6.1)	(10.6)	4.5
Net change in cash and cash equivalents	$ 835.7	$ 644.8	$ 190.9

Operating Activities

Cash flows provided by operations for the nine months ended September 30, 2019 was $1,567.8 compared to $342.6 for the nine months ended September 30, 2018. The increase in cash was primarily due to the acquisition of Wilson Therapeutics in the second quarter 2018. This increase was offset by upfront payments made in connection with agreements entered into with Zealand, Affibody and Eidos, payment of a sales-based milestone to Enobia Pharma Corp. and increases due to the timing of cash receipts and other payments during the nine months ended September 30, 2019 as compared to the same period in the prior year.

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

Investing Activities

Cash flows provided by (used in) investing activities for the nine months ended September 30, 2019 was $(46.6) compared to $418.3 for the nine months ended September 30, 2018. The increase in cash used in investing activities as compared to the prior year was primarily attributable to purchases and sales of available-for-sale debt securities, which resulted in a net cash inflow of $159.8 for the nine months ended September 30, 2019, compared to net cash inflow of $585.0 for the nine months ended September 30, 2018. Purchases of strategic equity investments for Zealand, Caelum and Eidos resulted in $63.7 in cash outflows during the nine months ended September 30, 2019 with no comparable activity in the prior year. Offsetting these impacts were decreases in purchases of property, plant and equipment during the nine months ended September 30, 2019 as compared to the same period in the prior year.

Financing Activities

Cash flows used in financing activities for the nine months ended September 30, 2019 was $(679.4) compared to $(105.5) for the nine months ended September 30, 2018. The increase in cash used for financing activities was primarily due to an increase in payments on our revolving credit facility and term loan facility of $315.4 and increased common stock repurchases of $298.5, as compared to the nine months ended September 30, 2018.

Contractual Obligations

Other than potential payments related to agreements with Caelum, Zealand, Affibody, Eidos, and Stealth there have been no significant changes to the disclosure of payments we have committed to make under our contractual obligations as summarized in our Annual Report on Form 10-K for the twelve months ended December 31, 2018, in the section titled “Management's Discussion and Analysis of Financial Condition and Results of Operations” under the caption “Contractual Obligations.”

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

(amounts in millions, except percentages)

Interest Rate Risk

As of September 30, 2019, we invested our cash in a variety of financial instruments, principally money market funds, corporate bonds, municipal bonds, commercial paper and government-related obligations. Most of our interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate. Our investment portfolio is comprised of marketable debt securities of highly rated financial institutions and investment-grade debt instruments, and we have guidelines to limit the term-to-maturity of our investments. Based on the type of securities we hold, we do not believe a change in interest rates would have a material impact on our financial statements. If interest rates were to increase or decrease by 1%, the fair value of our investment portfolio would increase (decrease) by approximately $0.5 and $(0.5), respectively.

On June 7, 2018, we entered into an Amended and Restated Credit Agreement (the Credit Agreement), with Bank of America N.A. as administrative agent. The Credit Agreement amended and restated our credit agreement dated as of June 22, 2015 (the Prior Agreement). Loans under the Credit Agreement bear interest at our option, at either the base rate or a Eurodollar rate, in each case plus an applicable margin. Under the Credit Agreement, the applicable margins on base rate loans range from 0.25% to 1.00% and the applicable margins on Eurodollar loans range from 1.25% to 2.00%, in each case based on our consolidated net leverage ratio (as calculated in accordance with the Credit Agreement).

Changes in interest rates related to the Credit Agreement could have a material effect on our financial statements.

To achieve a desired mix of floating and fixed interest rates on our term loan, we entered into a number of interest rate swap agreements that qualified for and are designated as cash flow hedges. As of September 30, 2019 we had cash flow hedges with aggregate amounts of approximately 73.9% of our current outstanding term loan covering periods over the next twelve months. If interest rates were to increase or decrease by 1%, interest expense over the next year would increase or decrease by $6.0, based on the unhedged portion of our outstanding term loan as of September 30, 2019.

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 42.6% and 43.2% of our net product sales were denominated in foreign currencies for the three and nine months ended September 30, 2019, respectively, and our revenues are also exposed to fluctuations in the foreign currency exchange rates over time. In certain foreign countries, we may sell in U.S. dollar, but our customers may be impacted adversely by fluctuations in foreign currency exchange rates which may also impact the timing and amount of our revenue.

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

We currently have a derivative program in place to achieve the following: (1) limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet, using contracts with durations of up to 8 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 September 30, 2019 and December 31, 2018, we held foreign exchange forward contracts with notional amounts totaling $2,330.7 and $2,523.0, respectively. As of September 30, 2019 and December 31, 2018, our outstanding foreign exchange forward contracts had a net fair value of $29.0 and $18.9, 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 as of September 30, 2019, 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 $122.8. The resulting loss on these forward contracts would be offset by the gain on the underlying transactions and therefore would have minimal impact on future anticipated earnings and cash flows. Similarly, adverse fluctuations in exchange rates that would decrease the fair value of our foreign exchange forward contracts that are not designated as hedge instruments would be offset by a positive impact of the underlying monetary assets and liabilities.

Credit Risk

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

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act), as of September 30, 2019. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2019, our disclosure controls and procedures were effective to provide reasonable assurance that information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure, and ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

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 September 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS.

For a discussion of legal matters as of September 30, 2019, see Note 18, *"Commitments and Contingencies," Contingent Liabilities*, within our notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

Item 1A. Risk Factors.

(amounts in millions, except percentages)

You should carefully consider the following risk factors before you decide to invest in Alexion securities and our business, because the risks described below may have a material impact on our business, operating results, financial condition, and cash flows. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of the following risks actually occurs, our business, financial condition and results of operations could be materially and adversely affected.

Risks Related to Revenue Concentration

We depend on the success of, and revenue from, SOLIRIS and if patients do not convert from SOLIRIS to ULTOMIRIS or ULTOMIRIS does not gain market acceptance, our future operating results may be adversely impacted.

Since 2007, our revenue has depended primarily on the sales of SOLIRIS. Unless we are able to develop or acquire new products and technologies, successfully commercialize ULTOMIRIS (and facilitate conversion from SOLIRIS to ULTOMIRIS for approved indications) as described below, and/or materially increase sales of STRENSIQ and KANUMA (two of our other currently approved products), we will remain dependent on sales of SOLIRIS as a source of our revenue.

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

While SOLIRIS has been studied for indications beyond PNH, aHUS, gMG and NMOSD (which are the current approved indications of SOLIRIS in the U.S.), there is no guarantee that we can obtain regulatory approval or achieve any commercial sales of SOLIRIS for other indications. Despite positive topline results from the Phase 3 PREVENT study of SOLIRIS in patients with anti-aquaporin-4 (AQP4) auto antibody-positive NMOSD and regulatory approval from the FDA in June 2019 and the European Commission in August 2019, we may not be able to obtain regulatory approval to sell SOLIRIS as a treatment for NMOSD in Japan or any other jurisdiction outside the U.S. or the European Union due to the failure to meet applicable regulatory requirements. Additionally, even if we obtain regulatory approval, physicians and patients may not accept SOLIRIS as a treatment for NMOSD or payers may not be willing to pay for or reimburse the costs of SOLIRIS as a therapy for NMOSD.

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

ULTOMIRIS has recently been approved for adult patients with PNH by the FDA, the Ministry of Health, Labour and Welfare (MHLW) and the European Medicines Agency (EMA) (and we may submit applications for approval of ULTOMIRIS for patients with PNH in additional jurisdictions). In addition, Ultomiris has recently been approved by the FDA for adult and pediatric patients (one month of age and older) patients with aHUS and we have submitted applications for approval of ULTOMIRIS for patients with aHUS in other countries.

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 PNH patients taking SOLIRIS and their physicians may decline to switch to ULTOMIRIS for many reasons including: reluctance to try a new therapy, lack of clinical evidence that ULTOMIRIS is superior to SOLIRIS, no (or limited) reimbursement by government or third-party payers (including as a result of SOLIRIS being available as an alternative therapy), or our inability to manufacture quantities necessary to meet demands.

If we achieve our goal of promptly facilitating the conversion of current PNH and aHUS patients from SOLIRIS to ULTOMIRIS, we anticipate that revenue from SOLIRIS, which accounted for approximately $3,563.0, or 86.3%, of our revenues in 2018, will decline as we move patients to ULTOMIRIS. We have established what we believe is a globally sustainable and durable pricing strategy for ULTOMIRIS that is intended to facilitate such 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% discount 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. (the only country for which we currently have ULTOMIRIS approval for this indication) at a discount to the cost of SOLIRIS for patients with aHUS in the U.S. of approximately 30% on an annual basis for an average adult patient on maintenance therapy (unlike PNH, the price in the first year of aHUS conversion to ULTOMIRIS represents an approximate discount of 20% to the cost of SOLIRIS).

In addition to the potential decrease in revenue due to the above described discounts of ULTOMIRIS (compared to SOLIRIS) for PNH and aHUS as we facilitate conversion from SOLIRIS, if we are unable to facilitate such conversion to ULTOMIRIS (and subsequently maintain those patients on ULTOMIRIS) prior to the loss of intellectual property or regulatory exclusivities for SOLIRIS, our future revenues would be adversely impacted as we would expect that we would face biosimilar competition for SOLIRIS and these biosimilars would have comparable safety and efficacy to SOLIRIS and would be sold at a discount to SOLIRIS.

Risks Related to Pricing and Reimbursement

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

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

Our ability to set the price for our products varies significantly from country to country, including in those countries where pricing, coverage, reimbursement or funding of prescription drugs are subject to governmental control. We may be unable to timely or successfully negotiate coverage, pricing and reimbursement on terms that are favorable to us (or at all), or such coverage, pricing and reimbursement may differ in separate regions in the same country. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed, which could delay market entry (or, if pricing is not approved, we may be unable to sell at all in a country where we have received regulatory approval for a product). In addition, authorities in some countries impose additional obligations, such as HTAs, which assess how well a pharmaceutical works in relation to its cost. Additionally, U.S. payers are increasingly considering new metrics as the basis for reimbursement rates. If our products do not meet or surpass these metrics, including any HTAs and other metrics imposed on our products, these payers may not reimburse for use of our products or may reduce the rate of reimbursement for our products and as a result we expect revenue from such product may decrease. We may also, in some cases, elect to reduce prices or reimbursement with third parties which we believe provides value in the long term (but negatively impacts revenue).

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 a number of proposals to implement such controls, among these was a recommendation to move from the current U.S. pricing and reimbursement regime to one that would establish pharmaceutical pricing by reference to a target price derived from the international price index (such a change may be expected to result in significant savings for the government for purchases of certain pharmaceuticals). 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), which accounted for a significant portion of our revenue in 2018, were to move to a pricing system based on the international price index (or similar model) that were to apply to our products, we expect that our revenues for sales in the U.S. (or any other country adopting such a price index) would decrease, and such decrease may be material in amount.

Further, other countries have already established pricing and reimbursement amounts by reference to the price of the same or similar products in other countries. Therefore, if coverage or the level of reimbursement is 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. In Canada, for example, the Federal Court of Canada recently confirmed the decision of the Patented

Medicine Prices Review Board (PMPRB) that we had excessively priced SOLIRIS and ordered that the price be decreased to no higher than the lowest price in seven comparator countries (See Note 18 to the condensed consolidated financial statements for more information on this matter). If upheld, we expect that this lower price may have an adverse impact in Canada and in the jurisdictions that set prices by reference to prices in Canada.

Due to the cost of our therapies, any potential increase in the number of patients receiving our products (for example, we expect there may be increases in sales of SOLIRIS for patients with NMOSD as we launch for that indication), may cause third-party payers to modify, limit or eliminate coverage or reimbursement for our products because they may require an allocation of a greater percentage of the potential financial resources of any public or private payer for our products.

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

- establishing formularies under which only selected drugs are covered (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 type of treatment.

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

In countries where patients have access to insurance, their insurance co-payment amounts or other benefit limits may represent a barrier to obtaining or continuing use of our products or adoption of new treatment options, such as ULTOMIRIS. The 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 treatment for PNH and aHUS, including SOLIRIS, among other therapies. Such organizations assist patients whose insurance coverage imposes prohibitive co-payment amounts or other expensive financial obligations. Such organizations' ability to provide assistance to patients is dependent on funding from external sources, and we cannot guarantee that such funding will be provided at adequate levels, if at all. We have also provided our products without charge to patients who have no insurance (or limited insurance) coverage for drugs through related charitable purposes.

We are not able to predict the financial impact of the support we may provide for these and other charitable purposes; however, substantial support could have a material adverse effect on our profitability in the future. As third-party payers attempt to contain health care costs they are demanding price discounts or rebates and limiting both the types and variety of drugs that they may cover and the amounts that they will pay for drugs. As a result, they may not cover or provide adequate payment to patients for our products or they may demand discounts or rebates from us, which may be material.

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

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 have invested, and continue to invest, significant amounts in acquiring new products and technologies and advancing our existing product candidates and technologies. Our long-term success and revenue growth and diversification will depend upon the successful identification, acquisition (including licenses from third parties), development and commercialization of new products and technologies, and approval of additional indications for our existing products and products under development. Product development (including products acquired in connection with acquisitions) is very expensive, takes significant time to obtain regulatory approval and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. The process for obtaining regulatory approval to market a biologic is expensive, often takes many years, and can vary substantially based on the type, complexity, the novelty of the product candidates involved and the indications to be treated. Further, success in early clinical trials, which may lead to further investment in a product candidate by us, may not result in success in later stage trials. In addition, our recent acquisitions have focused on new technologies with which we have very limited experience, including antibody therapeutics targeting the neonatal Fc receptor, which may make the development, approval and commercialization of such potential products challenging for us.

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

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

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

The therapies that we have developed and that are in our product pipeline and in preclinical development target diseases that have a limited number of patients and for which, in many cases, there are either no or limited diagnostics tools. For example, KANUMA and STRENSIQ are currently approved to treat ultra-rare diseases with small patient populations that have not been definitively determined. Our development pipeline programs that may be the basis for future revenue growth also focus on rare (and ultra-rare) diseases for which there are a very limited number of patients. The lack of diagnostic tools, coupled with the fact that there is frequently limited awareness among certain health care providers concerning the rare diseases we treat, often means that a proper diagnosis can, and frequently does, take years to identify (or an appropriate diagnosis may never be made for certain patients). As a result, we may not be able to grow our revenues (even as we introduce new products or as existing products are approved for additional indications). There can be no guarantee that any of our programs will be effective at identifying patients, and even if we can identify patients that our therapies can help, the number of patients that our therapies treat may turn out to be lower than we expect, may not be otherwise amenable to treatment with our products (such as KANUMA and STRENSIQ), or new patients may become increasingly difficult to identify, all of which may adversely affect our results of operations and our business. In addition, even in instances where we do add patients, the number may be less than the number of patients that discontinue use of the applicable product in a given period resulting in a net loss of patients and potentially decreased revenue.

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

Our products may not gain or maintain market acceptance among physicians, patients, healthcare payers and others. Although we have received regulatory approval for certain of our products in certain territories, such approvals do not guarantee future revenue. We cannot predict whether physicians, other healthcare providers, government agencies or private insurers will determine or continue to accept that our products are safe and therapeutically effective and that the benefits are meaningful relative to the cost. Nor can we predict whether patients, physicians or payers will continue use of SOLIRIS or elect to convert to ULTOMIRIS or elect to utilize alternative treatments that may become available (which may be sold at a significant discount to SOLIRIS or ULTOMIRIS). Physicians' willingness to prescribe, and patients' willingness to accept, our products, depends on many factors, including:

- prevalence and severity of adverse side effects in both clinical trials and commercial use;
- the timing of the market introduction of competitive drugs and biosimilars;
- demonstrated clinical safety and efficacy compared to other drugs;
- perceived cost-effectiveness and/or evaluations in health technology assessments (HTAs);
- pricing and availability of reimbursement from third-party payers, including governmental entities;
- convenience and ease of administration;
- effectiveness of our marketing strategy;
- publicity concerning our products and our other product candidates (and those of competitive products); and
- availability of alternative treatments.

The likelihood of physicians to prescribe SOLIRIS and ULTOMIRIS for patients with aHUS may also 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, we are aware that some healthcare providers have determined not to continue SOLIRIS treatment for some patients with aHUS. While SOLIRIS as a treatment for aHUS is recommended by some regulatory authorities to be used for the duration of a patient's lifetime, we are aware that some healthcare providers prescribe SOLIRIS for aHUS for a shorter time period and, in some cases, may prescribe SOLIRIS for aHUS in emergency or acute situations only. Decisions such as this by aHUS patients and healthcare providers to use our products for a period that is less than the remaining lifetime of the patient or in only acute circumstances can cause our SOLIRIS revenues, and revenues for our other products, to fluctuate and past sales of our products may not be indicative of future sales for such products.

If our products fail to achieve or maintain market acceptance among the medical community or patients in a particular country, we may not be able to market and sell our products successfully in such country, which may limit our ability to generate revenue and could harm our overall business.

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

The testing, manufacturing, marketing and sale of biologics for use in humans may cause harm to patients, which exposes us to product liability risks and regulatory penalties.

Our products and our product candidates treat patients with rare diseases and, as a result, we generally are able to test our products in only a small number of patients. As more patients use our products, including more children and adolescents, new risks and side effects may be discovered, the rate of known risks or side effects may increase, and risks previously viewed as less significant could be determined to be significant. Previously unknown risks and adverse effects may also be discovered in connection with unapproved uses of our products, which may include administration of our products under acute emergency conditions, such as the Enterohemorrhagic E. coli health crisis in Europe, primarily Germany, which began in May 2011. Under pharmacovigilance guidelines, we are required to timely report any adverse events any patient using our products experiences and any clinical evaluations of outcomes in the post-marketing setting are required to be reported to appropriate regulatory agencies in accordance with relevant regulations, as a result any potential adverse events will be promptly brought to the attention of regulators that may likely require prompt remedial action (and any failure to report these adverse events or report such events in a timely manner may result in penalties being imposed on Alexion by regulators). In the event any new risks or adverse effects are discovered as new patients are treated for approved indications, or as our products are studied in or used by patients for other indications, regulatory authorities may delay or revoke their approvals, we may be required to conduct additional clinical trials and safety studies, make changes in labeling, reformulate our products or make changes and obtain new approvals for our and our suppliers' manufacturing facilities. If we experience any of the foregoing actions, it may harm our reputation and, particularly given that we rely on a very limited number of products for our revenue, our business and results of operations could be materially and adversely impacted. Further, any investigation into the circumstances surrounding an adverse event may be costly and time consuming (even if it is ultimately determined that the adverse event is not the result of the use of our product) or the investigation may not be sufficiently conclusive to prevent a regulatory authority from taking one of the foregoing actions against us.

In addition, many patients who use our products are already very ill and may suffer adverse events, including death, during treatment for reasons that may or may not be related to our products. Also, there are risks associated with our products; for example, use of C5 Inhibitors, such as SOLIRIS and ULTOMIRIS, is associated with an increased risk for certain types of infection, including meningococcal infection. In certain cases, a physician may not have the opportunity to timely vaccinate a patient in the event of an acute emergency episode, such as in a patient presenting with aHUS, which could result in the patient using SOLIRIS or ULTOMIRIS experiencing a life-threatening meningococcal infection (and even in certain cases in which a vaccination can be delivered to the patient, it may not, eliminate all risk of meningococcal infection). Patients using our products and product candidates have died or suffered potentially life-threatening conditions either during or after ending their treatments, and these include patients who have died while participating in a clinical trial. We may be sued by patients who are harmed during the course of using our products, whether as a prescribed therapy, during a clinical trial, during an investigator initiated study, or otherwise. Any such product liability lawsuit or injury claim, which could include class actions, could harm our reputation among patients, physicians, payers and others and require us to pay substantial amounts of money to injured patients, and even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations due to the expense of defending any such claim. While we do have product liability insurance, it may not cover all potential types of liabilities or may not cover certain liabilities completely. Moreover, we may not be able to maintain our insurance on acceptable terms, or at all.

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

We expect that the business environment in which we operate will become increasingly competitive. Currently, certain of our products are the only approved therapy for the indication they treat. For example, SOLIRIS and ULTOMIRIS are the only approved treatments of PNH and aHUS. In the future, we expect that SOLIRIS and ULTOMIRIS may compete with new, novel drugs and pharmaceuticals currently in development. For example, several companies are developing and engaged in clinical trials for therapies to treat PNH, aHUS, gMG and NMOSD. Additionally, other pharmaceutical companies have publicly stated that they are developing and intend to commercialize a SOLIRIS biosimilar. For example, in 2019, a SOLIRIS biosimilar was approved in Russia for the treatment of PNH and aHUS and other SOLIRIS biosimilars may be approved in Russia and other jurisdictions in the future. We have experienced a decrease in revenue from sales of SOLIRIS in Russia following the introduction of the biosimilar and expect that Russia will account for a minor portion, if any, of future SOLIRIS revenue. Other biosimilars may be commercially available in other jurisdictions in the future, including the U.S., Europe and Japan and we could experience loss of revenue. STRENSIQ and KANUMA may also experience competition in the future. We are also aware of companies that have initiated or are planning to initiate studies for diseases that we are also targeting with our product pipeline. Our revenues could be negatively affected if patients or potential patients enroll in our clinical trials or clinical trials of other companies with respect to diseases that we also target with approved therapies.

Other pharmaceutical companies have publicly announced intentions to establish or develop rare disease programs and may introduce products that compete with ours (or products that are in our pipeline). These and other companies, many of which have significantly greater financial, technical and marketing resources than us, may commercialize products that are cheaper, more effective, safer, have less frequent dosing schedules, or easier to administer than our products. Our current and future competitors may develop products that are more broadly accepted or may receive patent protection that dominates, blocks or adversely affects our product development or business. These competitive products, including any biosimilars approved under alternative regulatory pathways, may significantly reduce both the price that we receive for such marketed products and the volume of products that we sell, which may negatively impact our revenues and profitability. Given that a significant portion of our 2018 revenue was attributable to SOLIRIS, one or more competitive 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.

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

There is no guarantee that any regulatory authorities (beyond the FDA, MHLW or EMA) will promptly approve the use of ULTOMIRIS in PNH patients or that they will approve the use of ULTOMIRIS in PNH patients at all. We believe that there may be additional important potential markets for ULTOMIRIS and if we are not able to sell ULTOMIRIS in these geographies, our business may be adversely impacted.

Subject to successful completion of clinical trials, we intend to pursue marketing approval for ULTOMIRIS in additional jurisdictions and for additional indications as well as other delivery mechanisms. The FDA, the EMA or the MHLW could reject our applications for indications beyond PNH (and the other regulatory authorities could reject our application for ULTOMIRIS for PNH) or for a subcutaneous delivery mechanism for many reasons, including due to a finding of inadequate safety, tolerability, potency or efficacy profiles. Additionally, these and other regulatory agencies may request that we provide additional safety or efficacy data, which may require significant additional time and expense to generate prior to a decision on approval (and any additional data that is generated may not be indicative of safety and efficacy required by these agencies).

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

Risks Related to Business Operations

We rely on a limited number of facilities to produce our products and manufacturing issues at our facilities or the facilities of our third party service providers could cause product shortages, stop or delay commercialization of our products, disrupt or delay our clinical trials or regulatory approvals, and adversely affect our business.

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

If we and/or our third party suppliers fail to meet the highly technical requirements/specifications of manufacturing our biologic products and our strict quality and control specifications, we (or they) may be unable to manufacture or supply our products. We depend on our third party manufacturers to perform effectively on a timely basis and to comply with regulatory requirements and meet our product specifications. If they are unable to do so, our contractual rights to address any failures and right to recover damages are limited. Our failure or the failure of our third-party manufacturers to produce sufficient quantities of our products and product candidates could result in lost revenue, diminish our profitability, delay the development of our product candidates, delay regulatory approval, result in the rejection of our product candidates or result in supply shortages for our patients, which may lead to lawsuits, loss of revenue or could accelerate introduction of competing products to the market. For example, we recently experienced unexpected chemistry, manufacturing and control (or CMC) issues with our recently acquired ALXN 1830 program that has 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.

As noted above, the manufacture of our products and product candidates is at high risk of product loss due to contamination, equipment malfunctions, human error or raw material shortages, which may result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or manufacturing facilities, or the facilities of our third party manufacturers, we or our third party manufacturers may need to close our or their manufacturing facilities for an extended period of time to investigate and remediate the contaminant.

If we underestimate demand for ULTOMIRIS, SOLIRIS or any of our products, or experience product interruptions at Alexion’s internal manufacturing facilities or a facility of a third party provider, including as a result of risks and uncertainties described in this Quarterly Report on Form 10-Q, we may not be able to increase our revenues and alternative therapies may gain greater market acceptance.

We also face external factors, many of which are beyond our control, that could cause production interruptions at our facilities or at the facilities of our third party providers, including natural disasters, labor disputes, acts of terrorism or war.

The risks to our business of any manufacturing stops or interruptions (whether the result of internal or external factors) are amplified because we rely on a limited number of facilities to produce our products and product candidates. For example, each of our products is manufactured at only one to two facilities. Sales of SOLIRIS, which accounted for 86.3% of our revenue for the fiscal year ended December 31, 2018, in the U.S., the EU, Japan and certain other territories were manufactured exclusively by Lonza at its facilities in Singapore and Spain. Manufacturing SOLIRIS for commercial sale in certain other territories may only be performed at a single facility in some cases until such time as we have received the required regulatory approval for an additional facility, if ever. We expect that we will continue to rely on a very limited number of manufacturing facilities in the future for all of our products, including ULTOMIRIS.

We and our third party providers are required to maintain compliance with cGMP and other stringent operation and manufacturing requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. Governmental authorities will generally not permit products manufactured at a facility that is not registered by the applicable government agency to enter into the country and such products may be returned for failure to comply with such regulation, which may decrease or delay sales and result in the loss of inventory. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or comply with 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 challenges. We have completed the build-out of a fill-finish facility in Ireland to support global drug product manufacture or vial fill finish of SOLIRIS and certain of our other clinical and commercial products. We completed construction of a facility in Dublin, Ireland in the fourth quarter of 2015, which is comprised of laboratories, packaging and warehousing operations. We have also completed construction of new biologics manufacturing facilities at both our Athlone and Dublin sites. Despite the significant investment we have made in these facilities and operations, we cannot guarantee that we will be able to successfully and timely complete the appropriate validation processes or obtain the necessary regulatory approvals for these and other facilities, or that we will be able to perform the intended manufacturing and supply chain services at these facilities for commercial or clinical use. Prior to such time, we may continue to rely on third parties for these services.

If we experience any manufacturing issues, we may be unable to timely identify alternative manufacturers, and if we are able to timely identify alternative manufacturers, such alternative manufactures may not be able to satisfy our requirements. No guarantee can be made that regulators will approve additional third party providers in a timely manner or at all, or that any third party providers will be able to perform services for sufficient product volumes for any country or territory. Further, due to the nature of the current market for third-party commercial manufacturing, many arrangements require substantial penalty payments by the customer for failure to use the manufacturing capacity for which it contracted. The payment of a substantial penalty could harm our financial condition and may restrict our ability to transition to internal manufacturing or manufacturing by other third parties. In addition, the terms and conditions to engage an additional third party manufacturer may not be as favorable to us as our current arrangements and may likely reduce the profit on the sales of any products to which they relate.

In addition, KANUMA is a transgenic product and the facilities on which we rely to produce raw material for KANUMA are the only animal facilities in the world that produce the necessary egg whites from transgenic chickens. Natural disasters, disease, such as exotic Newcastle disease or avian influenza, or other catastrophic events could have a significant impact on the supply of unpurified KANUMA, or destroy our animal operations altogether. If our animal operations are disrupted, it may be extremely difficult to set up another animal facility to supply the unpurified KANUMA.

Any adverse developments affecting our manufacturing operations or the operations of our third-party providers could result in a product shortage of clinical or commercial requirements, withdrawal of our product candidates or any approved products, shipment delays, lot failures or recalls. We may also have to write-off inventory and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Each of these could have an adverse material impact on our business individually or in the aggregate.

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

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

We also depend on a very limited number of third party providers for supply chain services with respect to our clinical and commercial product requirements, including product filling, finishing, packaging and labeling.

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

The success of our business may also depend on the security of our products while in the supply chain for delivery to patients, which, as noted above, is dependent on third-party providers. For example, if our products are not fully and adequately secured from unauthorized access by third parties, any of our products may be tampered with or contaminated. If our products were exposed to any tampering or contamination, or if they are not transported in accordance with the required specifications, our patients may be harmed through use of our products, and such harm may be severe. In addition, if the supply chain is not secure (or our distributors do not exercise control over our products while in their possession), we are also at risk for our products to be diverted to patients other than those who are the intended recipient or to patients who do not have a prescription to receive our therapies (or it may be used for treatment by physicians who have not completed the necessary REMs protocols in order to treat patients) or it may be sold by distributors, channels or other entities that are not authorized by Alexion to sell our products. In addition, an unauthorized distributor may not properly store or ship our products, thereby exposing patients to potential harm from use of the product that was not handled in accordance with our standards. 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. Most of our products are relatively new to the market, and we have recently hired several senior members of our sales and commercial team. In addition, in order to gain greater efficiencies in our operations, we have begun to implement a plan pursuant to which certain portions of our international commercial operations will transition to a new operating model in which sales and marketing efforts in designated countries will be conducted to a greater extent by third-parties to promote and sell our products, and our direct sales and marketing presence will decrease (or be eliminated) in these regions.

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

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

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

Completion of preclinical studies or clinical trials does not guarantee that we will initiate additional studies or trials for our product candidates, if further studies or trials are initiated, what the scope and phase of the trial will be or that they will be completed, or if these further studies or trials are completed, that the design or results may provide a sufficient basis to apply for or receive regulatory approvals or to commercialize products. Results of clinical trials could be inconclusive, requiring additional or repeat trials. Data obtained from preclinical studies and clinical trials are subject to varying interpretations that could delay, limit or prevent regulatory approval. If the design or results achieved in our clinical trials are insufficient to proceed to further trials or to sustain regulatory approval of our product candidates, we could be materially adversely affected. Failure of a clinical trial to achieve its pre-specified primary endpoint generally increases the likelihood that additional studies or trials 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) in scientifically similar indications.

We are currently planning and conducting several clinical trials of products and product candidates that we anticipate may be important to our goal of expanding our business and diversifying our product portfolio. These trials may not yield the anticipated results for a number of reasons. For example, the fact that we have obtained marketing authorization in the U.S., EU and Japan for ULTOMIRIS as a treatment for PNH does not mean that ULTOMIRIS will be approved as a treatment for additional indications in each of those jurisdictions or that any clinical trials may achieve its designated endpoints and prove to be safe and effective for use in patients with these additional indications. In addition, we are also conducting clinical trials in therapeutic areas with which we have limited experience (for example, in 2018 we acquired ALXN1840 (WTX101), a therapy for Wilson’s disease acquired from Wilson Therapeutics currently in Phase III clinical trials) and with technology platforms with which we also have limited experience (for example, in 2018 we acquired Syntimmune that develops humanized monoclonal antibody that inhibits the interaction of FcRn with Immunoglobulin G (IgG) and IgG immune complexes). Each of these clinical trials, and any other trial we commence, is subject to the risks highlighted in the preceding paragraph and the investments we have made in these technologies may not generate the expected returns if the clinical trials do not produce results that will meet the requirements of regulators and the needs of patients and their healthcare providers.

In addition, we intend to further increase the number of products in our preclinical, early-stage clinical and advanced clinical pipeline and the number of indications that our products address. For example, in 2020 we plan to initiate a Phase II/III clinical trial for ULTOMIRIS as a treatment for Amyotrophic Lateral Sclerosis (ALS) and an exploratory clinical study in Primary Progressive Multiple Sclerosis (PPMS). There is no guarantee that the Phase II/III clinical trial for ALS or exploratory clinical study in PPMS will provide sufficient evidence to advance our research beyond the these stages. Further, we may expend significant resources in an effort to establish that ULTOMIRIS is a potential therapy for ALS or PPMS (and on other products in development) and these may not meet the standard to advance to additional trials or regulatory approval. In the event that a product does satisfactorily establish proof of concept, and it does advance into preclinical or clinical trials, such product may face the risks and challenges identified in the preceding paragraph.

Our clinical studies may be costly and lengthy, and there are many reasons why drug testing could be delayed or terminated.

For human trials, patients must be recruited and each product candidate must be tested at various doses and formulations for each clinical indication. In addition, to ensure safety and effectiveness, the effects of drugs often must be studied over a long period of time, especially for the chronic diseases that we are studying. Many of our programs focus on diseases with small patient populations making patient enrollment difficult. Insufficient patient enrollment in our clinical trials could delay or cause us to abandon a product development program. We may decide to abandon development of a product candidate or a study at any time due to unfavorable results or other reasons, including if there are concerns about patient safety. We may have to spend considerable resources repeating clinical trials or conducting additional trials, either of which may increase costs and delay revenue from those product candidates, if any. We may open clinical sites and enroll patients in countries where or for indications in which we have little experience.

We rely on a small number of clinical research organizations to carry out our clinical trial related activities, and one contract research organization (CRO) is responsible for many of our studies. We rely on such parties to accurately report their results. Our reliance on CROs may impact our ability to control the timing, conduct, expense and quality of our clinical trials. In addition, we may be responsible for any errors in clinical trials by a CRO as a result of the performance of services in connection with a clinical trial on our behalf. And regulatory agencies, in connection with a potential product approval or as part of ongoing monitoring, will review a CROs compliance with regulatory requirements relating to clinical trials and we may be subject to findings and regulatory action (including denial or delay of product approval) if a CRO fails to comply with regulations.

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

- delay or failure in obtaining institutional review board (IRB) approval or the approval of other reviewing entities to conduct a clinical trial at each site;
- delay or failure in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- delay or failure in having patients complete a trial or return for post-treatment follow-up;
- long treatment time required to demonstrate effectiveness;
- lack of sufficient supplies of the product candidate;
- disruption of operations at the clinical trial sites;
- adverse medical events or side effects in treated patients;
- failure of patients taking the placebo to continue to participate in our clinical trials;
- insufficient clinical trial data to support safety and effectiveness of the product candidates;
- lack of effectiveness or safety of the product candidate being tested;
- inability to manufacture product candidates that meet required specifications or to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner;
- decisions by regulatory authorities, the IRB, ethics committee, or us, or recommendation by a data safety monitoring board, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- failure to obtain the necessary regulatory approvals for the product candidate or the approvals for the facilities in which such product candidate is manufactured; and
- decisions by competent authorities, IRBs or ethics committees to demand variations in protocols or conduct of clinical trials.

We may not accurately forecast demand for our products, including our new products, or the conversion of PNH and aHUS patients to ULTOMIRIS, which may cause our operating results to fluctuate.

Our quarterly revenues, expenses and net income (loss) may fluctuate, even significantly, due to certain risks, including those described in these “Risk Factors” as well as the timing of charges and expenses that we may take, acquisitions (such as the Wilson Therapeutics and Syntimmune acquisitions) and the impact of converting patients from Soliris to Ultomiris. In the future, we may not generate sufficient revenues or control expenses to achieve our financial goals. We may not be able to sustain or increase profitability on a quarterly or annual basis. You should not consider our financial performance, including our revenue growth, in recent periods as indicative of our future performance. Since we have a limited sales and operating history with certain of our products and for new indications of existing products (such as SOLIRIS as a treatment for NMOSD), we may not be able to accurately forecast demand for our products or for new indications. STRENSIQ and KANUMA, also relatively new products, each received marketing approval in 2015, and both products treat rare diseases for which there was no existing therapy in a new therapeutic area. Since approval of ULTOMIRIS as a treatment for PNH, we have undertaken efforts to facilitate the conversion of PNH patients from SOLIRIS to ULTOMIRIS. Product demand and, in the case of conversion to ULTOMIRIS, product preference and conversion, is dependent on a number of factors, many of which are beyond our control. For these reasons, we may not be able to accurately forecast demand for our products.

We cannot guarantee that we will achieve our financial goals, including our ability to maintain profitability on a quarterly or annual basis in the future.

Our investors and investment analysts may have widely varying expectations that may be materially higher or lower than actual revenues and profits and if our revenues and profits are different from these expectations, our stock price may experience significant volatility. Our revenues and profits are also subject to foreign exchange rate fluctuations due to the global nature of our operations and our results of operations could be adversely affected due to unfavorable foreign exchange rates. Although we use derivative instruments to manage foreign currency risk, our efforts to reduce currency exchange losses may not be successful.

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

As we attempt to expand our pipeline, obtain regulatory approval for new products, facilitate the conversion of patients from SOLIRIS to ULTOMIRIS , seek regulatory approval for existing products in new jurisdictions and approval of new indications for existing products (such as SOLIRIS as a treatment for NMOSD), we may have substantial expenses as we continue our research and development efforts and our efforts to develop the assets we have acquired through acquisitions, collaborations and in-licenses, 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. In addition, these expenses may increase and such increases may exceed analyst and investor expectations.

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

We have undertaken corporate restructuring activities to re-align our global organization with our re-focused strategy, reduce costs, and realize operational efficiencies. We estimate that our most recent restructuring, which includes our transition in certain jurisdictions from a direct sales model to increased use of third parties for sales and marketing functions, will result in a charge of up to $25.0 in 2019. These recent restructuring activities, including work force reductions, closing certain operational sites and our increased use of third parties in certain countries to sell, market and distribute products (and rely less on a direct sales force), subject us to many risks, including loss of business continuity, unanticipated costs, and higher than usual employee turnover. In addition, we will not exercise the same degree of control over any third parties that we do over our direct sales force and the ability to direct the third party and provide incentives for such third party to sell our products may not be as strong as in the case of a direct sales force. This transition and greater reliance on third party sales force, marketers and distributors 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 changes in operational methods pursuant to this restructuring. The expected cost savings and operational efficiencies from the restructuring activities are based on assumptions and expectations that we believe were reasonable in our judgment at the time made but may not be achieved due to unforeseen difficulties and challenges that are beyond our control. If these assumptions and expectations are incorrect or if we experience delays or unforeseen events in realizing the benefits of the restructuring activities, our business operations and financial results may be harmed.

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

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

The success of our business is dependent in large part on our continued ability to attract and retain our senior management, and other highly qualified personnel in our scientific, clinical, manufacturing and commercial organizations. There is intense competition in the biopharmaceutical industry for these types of personnel. In March 2017, our Board appointed a new Chief Executive Officer (CEO) and we have experienced other recent significant management changes. In addition, since 2017, we have moved our global headquarters and undertaken company-wide restructurings with the goal of re-aligning our global organization with our re-focused strategy and to make our international operations more efficient and effective. The relocation of our headquarters and restructurings have the potential to adversely impact our ability to recruit and/or retain key employees as well as to disrupt our business operations, financial conditions, programs, plans and strategies.

Our business is specialized and global and we must attract and retain highly qualified individuals across many geographies. We may not be able to continue to attract and retain the highly qualified personnel necessary to develop, manufacture and commercialize our products and product candidates. If we are unsuccessful in our recruitment and retention efforts, or if our recruitment efforts take longer than anticipated, our business may be harmed.

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

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

In addition, we have substantial contingent liabilities, including milestone and royalty obligations under acquisitions and strategic transactions, and we have been, and in the future may again be, engaged in disputes with certain counterparties regarding potential milestone and royalty obligations. Our increased indebtedness, including increased interest expense, together with our significant contingent liabilities, could, among other things:

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

The Amended and Restated Credit Agreement requires us to comply with certain financial covenants and negative covenants, restricting or limiting our ability and the ability of our subsidiaries to, among other things, incur additional indebtedness, grant liens, and engage in certain investment, acquisition and disposition transactions, subject to limited exceptions. If an event of default occurs, the interest rate may increase and the administrative agent may be entitled to take various actions, including the acceleration of amounts due under the Amended and Restated Credit Agreement. If the interest rate imposed under our Amended and Restated Credit Agreement were to increase as a result of a default, our expenses may increase and we may need to allocate additional funds to this interest expense (which may limit the use of these funds for other purposes, including growing our business or responding to changes in our business and industry). If some or all of the amounts outstanding under the Amended and Restated Credit Agreement were to be accelerated by the lenders, we may not have sufficient cash on hand to pay the amounts due, we may not be able to refinance such debt on terms acceptable to us (or at all) and we may be required to sell certain assets on terms that are unfavorable to us.

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

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

We may need to raise additional capital to supplement our existing funds and cash generated from operations for working capital, capital expenditure and debt service requirements, and other business activities (including business and technology acquisitions). Funding needs may shift and the amount of capital we may need depends on many factors, including, the cost of any acquisition or any new collaborative, licensing or other commercial relationships that we may establish, the time and cost necessary to build new manufacturing facilities or enhance our manufacturing operations, amounts we may need to pay in connection with the resolution of any government investigation or litigation matter (including any securities class action matter or any product liability claim or any tax assessment), 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.

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

As a biopharmaceutical company, our business involves the use of certain hazardous materials in our research, development, manufacturing and other activities. We and our third party providers are subject to various federal, state and local and foreign environmental laws and regulations concerning the handling and disposal of non-hazardous and hazardous wastes, such as medical and biological wastes, and emissions and discharges into the environment, such as air, soils and water sources. We also are subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment and a current or previous owner or operator of property may be liable for the costs of remediating its property or locations, without regard to whether the owner or operator knew of or caused the contamination. Although our safety procedures for handling and disposing of hazardous materials are designed to comply with the laws and regulations established by state, federal and foreign regulations, the risk of loss of, or accidental contamination or injury from, these materials cannot be eliminated. If an accident or environmental discharge occurs, or if we discover contamination caused by prior owners and operators of properties we acquire, we could be liable for remediation obligations, damages and fines that could exceed our insurance coverage and financial resources. Such obligations and liabilities, which to date have not been material, could have a material impact on our business and financial condition. Additionally, the cost of compliance with environmental and safety laws and regulations may increase in the future, and we may be required to dedicate more resources, including substantial financial resources, to comply with such laws and regulations or purchase supplemental insurance coverage, which may not be available on acceptable terms or at all.

In order to meet one of our key business objectives of advancing and rebuilding our product pipeline, we plan to expand our business and product offerings through acquisitions of businesses and technologies. Our efforts to identify opportunities or complete transactions that satisfy our strategic criteria may not be successful, and we may not realize the anticipated benefits of any completed acquisition or other strategic transaction.

As noted above, in 2018 a substantial portion of our total revenue was derived from SOLIRIS. We expect that there may be increased competition to SOLIRIS from, among other products and therapies, biosimilars, and we are still in the early stages of the launch of ULTOMIRIS for PNH and cannot guarantee that our efforts to facilitate the conversion of patients from SOLIRIS to ULTOMIRIS will be successful (or that we will obtain clearance for ULTOMIRIS for additional indications or in any additional jurisdictions). As a result, we have identified rebuilding our product pipeline as a key strategic objective and, in order to achieve this objective, we expect to purchase businesses and acquire, co-develop or license technologies and products from third parties in the future. For example, among other transactions, we have completed acquisitions of Wilson Therapeutics and Syntimmune, Inc. and recently signed a definitive agreement to acquire Achillion Pharmaceuticals. We anticipate that we will regularly evaluate potential merger, acquisition, partnering and in-license opportunities in an effort to expand our pipeline or product offerings, and enhance our research platforms. Acquisitions of new businesses or products and in-licensing of new technologies and products may involve numerous risks, including:

- substantial cash expenditures;
- potentially dilutive issuance of equity securities and incurrence of debt;
- assumption of material liabilities in connection with the target or purchased technology, some of which may be difficult or impossible to identify at the time of acquisition;
- difficulties in assimilating the operations of the acquired companies;
- failure of any acquired businesses or products or in-licensed products or technologies to achieve the scientific, medical, commercial or other results we anticipate;
- diverting our management’s attention away from other business opportunities and concerns;
- the potential loss of our key employees or key employees of the acquired companies; and
- risks of entering disease areas and indications in which we have limited or no direct experience.

A substantial portion of our strategic efforts are focused on opportunities for rare disorders, but the availability of such opportunities is limited. We may not be able to identify opportunities that satisfy our strategic criteria or are acceptable to us or our stockholders. Several companies have publicly announced intentions to establish or develop rare disease programs and we may compete with these companies (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 terms that we or our stockholders find acceptable, or at all. In such event, we may not be able to rebuild our pipeline and any future revenue may remain largely dependent on our existing products which, as noted above, may be subject to increasing competition from biosimilars and other competitive or novel therapies.

Even if we are able to successfully identify and complete acquisitions and other strategic transactions, we may not be able to integrate or take full advantage of them. An acquisition or other strategic transaction may not result in short-term or long-term benefits to us. We may also incorrectly judge the value or worth of an acquired company or business or an acquired or in-licensed product, particularly if the acquired technology is in preclinical trials or early-stage clinical trials.

To effectively manage our current and future potential growth, we must continue to effectively enhance and develop our global employee base and our operational and financial processes. Supporting our growth strategy may require significant capital expenditures and management resources, including investments in research, development, sales and marketing, manufacturing and other areas of our operations. The development or expansion of our business, any acquired business or any acquired or in-licensed products may require a substantial capital investment by us and we may likely incur substantial expenses in advancing acquired products to commercialization. We may not have the necessary funds for these capital expenditures and expenses or they might not be available to us on acceptable terms. We may also seek to raise funds by incurring additional indebtedness and selling shares of our capital stock, which could dilute current stockholders' ownership interest in our company, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest in us upon conversion.

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

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

As of September 30, 2019, the net carrying value of our goodwill and other intangible assets, net totaled $8,447.5. As required by GAAP, we periodically assess these assets to determine if there are indicators of impairment. We have recorded charges that include inventory write-downs for failed quality specifications or recalls, impairments with respect to investments and acquisitions, fixed assets and long-lived assets, outcomes of litigation and other legal or administrative proceedings, regulatory matters and tax matters, and payments in connection with acquisitions and other business development activities, such as milestone payments. The impairment of tangible and intangible assets may be triggered by developments both within and outside our control. Deteriorating economic conditions, technological changes, disruptions to our business, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in the use of the assets, intensified competition, divestitures, market capitalization declines and other factors may impair our goodwill and other intangible assets. Any charges relating to such impairments could adversely affect our results of operations in the periods in which an impairment is recognized. As part of our standard quarterly procedures, we reviewed the KANUMA asset as of September 30, 2019 and determined that there were no indicators of impairment. We will continue to review the related valuation and accounting of this asset in future quarters as new information becomes available to us. Cash flow models used in our assessments are based on our commercial experience with KANUMA to date and require the use of significant estimates, which include, but are not limited to, long-range pricing expectations and patient-related assumptions, including patient identification, conversion and retention rates. As we continue to sell this product, 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. The net book value of the KANUMA intangible asset as of September 30, 2019 was $3,057.5.

Our business could be adversely affected by litigation, government investigations and enforcement actions.

We operate in many jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the U.S. or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, 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. See Note 18, *"Commitments and Contingencies"* to the footnotes to the consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for information on our material legal proceedings. For example, in May 2015, we received a subpoena in connection with an investigation by the Enforcement Division of the SEC requesting information related to our grant-making activities and compliance with the Foreign Corrupt Practices Act (FCPA) in various countries. In addition, in October 2015, we received a request from the U.S. Department of Justice (DOJ) for the voluntary production of documents and other information pertaining to Alexion's compliance with FCPA. The SEC and DOJ also seek information related to Alexion's recalls of specific lots of SOLIRIS and related securities disclosures. Alexion is cooperating with these investigations. The investigations have focused on operations in various countries, including Brazil, Colombia, Japan, Russia and Turkey, and Alexion's compliance with the FCPA and other applicable laws. Any determination that our operations or activities are not in compliance with existing laws or regulations, by the SEC or DOJ in the above referenced matter for example, could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief, exclusion from the federal healthcare programs, healthcare debarment, product recalls, reputational damage and modifications of our business practices and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations. In addition, we may be required to expend significant resources to defend the securities class action filed in December 2016 and, if we were found to have violated the securities laws, we could be required to pay significant damages to the plaintiffs. Legal proceedings, government investigations, including the SEC and DOJ investigations and the August 2019 tax assessment in Brazil, and enforcement actions have been and we expect may continue to be expensive and time consuming. Any future litigation or investigation may also likely be expensive and time consuming.

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

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

We have designed, and from time to time we modify, our corporate structure, the manner in which we develop and use our intellectual property, and our intercompany transactions between our affiliates in a way that is intended to enhance our operational and financial efficiency and increase our overall profitability. The application of the tax laws and regulations of various countries in which we operate and to our global operations is subject to interpretation. We also must operate our business in a manner consistent with our corporate structure to realize such efficiencies. The tax authorities of the countries in which we operate may challenge our methodologies for valuing developed technology or for transfer pricing or other operations. If tax authorities determine that the manner in which we operate results in our business not achieving the intended tax consequences, our effective tax rate could increase (and such increase may be material) and harm our financial position and results of operations. In addition, certain governments are considering and may adopt tax reform measures that significantly increase our worldwide tax liabilities. The Organization for Economic Co-operation and Development and other government bodies have focused on issues related to the taxation of multinational corporations, including, in the area of "base erosion and profit shifting," where payments are made from affiliates in jurisdictions with high tax rates to affiliates in jurisdictions with lower tax rates. It is possible that these reform measures could increase our effective tax rate (and such increase may be material) and harm our financial position and results of operations over the next several years.

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

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

- difficulties or the inability to obtain necessary foreign regulatory or reimbursement approvals of our products in a timely manner or at all;
- political or economic determinations that adversely impact pricing or reimbursement policies;
- economic problems or political instability;
- fluctuations in currency exchange rates;

- difficulties or inability to obtain financing in markets;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- customs and tax officials in foreign jurisdictions may disagree with the value we set when we or others import our products (including products that are donated for charitable purposes 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 18 to the condensed 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 tax, employment and labor laws;
- costs and difficulties in recruiting and retaining qualified managers and employees to manage and operate the business in local jurisdictions;
- costs and difficulties in managing and monitoring international operations; and
- longer payment cycles.

Additionally, our business and marketing methods are subject to the laws and regulations of the countries in which we operate, which may differ significantly from country to country and may conflict with U.S. laws and regulations. The FCPA and anti-bribery laws and regulations in the locations in which we operate our business are extensive and far-reaching, and we must maintain accurate records and control over the activities of our distributors and third party service providers in countries where we operate. We have policies and procedures, and we are currently implementing an enhanced company-wide compliance program and effort, designed to help us and our representatives, including our employees and our vendors and distributors, comply with such laws, however we cannot guarantee that these policies and procedures will protect us against liability under the FCPA or other anti-bribery laws for actions taken by us, 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 operate. In addition, as we move 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.

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

We conduct a substantial portion of our business in currencies other than the U.S. dollar. We are exposed to fluctuations in foreign currency exchange rates and such fluctuations affect our operating results. The exposures result from portions of our revenues, as well as the related receivables, and expenses that are denominated in currencies other than the U.S. dollar, including the Euro, Japanese Yen, British Pound, Canadian dollar and Turkish Lira. As the U.S. dollar strengthens against these foreign currencies, the relative value of sales made in the respective foreign currencies decrease. When the U.S. dollar weakens against these currencies, the relative value of such sales increase. We manage a portion of our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. We enter into foreign exchange forward contracts to hedge exposures resulting from portions of our forecasted revenues, including intercompany revenues that are denominated in currencies other than the U.S. dollar. The purpose of the revenue hedges is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. Further, we enter into foreign exchange forward contracts, with durations of approximately eight months, designed to limit the balance sheet exposure of monetary assets and liabilities. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results. Gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. While we attempt to hedge certain currency risks, currency fluctuations between the U.S. dollar and the currencies in which we do business have, in the past, caused foreign currency transaction gains and losses and have also impacted the amounts of revenues and expenses calculated in U.S. dollars and will do so in the future. Likewise, past currency fluctuations have at times resulted in foreign currency transaction gains, and there can be no assurance that these gains can be reproduced. Any significant foreign currency exchange rate fluctuations could adversely affect our financial condition and results of operations.

Risks Related to the Regulatory Environment

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

We and our current and future third party vendors, contract manufacturers, CROs, distributors and suppliers and logistic providers are subject to rigorous and extensive regulation by governmental authorities around the world, including the FDA, EMA, the competent authorities of the EU Member States and the MHLW. These regulations, many of which are complex, relate to almost all aspects of our business, including GCP, GLP, cGMP and pharmacovigilance rules (for additional information on the regulations relating to our business, see “Business - Government Regulation” in Item 1 in our Annual Report on Form 10-K for the year ended December 31, 2018). If we or a regulatory agency discover previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured (such as product contamination), or in the case of KANUMA, problems with animal operations, a regulatory agency may impose restrictions on that applicable product, the manufacturing facility or us. We have received a Warning Letter from the FDA relating to compliance with FDA’s cGMP requirements at one of our facilities, which was remediated. If we had failed to address the FDA’s concerns or if we (or one of our third party contract manufacturers) were to receive another Warning Letter in the future relating to cGMP or other applicable regulations, the FDA or other regulatory authorities could take regulatory action, including fines, civil penalties, recalls, seizure of product, suspension of manufacturing operations, operating restrictions, injunctions, suspension of clinical trials, withdrawal of FDA (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 initiate a recall or withdrawal of our products. In addition to our manufacturing operations and those of contract manufacturers’ manufacturing operations being subject to inspection and potential regulatory action for failure to comply with (among other regulations) cGMP, our animal operations may also be subject to FDA and U.S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA APHIS) inspection to evaluate whether our animal husbandry, containment, personnel, and record keeping practices are sufficient to ensure safety and security of our transgenic chickens and animal products (e.g., eggs, waste, etc.). Any failure to ensure safety and security of our transgenic chickens and/or animal products could result in regulatory action by the FDA or another regulatory body, including USDA APHIS.

Failure to comply with the laws and requirements, including statutes and regulations, administered by the FDA, the EC, the competent authorities of the EU Member States, the MHLW or other 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 of production;
- operating restrictions, such as a shutdown of production facilities or production lines, or new manufacturing requirements;
- suspension or termination of ongoing clinical trials;
- delays in approving or refusal to approve our products including pending BLAs or BLA supplements for our products or a facility that manufactures our products;
- seizing or detaining product;
- requiring us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;

- injunctions; and/or
- criminal prosecution.

In addition, we are subject to antitrust regulations with respect to our acquisitions, as well as our interactions with other participants in the markets we currently serve or may serve in the future. In addition, these antitrust laws are vigorously enforced in the U.S. and in other jurisdictions in which we operate. In connection with any business development transaction, acquisition, development agreement or collaboration that is reviewed by regulatory authorities, there can be no assurance that these antitrust approvals will be obtained. In addition, the governmental entities from which these approvals are required may impose conditions on the completion of such business development transaction or require changes to the terms of the applicable transaction. In addition, the regulatory review process may cause a delay in the closing of a transaction beyond the time that we anticipate and communicate. Any conditions or unexpected delays in approval could have the effect of jeopardizing or delaying completion of the applicable transaction or reducing the anticipated benefits of the transaction (or, as noted above, may prohibit closing of the transaction).

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

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

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

Following marketing approval of a pharmaceutical product, the safety profile of such product continues to be closely monitored by the FDA and other foreign regulatory authorities. Regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, finishing, filling, labeling, advertising, promotion, risk mitigation, adverse event reporting requirements and export of biologics. For example, the REMS program for SOLIRIS, most recently updated by the FDA in 2015, requires prescribing information regarding the level of fever needed to seek medical attention and reporting adverse events. Future changes to the SOLIRIS REMS (or similar requirements for other products) could be costly and burdensome to implement.

We are required to report any serious and unexpected adverse experiences and certain quality problems with our products to the FDA, the EMA, the MHLW and other health agencies. Adverse safety events involving our products may have a negative impact on our business. Discovery of safety issues with our products could result in product liability claims and could cause additional regulatory scrutiny and requirements for additional labeling or safety monitoring, withdrawal of products from the market and the imposition of fines or criminal penalties. In addition, governmental authorities are making greater amounts of safety information directly available to the public through periodic safety update reports, patient registries and other reporting requirements. The reporting of adverse safety events may also damage physician, patient and/or investor confidence in our products and our reputation. Any adverse events in connection with the use of our products could result in liabilities, loss of revenues, material write-offs of inventory, material impairments of intangible assets, goodwill and fixed assets, material restructuring charges and other adverse impacts on our results of operations.

Regulatory agencies periodically inspect our pharmacovigilance processes. If these regulatory agencies determine that we or other parties whom we do not control that perform services on our behalf, including clinical trial investigators, have not complied with the applicable reporting or other pharmacovigilance requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including monetary fines, marketing authorization withdrawal and other penalties.

As a condition of approval for marketing our products, governmental authorities may require us to conduct additional studies. In connection with the approval of SOLIRIS in the U.S., EU and Japan, for the treatment of PNH, we agreed to establish a PNH Registry, monitor immunogenicity, monitor compliance with vaccination requirements, and determine the effects of anticoagulant withdrawal among PNH patients receiving eculizumab, and, specifically in Japan, we agreed to conduct a trial in a limited number of Japanese PNH patients to evaluate the safety of a meningococcal vaccine. In connection with the approval of SOLIRIS in the U.S. for the treatment of aHUS, we agreed to establish an aHUS Registry and complete additional human clinical studies in adult and pediatric patients. Furthermore, in connection with the approval of STRENSIQ in the U.S., we agreed to conduct a prospective observational study in treated patients to assess the long-term safety of STRENSIQ therapy and to develop complementary assays. Similarly, in connection with the approval of KANUMA in the U.S., we agreed to conduct a long-term observational study of treated patients, either as a standalone study or as a component of the existing LAL Registry. In the EU, in connection with the grant of authorization for STRENSIQ, we agreed to conduct a multicenter, randomized, open-label, Phase 2a study of STRENSIQ in patients with HPP and to extend the studies ENB-008-10 and ENB-009-10 to provide efficacy data in patients 13 to 18 years of age, which we have commenced.

In the U.S., the FDA can also propose to withdraw approval for a product if it determines that such additional studies are inadequate or if new clinical data or information shows that a product is not safe for use in an approved indication.

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

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

We are subject to healthcare “fraud and abuse” laws, such as the 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; 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.

Other related federal and state laws and regulations that may affect our ability to operate include, among others, the federal False Statements Statute, the federal Civil Monetary Penalties Law, HIPAA, the federal Open Payments program, state anti-kickback and false claims acts, and state and local disclosure requirements and marketing restrictions. Additional information about the scope of these requirements and potential penalties is provided under *“Government Regulation - Fraud and Abuse”* included in Part I, Item 1 in our Annual Report on Form 10-K for the year ended December 31, 2018.

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. We also now have similar reporting obligations throughout the EU. Failure to comply with the reporting requirements may result in significant civil monetary penalties.

Violations of U.S. federal and state fraud and abuse laws (and comparable laws in foreign jurisdictions) may result in criminal, civil and administrative sanctions, including fines, damages, civil monetary penalties (which may be material in amount) and exclusion from federal healthcare programs (including Medicare and Medicaid). Any action initiated against us for violation of these laws, even if we successfully defend against it, could require the expenditure of significant resources and generate negative publicity, which could materially adversely affect our ability to operate our business and our financial results.

Finally, the FDA, the EU and EU Member States and the MHLW impose restrictions on the promotion and marketing of drug products and prohibit pharmaceutical manufacturers from promoting products for indications other than those cleared or approved by regulatory authorities or for use in manner that is not consistent with the product label approved by regulatory agencies, or off-label promotion. In certain instances, physicians are, however, in their medical judgment permitted to use products for unapproved purposes and we are aware of such uses of SOLIRIS. For information regarding a recent MHLW inquiry focused on our communication efforts regarding the proper use of SOLIRIS in Japan for aHUS, see Note 18, *"Commitments and Contingencies"* to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. 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 or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, product withdrawal or recall, injunction, seizure, civil fine and criminal penalties. It is also possible that other enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false or fraudulent claims for payment of government funds.

The sales and marketing practices of the pharmaceutical industry have been the subject of increased scrutiny from authorities such as the DOJ, and we expect that this trend may continue and may increase. If the government or the courts determine that we breached any of these sales and marketing laws, we may be subject to penalties identified above. Any action against us for violation of these laws, even if we successfully defend against them, also could cause us to incur significant legal expenses, harm our reputation and divert our management's attention from the operation of our business.

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

We are subject to the FCPA, the U.K. Bribery Act and other anti-corruption laws and regulations that generally prohibit companies and their intermediaries from making improper payments to government officials and/or other persons for the purpose of obtaining or retaining business and we operate in countries that are recognized as having a greater potential for governmental and commercial corruption. While we have, 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. 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 seek information related to our recalls of specific lots of SOLIRIS and related securities disclosures. In December 2016, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents relating generally to our support of certain 501(c)(3) organizations (as described in Note 18, *Commitments and Contingencies* to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q). We settled this investigation with the DOJ and the Office of Inspector General of the U.S. Department of Health and Human Services in April 2019 which resulted in a payment to the government of $13.1. In May 2017, Brazilian authorities seized records and data from our Sao Paulo, Brazil offices as part of an investigation being conducted into our Brazilian operations. In October 2018, the MHLW conducted an inspection of our Japanese operations and in March 2019, the MHLW indicated that its investigation is complete. We are cooperating with the open investigations. 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 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 and the October 2018 investigation by the MHLW has been closed by the MHLW, 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 stricter or greater than the terms or amounts 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.

Changes in healthcare laws and implementing regulations, as well as changes in healthcare policy, may affect coverage and reimbursement of our products in ways that we cannot currently predict and these changes could adversely affect our business and financial condition.

In the U.S., there have been a number of legislative and regulatory initiatives focused on containing the cost of healthcare. The PPACA substantially changed the way healthcare is financed by both governmental and private insurers in the U.S., and significantly impacts the pharmaceutical industry. The PPACA contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under health insurance exchanges, expansion of the 340B program, expansion of state Medicaid programs, fraud and abuse enforcement and rules governing the approval of biosimilar products (and allowing biosimilars access to the market in accordance with the FDA's Biosimilars Action Plan). These changes may impact existing government healthcare programs and may result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. In 2016, CMS implemented changes to the Medicaid Drug Rebate Program under the PPACA. Moreover, in the future, Congress could enact legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate Program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate Program has and may continue to increase our costs and the complexity of compliance, has been and may be time-consuming, and could have a material adverse effect on our results of operations.

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

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

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

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 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. The announcement or adoption of regulatory or legislative proposals could delay or prevent our entry into new markets, affect our reimbursement or sales in the markets where we are already selling our products and materially harm our business, financial condition and results of operations.

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

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate Program and we have obligations to report the average sales price under the Medicare program. Under the Medicaid Drug Rebate Program, we are required to pay a rebate to each state Medicaid program for quantities of our products that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our products under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS. Any failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results.

Pricing and rebate calculations vary among products and programs. The calculations, including those in connection with the Medicaid Drug Rebate Program and 340B drug pricing program (as described further below) are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. We cannot assure you that our submissions will not be found by CMS or other applicable government authorities to be incomplete or incorrect. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. For example, if we become aware that our reporting to CMS for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due, and CMS may request or require restatements for earlier periods as well. Such restatements and recalculations increase our costs for complying with the laws and regulations governing these programs, including the Medicaid Drug Rebate Program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities under the 340B pricing program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, civil monetary penalties can be applied if we are found to have knowingly submitted any false pricing information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, or if we fail to submit the required pricing data on a timely basis. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. If a governmental authority, such as CMS, were to take any of the foregoing actions, our business and results of operations may be negatively impacted.

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

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The 340B pricing program is described in Pharmaceutical Pricing and Reimbursement in Item 1 Business in our Annual Report on Form 10-K for the year ended December 31, 2018. The 340B ceiling price is calculated using a statutory formula, which is based on, among other prices, the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program. We are a participant in the 340B drug pricing program and are, for the applicable covered entities, subject to the price ceiling. Any changes to the 340B drug pricing program, including:

- the method of calculating the 340B ceiling price for our products;
- any expansion of the entities that qualify as covered entities; and
- any requirement that participating manufacturers agree to provide 340B discounted pricing on drugs used in an inpatient setting;

could have a material and negative impact our revenue and 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.

In addition, the agreement that manufacturers must sign to participate in the 340B pricing program obligates a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs.

Beyond the Public Health Service's 340B drug pricing program, federal law requires that a company must participate in the Department of Veterans Affairs Federal Supply Schedule (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, 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, govern the collection, use, disclosure, and protection of personal information. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. EU Member States and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EC adopted the EU Data Protection Directive, as implemented into national laws by the EU Member States, which imposes strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from different EU Member States have interpreted the privacy laws differently, which adds to the complexity of processing personal data in the EU, and guidance on implementation and compliance practices are often updated or otherwise revised. Any failure to comply with the rules arising from the EU Data Protection Directive and related national laws of EU Member States could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

In May 2016, the EU formally adopted the General Data Protection Regulation, which applies in all EU Member States and went into effect on May 25, 2018 and replaced the EU Data Protection Directive on that date. The regulation introduces new data protection requirements in the EU and substantial fines for breaches of the data protection rules. It increases our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules.

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

We are increasingly dependent on our information technology systems and infrastructure for our business. We collect, store and transmit sensitive information including intellectual property, proprietary business information and personal information in connection with business operations. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack by third parties with a wide range of motives and expertise, including organized criminal groups, “hacktivists,” patient groups, disgruntled current or former employees and others. Cyber-attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance. We have implemented information security measures designed to protect patients’ personal information against the risk of inappropriate and unauthorized external use and disclosure. However, despite these measures, and due to the ever changing information cyber-threat landscape, we may be subject to data breaches through cyber-attacks. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. If our 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. Any one of these events could cause our business to be materially harmed and our results of operations may be adversely impacted.

Negative public opinion and increased regulatory scrutiny of recombinant and transgenic products, genetically modified products and genetically modified animals generally may damage public perception of our current and future products or adversely affect our ability to conduct our business and obtain regulatory approvals we may seek.

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

Risks Related to Intellectual Property

If we cannot obtain new patents, maintain our existing patents and protect the confidentiality and proprietary nature of our trade secrets and other intellectual property, our business and competitive position may be harmed.

Our success depends in part on our ability to obtain and maintain patent and regulatory protections for our products and investigational compounds, to preserve our trade secrets and other proprietary rights, to operate without infringing the proprietary rights of third parties and to prevent third parties from circumventing our rights. Due to the time and expense of bringing new products through development and regulatory approval to the marketplace, there is particular importance in obtaining patent and trade secret protection for significant new technologies, products and processes.

We have and may in the future obtain patents or the right to practice patents through ownership or license. Our patent applications may not result in the issue of patents in the U.S. or other countries. In addition, a patent may be issued in one country, but a counterpart patent may not be issued in another country. For example, the European Patent Office in September 2019 rejected a patent application relating to the composition of matter for SOLIRIS , while a similar patent was granted in the U.S. and Japan. We are considering whether to have this decision reviewed on appeal.

Even if a patent is issued, that is not conclusive as to inventorship, scope, validity or enforceability and therefore that patent may not afford adequate (or any) protection for our products. Third parties may challenge our patents, and have challenged our patents in the past and, in some cases have been successful in such challenges. For example, on January 21, 2019, the Opposition Division of the European Patent Office determined, following multi-party opposition proceedings, to revoke our European patent No. 2359834, which relates to the formulation of SOLIRIS and on August 30, 2019 the U.S. Patent and Trademark Office instituted inter partes review of three of our patents that relate to SOLIRIS. In addition to the protections afforded by patents (which, as noted above are subject to challenge and potentially invalidation), certain of our products do benefit from regulatory protections for applicable indications in certain geographies that allow such protections. For example, SOLIRIS is protected in Europe by orphan drug exclusivity through late 2023 for aHUS and until 2027 for gMG.

If any of our patents are narrowed, invalidated, revoked or become unenforceable, competitors may develop and market products similar to ours that do not conflict with or infringe our patents rights, which could have a material adverse effect on our financial condition.

We may also finance and collaborate in research conducted by government organizations, hospitals, universities or other educational or research institutions. Such research partners may be unwilling to grant us exclusive rights to technology or products developed through such collaborations. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties. Our products and product candidates are expensive and time-consuming to test and develop. Even if we obtain and maintain patents, our business may be significantly harmed if the patents are not broad enough to protect our products from copycat products.

Significant legal questions exist concerning the extent and scope of patent protection for biopharmaceutical products and processes in the U.S. and elsewhere. Accordingly, there is no certainty that patent applications owned or licensed by us will issue as patents, or that our issued patents will afford meaningful protection against competitors. Once issued, patents are subject to challenge through both administrative and judicial proceedings in the U.S. and other countries. Such proceedings include re-examinations, inter partes reviews, post-grant reviews and interference proceedings before the U.S. Patent and Trademark Office, as well as opposition proceedings before the European Patent Office and other non-U.S. patent offices. Certain countries have laws that provide stronger bases for challenging third party patent rights than are available to challenge patents in other countries. Therefore, we may be able to defend our patents against a third party claim in one country but counterpart patents may be invalidated in other countries and we may be able to invalidate a third-party patent in one country but not invalidate its counterpart patents in other countries. Litigation may be required to enforce, defend or obtain our patent and other intellectual property rights. Any administrative proceeding or litigation could require a significant commitment of our resources and, depending on outcome, could adversely affect the scope, validity or enforceability of certain of our patent or other proprietary rights.

In addition, our business requires using sensitive technology, techniques and proprietary compounds that we protect as trade secrets. However, we may also rely heavily on collaboration with, or discuss the potential for collaboration with, suppliers, outside scientists and other biopharmaceutical companies, including in connection with development efforts such as those with Complement Pharma and Dicerna. Collaboration and discussion of potential collaboration present a strong risk of exposing our trade secrets. If our trade secrets were exposed, we may lose the protection and potential exclusive rights afforded by trade secret law, and such exposure may likely help our competitors and allow them to access technology without restriction and adversely affect our business prospects.

If we are found to be infringing third party patents, we may be forced to pay damages to the patent owner and/or obtain a license to continue the manufacture, sale or development of our products. If we cannot obtain a license, we may be prevented from the manufacture, sale or development of our products or product candidates, which may adversely affect our business.

Parts of our technology, techniques, proprietary compounds and potential product candidates, including those which are or may be in-licensed, may be found to infringe patents owned by or granted to others. We have and may in the future receive notices claiming our products infringe third party patents and third parties have and may in the future file civil lawsuits against us claiming infringement of their intellectual property rights. In late-2018, Chugai Pharmaceutical Co., Ltd. filed suits in the U.S. and Japan alleging that ULTOMIRIS infringes a U.S. and two Japanese patents, respectively, held by Chugai (See Note 18, *Commitments and Contingencies* to the footnotes to the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for information regarding these legal proceedings with Chugai). Additional third parties may claim that the manufacture, use or sale of our products or product candidates infringes patents owned or granted to such third parties. We are aware of patents owned by third parties that might be claimed by such third parties to be infringed by the development and commercialization of our products or investigational compounds. In respect to some of these patents, we have obtained licenses, or expect to obtain licenses. However, with regard to other patents, we have determined in our judgment that:

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

Any holder of these patents or other patents covering similar technology could sue us for damages and seek to prevent us from manufacturing, selling or developing our products. Intellectual property disputes, such as those initiated by Chugai, can be costly and time consuming to defend. Prior to launch of a new product (or an existing product for a new indication), for various reasons, a patent owner may not be able to assert its patent rights so it is possible that any potential challenges to our products may be made after a product has been commercialized and not necessarily while the product is in development, in clinical trials or during the regulatory review process. If we cannot successfully defend against any future actions or conflicts, if they arise, we may incur substantial legal costs and may be liable for damages, be required to obtain costly licenses or be forced to stop manufacturing, using or selling our products (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), which may adversely affect our business. We may seek to obtain a license prior to or during legal actions in order to reduce the risks in connection with product launches (or at a later time 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 addition, even if we obtained a license, it would likely be non-exclusive and any competitive advantage resulting from the licensed technology may be of limited value and the same technology could be utilized by competitors.

In some instances, we believe we may prevail in a patent infringement action. There can, however, be no assurance that the court will agree with our position or that they will decide this or any other infringement case in our favor. Nor can we be certain that, if we do not prevail in litigation, that we may be able to obtain a license to any third-party patent on commercially reasonable terms or at all; successfully develop non-infringing alternatives on a timely basis (or at all); or license alternative non-infringing technology, if any exists, on commercially reasonable terms (or at all). Any impediment to our ability to manufacture, use or sell approved forms of our products or our product candidates could have a material adverse effect on our business and prospects.

It is possible that we could lose market exclusivity for a product earlier than expected, which may harm our competitive position.

In our industry, much of an innovative product's commercial value is realized while it has market exclusivity. When market exclusivity expires and biosimilar or generic versions of the product are approved and marketed, there can be substantial decline in the innovative product's sales.

Market exclusivity for our products is based upon patent rights and certain regulatory forms of protection. The scope of our product patent rights vary from country to country and is dependent on the availability of meaningful legal remedies in each country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or loss of such rights, could be material to our business. In some countries, patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents or we did not file patents in those markets. Also, the patent environment is unpredictable and the validity and enforceability of patents cannot be predicted with certainty. Absent relevant patent protection for a product, once regulatory exclusivity periods expire, biosimilar or generic versions of the product can be approved and marketed. For example, in 2019, a SOLIRIS biosimilar was approved in Russia for the treatment of patients with PNH and aHUS. Even prior to the expiration of regulatory exclusivity, a competitor could seek to obtain marketing approval by submitting its own clinical trial data.

The market exclusivity of our products may be impacted by competitive products that are either innovative or biosimilar or generic copies. In our industry, the potential for biosimilar challenges has been an increasing risk to product market exclusivity. U.S. law includes an approval pathway for biosimilar versions of innovative biological products. Under the pathway, the FDA may approve products that are similar to (but not generic copies of) innovative biologics on the basis of less extensive data than is required for a full biologic license application. After an innovator has marketed its product for four years, other manufacturers may apply for approval of a biosimilar version of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory market exclusivity (i.e., the biosimilar product cannot be approved before 12 years after the innovative biological product). The law also provides a mechanism for innovators to enforce their patents that protect their products and for biosimilar applicants to challenge the patents. Such litigation may begin as early as four years after the innovative biological product is first approved by the FDA. Pathways for biosimilar products also exist in many other markets, including Europe, Japan and Russia. Other companies are developing and advancing SOLIRIS biosimilar programs, including conducting clinical trials. Competition, including from biosimilars approved for marketing, may likely result in a decrease in prices, increased promotion efforts and lower margins for our products. In addition, approval of a biosimilar that is substitutable for one of our products may increase the risk of accelerated market penetration by that biosimilar. Further, if patients or healthcare providers do not believe that ULTOMIRIS provides a compelling profile for patient conversion from SOLIRIS, a SOLIRIS biosimilar may not only be expected to have a material and negative impact on our SOLIRIS revenues and margins (which accounted for a significant percentage of our revenue in 2018), it may also have a material impact on ULTOMIRIS revenue and margins and the ability of ULTOMIRIS to gain market acceptance.

Our other products are also at risk from biosimilars. Other than SOLIRIS for the treatment of gMG and SOLIRIS and ULTOMIRIS as a treatment for PNH 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 novel therapy, our market share and our revenues could decline, particularly if the competitive product is perceived to be more effective or is less expensive than our product.

Risks Related to Our Common Stock

Our stock price is volatile.

The trading price of our common stock has been volatile and may continue to be volatile in the future. Many factors could have an impact on our stock price, including fluctuations in our or our competitors’ operating results, clinical trial results or adverse events associated with our products 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 SEC/DOJ investigation and the Chugai lawsuits alleging patent infringement, acquisitions or other strategic transactions, and the perceptions of our investors that we are not performing or meeting expectations. 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.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

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

The following table summarizes our common stock repurchase activity during the third quarter 2019:

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 Program
July 1-31, 2019	0.1	$ 124.1	0.1	$ 389.6
August 1-31, 2019	1.4	$ 112.2	1.4	$ 234.7
September 1-30, 2019	1.6	$ 104.3	1.6	$ 67.9
Total	3.1	$ 113.5	3.1	

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 the repurchase program, which superseded all prior repurchase programs. The repurchase program does not have an expiration date and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at our discretion.

On October 22, 2019, the Board of Directors approved a new share repurchase authorization of up to $1,000.0. The repurchase program does not have an expiration date and we are not obligated to acquire a particular number of shares of common stock. The repurchase program may be discontinued at any time at our discretion.

Item 5. OTHER INFORMATION.

None.

Item 6. EXHIBITS.

(a) **Exhibits:**

10.1 Employment Agreement, dated as of September 17, 2019, by and between Aradhana Sarin and Alexion Pharmaceuticals, Inc.**

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. Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 formatted in eXtensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018, (ii) the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2019 and 2018, (iii) the Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2019 and 2018, (iv) the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2018, (v) the Condensed Consolidated Statements of Changes in Stockholders' Equity the three and nine months ended September 30, 2019 and 2018, and (vi) Notes to Condensed Consolidated Financial Statements.

** Indicates a management contract or compensatory plan or arrangement required to be filed pursuant to Item 6 of Form 10-Q.

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: October 23, 2019		Ludwig N. Hantson, Ph.D. Chief Executive Officer (principal executive officer)
	By:	/s/ Paul J. Clancy
Date: October 23, 2019		Paul J. Clancy Executive Vice President and Chief Financial Officer (principal financial officer)

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (the "Agreement") dated as of September 17, 2019 by and between Alexion Pharmaceuticals, Inc., a Delaware corporation (the "Company"), on behalf of itself and its subsidiaries, related and affiliated companies, and all of their respective divisions, successors, and assigns (collectively, Alexion"), and Aradhana Sarin (the "Employee").

WHEREAS, the Company agrees to employ the Employee, subject to the terms and conditions contained in this Agreement; and

WHEREAS, the Employee agrees to accept employment with the Company, subject to the terms and conditions contained in this Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements herein contained, the parties agree as follows:

1. Employment Duties and Acceptance.

(a) The Company hereby employs the Employee, for the Term (as hereinafter defined), to render full-time services to the Company as Executive Vice President. Effective as of a date to be determined in the Company's discretion, Employee shall be appointed as the Company's Executive Vice President, Chief Financial Officer and shall perform the duties of such position, or such other position as the Employee shall reasonably be directed by the Company to perform. The Employee shall report to the Chief Executive Officer of the Company. The Employee hereby accepts such employment and agrees to render the services described above.

(b) During the Term, the Employee shall devote the Employee's full business time and best efforts, business judgment, skill and knowledge exclusively to the advancement of the business and interests of the Company and its Affiliates and to the discharge of the Employee's duties and responsibilities hereunder. Notwithstanding anything to the contrary herein, although the Employee shall provide services as a full-time employee, it is understood that the Employee, with the written consent of the Chief Executive Officer, may, without the receipt of remuneration: (1) have non full-time academic appointments; (2) participate in professional activities; (3) publish academic articles; and (4) participate in community and/or philanthropic activities (collectively, "Permitted Activities"); provided, however, that such Permitted Activities do not interfere with the Employee's duties to the Company, and, in the course of such Permitted Activities, the Employee does not in any way use or disclose Confidential Information or otherwise violate Sections 4 or 5 hereof.

2. Term of Employment.

The term of the Employee's employment under this Agreement shall commence as of September 17, 2019 (the "Effective Date") and shall end on the third anniversary thereof, unless sooner terminated pursuant to Section 6, 7 or 8 of this Agreement. Notwithstanding the foregoing, unless notice is given by the Employee or the Company at least sixty (60) days prior to the expiration of the Term of this Agreement (or at least sixty (60) days prior to the expiration of any extension hereof), the Term of the Agreement shall be automatically extended by one (1) year from the date it would otherwise end (whether upon expiration of the original Term or any extension(s) thereof), unless sooner terminated pursuant to Section 6, 7 or 8 hereof. The term of this Agreement as from time to time extended or renewed is hereafter referred to as "the Term of this Agreement" or "the Term".

3. Compensation and Benefits

(a) As compensation for services to be rendered pursuant to this Agreement, the Company agrees to pay the Employee, during the Term, an annual base salary of $800,000.00 (as it may be adjusted from time to time, the "Base Salary"), payable in accordance with its regular payroll practices. The Employee's Base Salary hereunder shall be reviewed in accordance with the regular performance review practices of the Board of Directors of the Company (the "Board") or the Leadership and Compensation Committee thereof (the "Committee") during the Term of the Agreement for increase at the discretion of the Board or the Committee.

(b) The Company agrees that the Employee shall be eligible for an annual performance bonus from the Company with respect to each fiscal year of the Company that ends during the Term, pursuant to the Company's management incentive bonus program in effect from time to time (such plan, as so in effect, the "Bonus Plan"). The Employee's target bonus under the Bonus Plan will be 70% of the Base Salary. The actual amount of any such bonus payable to the Employee under the Bonus Plan shall be determined by the Board or the Committee and paid by the Company in accordance with the terms of the Bonus Plan, subject to the Employee's remaining employed on the date that bonuses are paid under the Bonus Plan, except as otherwise expressly provided herein.

(c) The Employee shall be eligible to receive grants of stock-based awards under the equity incentive plan or program maintained by the Company as in effect from time to time (such plan, as so in effect, the "Equity Plan") in the discretion of the Board or the Committee. Any such stock-based award will be subject to the terms of the Equity Plan, the terms of the award agreement evidencing such stock-based award, and such other restrictions and limitations as are generally applicable to shares of the Company's common stock or Company employees or otherwise imposed by law.

(d) The Company shall pay or reimburse the Employee for all reasonable, customary and necessary business expenses actually incurred or paid by the Employee during the Term in the performance of services under this Agreement, subject to travel and other policies and such reasonable substantiation and documentation as may be required by the Company from time to time, provided that (1) the amount of expenses eligible for reimbursement during any calendar year may not affect the expenses eligible for reimbursement in any other taxable year, (2) reimbursement is made not later than December 31 of the calendar year following the calendar year in which the expense was incurred, and (3) the right to reimbursement is not subject to liquidation or exchange for any other benefit.

(e) During the Term, the Employee shall be eligible to participate in all employee benefit plans from time to time in effect for employees of the Company generally, except to the extent such plans are duplicative of benefits otherwise provided under this Agreement (e.g., a severance pay plan). Participation in such employee benefit plans will be subject to the terms of the applicable plan documents and generally applicable Company policies, as the same may be in effect from time to time, and any other restrictions or limitations imposed by law.

(f) During the Term, the Employee shall be eligible to earn paid vacation of four (4) weeks and for two (2) personal days, accruing over each calendar year, to be taken in accordance with applicable Company policy.

4. Confidentiality.

The Employee acknowledges and agrees that the Employee is bound by the terms and conditions of the Proprietary Information and Inventions Agreement that the Employee separately entered into with the Company and as may be amended from time to time (the "Proprietary Information and Inventions Agreement"). Notwithstanding any other provision of this Agreement, the Employee shall continue to be bound by the terms of such Proprietary Information and Inventions Agreement which shall survive the termination of this Agreement in accordance with its terms. Without limiting the Employee's obligations under the Proprietary Information and Inventions Agreement, the Employee agrees that during the Employee's employment with the Company, the Employee will have access to a variety of trade secret and/or confidential and proprietary information relating to Alexion's business that is not generally available to the public through legitimate means, including but not limited to information relating to business opportunities, operations, cost and pricing data, strategies, forecasts, customer lists, improvements, technologies, techniques, processes, research, methods, procedures, testing systems, assays, compounds, molecules, organisms, gene sequences, cell lines, other reagents, uses of any of the foregoing, manufacture of any of the foregoing, computer software and programs (including source code and related documentation), test and/or experimental data and results, specifications, laboratory notebooks and drawings, and/or other information which has not been made available to the general public by senior management (all of which information is collectively referenced as "Confidential Information"). The Employee acknowledges and agrees that such Confidential Information is Alexion property, and shall not, directly or indirectly, use or disclose it for the Employee's own or a third party's benefit.

5. Non-Competition, Non-Solicitation and Non-Disparagement.

In consideration of (i) the Employee's employment or continued employment; (ii) access to the Company's key business relationships and Confidential Information; (iii) the ability to participate in Company-sponsored programs or plans; and/or (iv) other fair and reasonable mutually agreed-upon consideration as set forth herein and provided to the Employee, the Employee agrees to the following restrictions, including without limitation the non-competition restriction in Section 5(d) below, which the Employee acknowledges are reasonable and necessary to protect Alexion's interests.

(a) Exclusive Services. During the Term, the Employee shall not (i) provide any services, directly or indirectly, to any other business or commercial entity without the consent of the Company, which may be withheld in the Company's sole discretion, or (ii) participate in the formation of any business or commercial entity without the consent of the Company, which may be withheld in the Company's sole discretion; provided, however, that nothing contained in this Section 5(a) shall be deemed to prohibit the Employee from acquiring, solely as an investment, shares of capital stock (or other interests) of any publicly traded corporation not exceeding 2% of such corporation's then outstanding shares of capital stock, and provided further, that nothing contained herein shall be deemed to limit the Employee's Permitted Activities pursuant to Section 1(b) hereof.

(b) Non-Recruitment of Restricted Employees. During the Term and during the Restricted Period following the termination of the Employee's employment for any reason, voluntary or involuntary, the Employee shall not, directly or indirectly: (i) solicit or recruit, or attempt to solicit or recruit, or otherwise encourage or entice, any Restricted Employee to end employment with or engagement by (or otherwise diminish such Restricted Employee's relationship with) Alexion; or (ii) hire or attempt to hire a Restricted Employee; or (iii) in any other way interfere with a Restricted Employee's relationship with Alexion. The "Restricted Period" means twelve (12) months, which shall be extended to two (2) years upon the Employee's breach of the Employee's fiduciary duty to Alexion and/or unlawful taking, physically or electronically, of property belonging to Alexion. A "Restricted Employee" means a person who is employed or engaged by Alexion as an employee or independent contractor (and has not received advance notice of Alexion's termination of his or her employment or engagement by Alexion) and: (i) with whom the Employee had business-related contact within the twenty-four (24) month period prior to the date of the Employee's termination of employment; or (ii) about whom the Employee had access to Confidential Information within the twenty-four month period prior to the date of the Employee's termination of employment.

(c) Non-Solicitation of Restricted Partners. During the Term and during the Restricted Period following the termination of the Employee's employment for any reason, voluntary or involuntary, the Employee shall not, directly or indirectly, call on, contact, service, or solicit, or attempt to call on, contact, service, or solicit, any Restricted Partner for the purpose of researching, developing, producing, distributing, marketing, providing, selling or commercializing a Competing Product. A "Restricted Partner" means a vendor, supplier, business partner, customer, or potential customer of Alexion: (i) whom the Employee called on, contacted, collaborated, serviced, or solicited for the research, development, production, distribution, marketing, providing, selling or commercialization of an Alexion product, product candidate, process or service within the twenty-four month period prior to the date of the Employee's termination of employment; or (ii) whose dealings with Alexion the Employee coordinated or supervised within the twenty-four month period prior to the date of the Employee's termination of employment; or (iii) about whom the Employee had access to Confidential Information within the twenty-four month period prior to the date of the Employee's termination of employment. A "Competing Product" is a product, product candidate, process or service that is or would be directly or indirectly competitive with a product, product candidate, process or service with which the Employee, within the twenty-four month period prior to the Employee's termination of employment, either worked or about which the Employee acquired Confidential Information.

(d) Non-Competition. During the Term and for the Restricted Period following the termination of the Employee's employment (other than termination by the Company without Cause or due to layoff), the Employee shall not, directly or indirectly: (i) own, operate, finance, control, or participate in the formation of, any Competing Organization in the Restricted Territory other than as a passive owner of not more than two percent (2%) of the outstanding shares of capital stock of any publicly traded corporation; or (ii) render services to, give advice to, consult with, or be employed by a Competing Organization in the Restricted Territory if such services, advice, consultation, or employment involve: (1) the research, development, production, distribution, marketing, providing, selling or commercialization of Competing Products; or (2) assisting others in the research, development, production, distribution, marketing, providing, selling or commercialization of Competing Products; or (3) developing or implementing strategies to compete with Alexion with respect to Competing Products; or (4) directly or indirectly supervising or managing employees or other personnel who compete with Alexion with respect to Competing Products; or (5) utilizing or disclosing Confidential Information. A "Competing Organization" means any person or entity that is engaged in, or about to become engaged in, the research, development, production, distribution, marketing, providing, selling or commercialization of a Competing Product. The "Restricted Territory" means the United States of America, and any other country (or political subdivision thereof) in which Alexion conducts business and in the twenty-four month period prior to the date of the Employee's termination of employment: (i) in which the Employee performed services for Alexion; or (ii) over which the Employee had sales or management responsibilities for Alexion; or (iii) in which Alexion employed or engaged Restricted Employees whom the Employee directly or indirectly supervised or managed or with whom the Employee collaborated; or (iv) about which the Employee had access to Confidential Information.

(e) Non-Disparagement. Except as set forth in Section 5(f) below, at no time during the Term of this Agreement or thereafter, regardless of the reason for termination of the Employee's employment, will the Employee do or say anything that disparages the Company, its Affiliates, its business, its management, its employees or its products in communications with any customer, client or the public. The Employee will, furthermore, not otherwise do or say anything that could disrupt the good morale of employees of the Company or any of its Affiliates, or that harms the interests or reputation of the Company or any of its Affiliates.

(f) Non-Interference. Nothing in this Agreement or the Proprietary Information and Inventions Agreement limits, restricts, or in any other way affects the Employee's communicating with any governmental agency, entity, or official regarding an alleged violation of federal or state law or regulation; communicating with any official or staff person of a governmental agency or entity, concerning matters relevant to the governmental agency or entity; or from otherwise making disclosures that are protected under applicable law, including, without limitation, the Defend Trade Secrets Act and any rule or regulation promulgated by the Securities and Exchange Commission (SEC), the Equal Employment Opportunity Commission (EEOC), or any other federal, state, or local government agency. By the Employee's signature below, the Employee acknowledges that the Company hereby has provided the Employee with written notice that the Defend Trade Secrets Act, 18 U.S.C. § 1833(b), provides an immunity for the disclosure of a trade secret to report suspected violations of law and/or in an anti-retaliation lawsuit, as follows: (1) An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (2) An individual who files a lawsuit against an employer for retaliation for reporting a suspected violation of law may disclose the trade secret to his or her attorney and use the trade secret information in the court proceeding, if the individual: (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order.

(g) Acknowledgment of Restrictions. The Employee acknowledges that the Employee has read and considered all the terms and conditions of this Agreement, including the restraints imposed upon the Employee pursuant to Sections 5(a)-(f) above. The Employee agrees without reservation that these restraints are necessary for the reasonable and proper protection of the Company and its Affiliates, including but not limited to the Company's trade secrets, Confidential Information, and customer goodwill, and are reasonable in respect to subject matter, length of time, and geographic area. If the Employee commits a breach, or threatens to commit a breach, of any of the provisions of Sections 4 or 5, the Company shall have the right and remedy to have the provisions of this Agreement specifically enforced by any court having equity jurisdiction, it being acknowledged and agreed that any such breach or threatened breach will cause irreparable injury to the Company and that money damages may not provide an adequate remedy to the Company. The Employee therefore agrees that the Company, in addition to any other remedies available to it, shall be entitled to preliminary and permanent injunctive relief against any breach or threatened breach by the Employee of any of the provisions of Sections 4 or 5, without having to post bond. So that the Company may enjoy the full benefit of the covenants contained above, the Employee agrees that the Restricted Period shall be tolled, and shall not run, during the period of any breach by the Employee of such covenants. The Employee agrees that each of the Company's Affiliates shall have the right to enforce all of the Employee's obligations to that Affiliate under this Agreement. No claimed breach of this Agreement or other violation of law attributed to Alexion, or change in the nature or scope of the Employee's employment or other relationship with Alexion shall operate to excuse the Employee from the performance of the Employee's obligations under this Agreement. The provisions of this Section 5 will remain in full force and effect regardless of any changes to the Employee's position, duties, authority, title, reporting relationship or principal work location.

(h) Modification. If any of the covenants contained in this Section 5, or any part thereof, is held to be unenforceable because of the duration or scope of such provision or the area covered thereby, the parties agree that the court making such determination shall have the power to reduce the duration and/or area of such provision, and that the parties intend for the court to modify the duration and/or area of such provision to the maximum extent permitted by law. The parties agree that in its reduced form, such provision shall then be enforceable.

(i) Severability. If any of the covenants contained in this Section 5, or any part thereof, is hereafter construed to be invalid or unenforceable, the same shall not affect the remainder of the covenant or covenants, which shall be given full effect without regard to the invalid portions. In the event that the courts of any state shall hold any such covenant wholly unenforceable by reason of the breadth of such scope or otherwise, it is the intention of the parties hereto that such determination not bar or in any way affect the Company's right to the relief provided above in the courts of any other states within the geographical scope of such other covenants, as to breaches of such covenants in such other respective jurisdictions, the above covenants as they relate to each state being, for this purpose, severable into diverse and independent covenants.

6. Termination by the Company.

The Company may terminate the employment of the Employee as follows during the Term of this Agreement if any one or more of the following shall occur:

(a) Death. If the Employee shall die during the Term, the Employee's employment hereunder shall automatically terminate.

(b) Disability. If the Employee shall become physically or mentally disabled so that the Employee is unable substantially to perform the essential functions of the Employee's position even with any reasonable accommodation required by law for (1) a period of 120 consecutive days, or (2) for shorter periods aggregating to 180 days during any twelve (12) month period, then the Company may terminate the Employee's employment hereunder upon written notice given by the Company to the Employee.

(c) For Cause. If the Employee acts, or fails to act, in a manner that provides Cause for termination, the Company may at any time terminate the Employee's employment hereunder upon written notice given by the Company to the Employee. For purposes of this Agreement, the term "Cause" means (1) the Employee's indictment for, or conviction of, a crime involving moral turpitude, or any other crime or serious offense involving money or other property which constitutes a felony in the jurisdiction involved, (2) the Employee's willful neglect or failure to discharge duties (including fiduciary duties), responsibilities and obligations with respect to the Company hereunder; provided such neglect or failure, if susceptible of cure, remains uncured for a period of thirty (30) days after written notice describing the same is given to the Employee; provided further that isolated and insubstantial neglect or failures shall not constitute Cause hereunder, (3) the Employee's material breach of this Agreement or any other material agreement with the Company, (4) the Employee's actual or threatened violation of Sections 4 or 5 hereof or the Employee's breach of any confidentiality provisions contained in the Proprietary Information and Inventions Agreement, (5) any act of fraud or embezzlement by the Employee involving the Company or any of its Affiliates, or (6) the Employee's material violation of Alexion's code of conduct, or similar code of business conduct, or any written employment policies of Alexion, each, as in effect from time to time.

(d) Without Cause. The Company may at any time terminate the Employee's employment hereunder without Cause upon written notice given by the Company to the Employee.

7. Termination by the Employee.

(a) Other than for Constructive Termination. The Employee may terminate Employee's employment hereunder at any time, for any reason and for no reason, upon not less than sixty (60) days' prior written notice to the Company.

(b) Constructive Termination. The Employee may terminate Employee's employment hereunder upon written notice to the Company if any one or more of the following shall occur, each of which is deemed a Constructive Termination:

(i) a material breach of the terms of this Agreement by the Company and such breach continues uncured for thirty (30) days after the Employee first gives written notice of such breach to the Company;

(ii) a written notice by the Company of its intent to relocate the Employee's place of employment to a location that is both (x) not the Employee's home, and (y) is beyond a 30-mile radius of the Employee's principal work location; or

(iii) a material breach by the Company of any other material agreement with the Employee and such breach continues uncured for thirty (30) days after the Employee first gives written notice of such breach to the Company.

Notwithstanding the foregoing, the Employee shall not be deemed to have a "Constructive Termination" unless the Employee gives the Company written notice of such a condition within ninety (90) days after such condition first comes into existence, the Company fails to remedy such condition within thirty (30) days after receiving the Employee's written notice and the Employee terminates Employee's employment not later than thirty (30) days after the Company so fails to remedy such condition.

8. Termination by Employee for Good Reason Following a Change in Control.

In addition to Section 7(b)(i) through (iii) above, during the period commencing on the Change in Control (as defined in Section 14) and ending on the eighteen (18) month anniversary of such Change in Control, the Employee may terminate Employee's employment upon expiration of ninety (90) days' prior written notice if "Good Reason" exists. For this purpose, termination by the Employee for "Good Reason" shall mean a termination by the Employee of Employee's employment hereunder following the initial occurrence, without Employee's prior written consent, of any of the following events, unless the Company or its successor fully cures all grounds for such termination within thirty (30) days after receipt of the Employee's written notice (it being understood that a termination of employment hereunder shall only be for Good Reason if the Employee terminates his employment not later than thirty (30) days after the Company so fails to cure such grounds):

(a) any material adverse change in the Employee's authority, duties, titles or offices (including reporting responsibility), from those existing immediately prior to the Change in Control;

(b) a diminution of the Employee's Base Salary or annual bonus opportunity as provided for in Section 3; or

(c) the failure of the Company to obtain the assumption in writing of its obligation to perform this Agreement by any successor to all or substantially all of the assets of the Company upon a merger, consolidation, sale or similar transaction.

9. Severance and Benefit Continuation.

(a) Termination for Cause or Voluntary Termination. In the event of a termination of the Employee's employment by the Company for Cause pursuant to Section 6(c) hereof or by the Employee pursuant to Section 7(a) hereof, no severance or other termination pay or benefits shall be due to the Employee and the only obligation of the Company shall be to pay the Employee any accrued but unpaid Base Salary as of the date of termination and any accrued but unpaid vacation as of the date of termination (the "Accrued Obligations"), which amounts shall be paid to the Employee within thirty (30) days of the date of termination. In the event of a termination of the Employee's employment pursuant to Section 7(a), the Company may elect to waive the period of notice required by Section 7(a), or any portion thereof, and, if the Company so elects, the Company will pay the Employee's Base Salary for the period so waived. Upon a termination covered by this Section 9(a), the Employee shall have the same opportunity to continue group health benefits at the Employee's expense in accordance with the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA") as is available generally to other employees terminating employment with the Company. Any outstanding equity awards previously granted to the Employee under the Equity Plan shall be treated in accordance with the terms of the Equity Plan and any individual award agreements under which such equity awards were granted. A termination of the Employee's employment that occurs by reason of the Employee's notice to the Company of non-renewal of the Term under Section 2 hereof will be treated as a termination by the Employee under Section 7(a).

(b) Termination for Death or Disability. In the event of the a termination of the Employee's employment pursuant to Section 6(a) or Section 6(b) by reason of the death or disability of the Employee, in addition to the Accrued Obligations, the Company shall pay the Employee (or the Employee's estate in the event of a termination due to death), a pro-rata annual bonus for the year in which such termination of employment occurs, calculated by multiplying the Employee's target annual bonus by a fraction, the numerator of which is the number of days the Employee was employed during such year and the denominator of which is 365 and shall provide the Health Continuation Benefit Payment (as defined in Section 9(c)(ii)). In the event of a termination of the Employee's employment due to death, the Company shall also pay to the Employee's estate an amount equal to three (3) months of Base Salary. The pro-rata bonus, Health Continuation Benefit Payment and the Base Salary shall be paid as provided in Section 9(e) below. All equity awards for which the vesting schedule is based solely on the passage of time and continuation of employment ("Time-Vesting Equity Awards") previously granted to the Employee shall become vested and shall remain exercisable for such periods as provided under the terms of the Equity Plan and any individual award agreements under which such awards were granted. All other equity awards previously granted to the Employee will vest only to the extent provided in the Equity Plan and the award agreements evidencing such awards.

(c) Involuntary Termination Other Than for Cause, Voluntary Termination Following Constructive Termination, or Non-Renewal by the Company. If (1) the Company terminates the Employee's employment pursuant to Section 6(d) hereof, (2) the Employee terminates the Employee's employment pursuant to Section 7(b) hereof or (3) at the end of the Term of this Agreement the Employee shall cease to be employed by the Company by reason of the Company's decision not to renew the Term under Section 2 hereof ("Non-Renewal"), and in each case the termination of employment does not occur within eighteen (18) months following the consummation of a Change in Control of the Company, then, in addition to the Accrued Obligations:

(i) the Company shall pay the Employee 1.5 times the sum of (A) the Employee's Base Salary at the time of Employee's termination of employment plus (B) the amount equal to the Employee's target annual bonus for the year in which the termination of employment occurs. Subject to Section 9(g), such amounts will be paid to the Employee in accordance with Section 9(e) below; and

(ii) if the Employee (and Employee's eligible dependents, as applicable), as of the date of Employee's termination of employment, participate in the Company's group medical, dental and vision plans, the Company shall pay the Employee a lump-sum amount that, after all applicable taxes and withholdings are deducted, is the economic equivalent of the monthly health premiums paid by the Company on behalf of the Employee and Employee's eligible dependents immediately prior to the date of Employee's termination of employment multiplied by eighteen (18) (the "Health Continuation Benefit Payment"). Subject to Section 9(g), such amounts will be paid to the Employee in accordance with Section 9(e) below;

(iii) all Time-Vesting Equity Awards previously granted to the Employee on or about the Effective Date, if any, shall fully and immediately vest as of the date of termination of employment, and all other Time-Vesting Equity Awards that have both been previously granted to the Employee and are at least 50% vested as of the date of termination of employment shall fully and immediately vest as of the date of termination of employment; any such Time-Vesting awards that consist of stock options shall become exercisable immediately prior to such termination of employment and shall remain exercisable for such periods as provided under the terms of the Equity Plan and any individual award agreements under which such equity awards were granted; and

(iv) all equity awards, other than the Time-Vested Equity Awards, previously granted to and earned by the Employee and that are at least 50% vested as of the date of termination of employment, shall fully and immediately vest as of the date of termination of employment and become exercisable immediately prior to such termination of employment, and shall remain exercisable for such periods as provided under the terms of the Equity Plan and any individual award agreements under which such equity awards were granted.

(d) Involuntary Termination Other Than for Cause, Voluntary Termination Following Constructive Termination or for Good Reason, or Non-Renewal by the Company, Upon a Change in Control. In the event that (1) the Company terminates the Employee's employment pursuant to Section 6(d) hereof, (2) the Employee terminates Employee's employment following a Constructive Termination under Section 7(b) hereof or for Good Reason under Section 8 hereof, or (3) there is a Non-Renewal by the Company, and in each case the termination of employment or Non-Renewal occurs within eighteen (18) months following the consummation of a Change in Control of the Company, then, in addition to the Accrued Obligations:

(i) the Company shall pay the Employee two (2) times the sum of (A) the Employee's Base Salary at the time of Employee's termination of employment plus (B) the amount equal to the Employee's target annual bonus for the year in which the termination of employment occurs. The Company also shall pay the Employee a pro-rata annual bonus for the year in which such termination of employment occurs, calculated by multiplying the Employee's target annual bonus by a fraction, the numerator of which is the number of days the Employee was employed during such year and the denominator of which is 365. Subject to Section 9(g), such amounts will be paid to the Employee as provided in Section 9(e) below;

(ii) the Company shall provide the Employee with the Health Continuation Benefit Payment. Subject to Section 9(g), such amounts will be paid to the Employee as provided in Section 9(e) below;

(iii) all Time-Vesting Equity Awards previously granted to the Employee shall fully and immediately vest and become exercisable immediately prior to such termination of employment and shall remain exercisable for such periods as provided under the terms of the Equity Plan and any individual award agreements under which such equity awards were granted; and

(iv) all equity awards, other than the Time-Vesting Equity Awards, previously granted to and earned by the Employee shall fully and immediately vest and become exercisable immediately prior to such termination of employment and shall remain exercisable for such periods as provided under the terms of the Equity Plan and any individual award agreements under which such equity awards were granted. All other non-Time Vesting awards previously granted to the Employee, but not earned as of the date of termination of employment, will vest, if at all, as determined in good faith by the Board of Directors based upon the achievement of performance conditions by the Employee and the Company.

(e) Payment of Severance and Benefits Subject to Release. The payments and benefits, including acceleration of vesting, provided in Section 9(b), 9(c) and 9(d) are intended as enhanced severance for a termination of employment by the Company or by the Employee in the circumstances provided and are subject to the Employee's continued compliance with the provisions of Sections 4 and 5 hereof. As a condition to receiving such payments (or having such acceleration become effective), the Employee (or Employee's estate or beneficiary or legal representative) shall first execute and deliver a comprehensive separation agreement including a general release of all claims against the Company, its Affiliates, agents and employees (other than any claims or rights pursuant to this Agreement or pursuant to equity or employee benefit plans), in a form and substance provided by and satisfactory to the Company (the "Release"). Subject to the foregoing and subject to Section 9(g) below, any payments under Section 9(b), Section 9(c)(i) and (ii) and Section 9(d)(i) and (ii) will be paid in a lump sum sixty (60) days after the date of termination of the Employee's employment. The Employee must execute and return the Release on or before the date specified by the Company in the prescribed form (the "Release Deadline"). The Release Deadline will in no event be later than fifty (50) days after the Employee's Separation from Service. If the Employee (or Employee's estate or beneficiary or legal representative) fails to return the Release on or before the Release Deadline, or if the Release is revoked by the Employee (or Employee's estate or beneficiary or legal representative), then the Employee (or the estate or beneficiary or legal representative) will not be entitled to the payments and benefits described in Section 9(b), 9(c) and 9(d).

(f) Termination of Employment and Separation from Service. All references in the Agreement to termination of employment, a termination, retirement, cessation of employment, separation from service, and correlative terms, that result in the payment or vesting of any amounts or benefits that constitute "nonqualified deferred compensation" within the meaning of Section 409A shall be construed to require a Separation from Service, and the date of such termination in any such case shall be construed to mean the date of the Separation from Service.

(g) Payment to a "Specified Employee". To the extent the Employee is a Specified Employee and any payment hereunder that is payable by reason of termination of the Employee's employment constitutes "nonqualified deferred compensation" subject to Section 409A and would otherwise have been required to be paid during the six (6)-month period following such termination of employment, it shall instead be delayed and paid, without interest, in a lump sum on the date that is six (6) months and one (1) day after the Employee's termination (or, if earlier, the date of the Employee's death).

(h) Termination of all Positions. In the event that the Employee's employment with the Company terminates for any reason, except as otherwise expressly provided by the Company, the Employee's employment with, or other service to, all Affiliates of the Company by which the Employee is then employed or otherwise engaged in service shall automatically and immediately terminate, including without limitation, all such positions, offices, directorships or otherwise that the Employee held with respect to the Company and all Affiliates.

10. Cooperation.

Following the termination of employment, the Employee agrees to cooperate with, and assist, the Company to ensure a smooth transition in management and, if requested by the Company, will be available to consult during regular business hours at mutually agreed upon times for up to a three-month period thereafter. At any time following the Employee's termination of employment for any reason, the Employee will provide such information as the Company may reasonably request with respect to any Company-related transaction or other matter in which the Employee was involved in any way while employed by the Company. The Employee further agrees to assist and cooperate with the Company in connection with the defense, prosecution, government investigation, or internal investigation of any claim or matter that may be made against, concerning, or by, the Company or its Affiliates. Such assistance and cooperation shall include timely, comprehensive, and truthful disclosure of all relevant facts known by the Employee to the Company, including through in-person interview(s) with the Company's internal Legal Department or outside counsel for the Company. The Employee shall be entitled to reimbursement for all properly documented expenses incurred in connection with rendering services under this Section, including, but not limited to, reimbursement for all reasonable travel, lodging, and meal expenses.

11. Indemnification.

The Company shall indemnify the Employee to the fullest extent permitted by applicable law and provided in its then-current articles of incorporation and by-laws. The Employee agrees to promptly notify the Company of any actual or threatened claim arising out of or as a result of the Employee's employment with the Company, or any continued consulting relationship with the Company pursuant to Section 10 above. The Company shall provide, at its expense, Directors and Officers insurance for the Employee in amounts reasonably satisfactory to the Employee, to the extent such insurance is available at reasonable rates, which determination shall be made by the Board of Directors. The Employee shall also be party to an Indemnification Agreement with the Company in the form provided by the Company. The Employee agrees to promptly notify the Company of any actual or threatened claim arising out of or as a result of the Employee's employment with the Company.

12. Excise Tax.

If any payment or benefit that the Employee would receive following a Change in Control of the Company or otherwise ("Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then such Payment shall be reduced to the Reduced Amount. The "Reduced Amount" shall be either (a) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (b) the largest portion, up to and including the total amount, of the Payment, whichever of the amounts determined under (a) and (b), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Employee's receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the following order: reduction of cash payments; cancellation of accelerated vesting of outstanding awards under the Equity Plan; and reduction of employee benefits. In the event that acceleration of vesting of outstanding awards under the Equity Plan is to be reduced, such acceleration of vesting shall be undertaken in the reverse order of the date of grant of the Employee's outstanding equity awards.

The accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the Change in Control of the Company shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, then the Company shall appoint another, nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

The accounting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Employee and the Company within a commercially reasonable period of time after the date on which the Employee's right to a Payment is triggered (if requested at that time by the Employee or the Company). Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Employee and the Company.

13. No Mitigation.

The Employee shall not be required to mitigate the amount of any payment provided for hereunder by seeking other employment or otherwise, nor shall the amount of any payment provided for hereunder be reduced by any compensation earned by the Employee as the result of employment by another employer after the date of termination of employment by the Company.

14. Definitions.

As used herein, the following terms have the following meaning:

(a) "Affiliate" means and includes any person, corporation or other entity controlling, controlled by or under common control with the corporation in question.

(b) "Change in Control" means the occurrence of any of the following events:

(i) Any Person, other than the Company, its affiliates (as defined in Rule 12b-2 under the Exchange Act) or any Company employee benefit plan (including any trustee of such plan acting as trustee), is or becomes the Beneficial Owner, directly or indirectly, of securities of the Company representing more than 40% of the combined voting power of the then outstanding securities entitled to vote generally in the election of Directors ("Voting Securities") of the Company, or

(ii) Individuals who constitute the Board of Directors of the Company (the "Incumbent Directors") as of the beginning of any twenty-four (24) month period (not including any period prior to the date of this Agreement), cease for any reason to constitute at least a majority of the Directors. Notwithstanding the foregoing, any individual becoming a Director subsequent to the beginning of such period, whose election or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the Directors then comprising the Incumbent Directors, shall be considered an Incumbent Director; or

(iii) Consummation by the Company of a recapitalization, reorganization, merger, consolidation or other similar transaction (a "Business Combination"), with respect to which all or substantially all of the individuals and entities who were the Beneficial Owners of the Voting Securities immediately prior to such Business Combination (the "Incumbent Shareholders") do not, following consummation of all transactions intended to constitute part of such Business Combination, beneficially own, directly or indirectly, 50% or more of the Voting Securities of the corporation, business trust or other entity resulting from or being the surviving entity in such Business Combination (the "Surviving Entity"), in substantially the same proportion as their ownership of such Voting Securities immediately prior to such Business Combination; or

(iv) Consummation of a complete liquidation or dissolution of the Company, or the sale or other disposition of all or substantially all of the assets of the Company, other than to a corporation, business trust or other entity with respect to which, following consummation of all transactions intended to constitute part of such sale or disposition, more than 50% of the combined Voting Securities is then owned beneficially, directly or indirectly, by the Incumbent Shareholders in substantially the same proportion as their ownership of the Voting Securities immediately prior to such sale or disposition.

For purposes of this definition 14(b), the following terms shall have the meanings set forth below:

(A) "Beneficial Owner" shall have the meaning set forth in Rule 13d-3 under the Exchange Act;

(B) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended; and

(C) "Person" shall have the meaning as used in Sections 13(d) and 14(d) of the Exchange Act.

(c) "Code" means the Internal Revenue Code of 1986, as amended.

(d) "Separation from Service" shall mean a "separation from service" (as that term is defined at Section 1.409A-1(h) of the Treasury Regulations under Section 409A after giving effect to the presumptions contained therein) from the Company and from all other corporations and trades or businesses, if any, that would be treated as a single "service recipient" with the Company under Section 1.409A-1(h)(3) of such Treasury Regulations. The Board or the Committee may, but need not, elect in writing, subject to the applicable limitations under Section 409A, any of the special elective rules prescribed in Section 1.409A-1(h) of the Treasury Regulations for purposes of determining whether a "separation from service" has occurred. Any such written election shall be deemed part of the Agreement.

(e) “Specified Employee” shall mean an individual determined by the Board, the Committee, or their delegate, to be a specified employee as defined in subsection (a)(2)(B)(i) of Section 409A. The Committee may, but need not, elect in writing, subject to the applicable limitations under Section 409A, any of the special elective rules prescribed in Section 1.409A-1(i) of the Treasury Regulations for purposes of determining “specified employee” status. Any such written election shall be deemed part of the Agreement.

15. Representations by Employee.

The Employee represents and warrants that the Employee has full right, power and authority to execute the terms of this Agreement; this Agreement has been duly executed by the Employee and such execution and the performance of this Agreement by the Employee does not result in any conflict, breach or violation of or default under any other agreement or any judgment, order or decree to which the Employee is a party or by which the Employee is bound. The Employee acknowledges and agrees that any material breach of the representations set forth in this Section will constitute Cause under Section 6.

16. Recoupment.

The Employee hereby acknowledges and agrees that the annual bonus described in Section 3(b) and all other payments or grants of incentive-based compensation payable to the Employee by the Company or its Affiliates (whether under this Agreement or otherwise) shall be subject to any applicable clawback or recoupment policy of the Company, as such policy may be amended and in effect from time to time, and shall be subject to recoupment under such policy or as otherwise required by applicable law or applicable stock exchange listing standards, including, without limitation, Section 10D of the Securities Exchange Act of 1934, as amended.

17. Notices.

All notices, requests, consents and other communications required or permitted to be given hereunder shall be in writing and shall be deemed to have been duly given if sent by private overnight mail service (delivery confirmed by such service), registered or certified mail (return receipt requested and received), telecopy (confirmed receipt by return fax from the receiving party) or delivered personally, as follows (or to such other address as either party shall designate by notice in writing to the other in accordance herewith):

If to the Company:

Alexion Pharmaceuticals, Inc.
121 Seaport Boulevard
Boston, Massachusetts 02210
Attn: General Counsel

If to the Employee: to the Employee’s address on file with the Company.

18. Notice and Right to Consult Counsel.

The Employee acknowledges and agrees that the Employee has been provided with this Agreement at least ten (10) business days before its Effective Date, during which time the

Employee shall have the right to consult with counsel at the Employee's sole expense. The Employee acknowledges that the Employee has been and is hereby advised of the Employee's right to consult an attorney before signing this Agreement. The Employee understands and agrees that voluntarily signing this Agreement before the expiration of ten (10) business days shall serve as a waiver of the ten (10)-day review period.

19. General.

(a) This Agreement shall be governed by and construed and enforced in accordance with the laws of the Commonwealth of Massachusetts without regard to its conflicts of laws rules. The Employee agrees to submit to the exclusive jurisdiction of the courts of or in the Commonwealth of Massachusetts in connection with any dispute arising out of this Agreement.

(b) This Agreement sets forth the entire agreement and understanding of the parties relating to the subject matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, relating to the subject matter hereof, except for the Proprietary Information and Inventions Agreement and the Indemnification Agreement. No representation, promise or inducement has been made by either party that is not embodied in this Agreement, and neither party shall be bound by or liable for any alleged representation, promise or inducement not so set forth.

(c) This Agreement may be amended, modified, superseded, canceled, renewed or extended, and the terms or covenants hereof may be waived, only by a written instrument executed by the parties hereto, or in the case of a waiver, by the party waiving compliance. The failure of a party at any time or times to require performance of any provision hereof shall in no manner affect the right at a later time to enforce the same. No waiver by a party of the breach of any term or covenant contained in this Agreement, whether by conduct or otherwise, or any one or more or continuing waivers of any such breach, shall constitute a waiver of the breach of any other term or covenant contained in this Agreement.

(d) This Agreement shall be binding upon the legal representatives, heirs, distributees, successors and assigns of the parties hereto. The Company may not assign its rights and obligation under this Agreement without the prior written consent of the Employee, except to a successor of substantially all the Company's business which expressly assumes the Company's obligations hereunder in writing. In the event of a sale of all or substantially all of the assets of the Company, the Company shall use its best efforts to cause the purchaser to expressly assume this Agreement. The Employee may not assign, transfer, alienate or encumber any rights or obligations under this Agreement, except by will or operation of law, provided that the Employee may designate beneficiaries to receive any payments permitted under the terms of the Company's benefit plans.

(e) If any portion or provision of this Agreement shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

(f) Provisions of this Agreement shall survive any termination of employment if so provided herein or if necessary or desirable fully to accomplish the purposes of other surviving provisions, including without limitation, the obligations of the Employee under Sections 4 and 5 hereof. Upon termination of the Employee's employment hereunder by either the Employee or the Company as permitted hereby, all rights, duties and obligations of the Employee and the Company to each other pursuant to this Agreement shall cease, except for the provisions hereof that contemplate performance after termination of employment, including without limitation the obligations of the Employee under Sections 4 and 5 hereof.

(g) This Agreement is intended to comply with the applicable requirements of Section 409A and shall be construed accordingly. Each payment made under this Agreement shall be treated as a separate payment and the right to a series of installment payments under this Agreement is to be treated as a right to a series of separate payments. In no event shall the Company have any liability relating to the failure or alleged failure of any payment or benefit under this Agreement to comply with, or be exempt from, the requirements of Section 409A.

(h) This Agreement may be executed in two or more counterparts, including by electronic delivery, each of which shall be deemed an original, and together, all of which shall constitute one original document. Original signatures that are transmitted by fax or electronic mail shall be considered original signatures under this Agreement. This Agreement is and shall be deemed to be executed under seal.

INTENDING TO BE BOUND, the parties have executed this Agreement under seal as of the date first above written.

ALEXION PHARMACEUTICALS, INC.
By: /s/ Ludwig Hantson
Name: Ludwig Hantson
Title: Chief Executive Officer

EMPLOYEE
/s/ Aradhana Sarin
Aradhana Sarin

Exhibit 31.1

I, Ludwig N. Hantson, Ph.D., certify that:

1 I have reviewed this quarterly report on Form 10-Q 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: October 23, 2019

/s/ LUDWIG N. HANTSON, Ph.D.

Chief Executive Officer

Exhibit 31.2

I, Paul J. Clancy, certify that:

1 I have reviewed this quarterly report on Form 10-Q 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: October 23, 2019

/s/ PAUL J. CLANCY

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 quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc. (the "Company") for the fiscal quarter ended September 30, 2019 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: October 23, 2019

/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 quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc. (the “Company”) for the fiscal quarter ended September 30, 2019 as filed with the Securities and Exchange Commission (the “Report”), I, Paul J. Clancy, 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:	October 23, 2019	/s/ PAUL J. CLANCY
		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.