ALEXION PHARMACEUTICALS, INC.
Form 10-Q
October 24, 2018
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q
x Quarterly report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934
For the quarterly period ended September 30, 2018
or
¨Transition report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934
For the transition period from to
Commission file number: 0-27756

ALEXION PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	13-3648318
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

121 Seaport Boulevard, Boston Massachusetts 02210
(Address of Principal Executive Offices) (Zip Code)
475-230-2596
(Registrant’s telephone number, including area code)
N/A
(Former name, former address, and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark 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. Check One:
Large accelerated filer x 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 x

Common Stock, $0.0001 par value	223,096,632
Class	Outstanding as of October 22, 2018

Alexion Pharmaceuticals, Inc.
Contents

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

	September 30, 2018	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$1,228.9	$584.4
Marketable securities	306.2	889.7
Trade accounts receivable, net	910.2	726.5
Inventories	432.7	460.4
Prepaid expenses and other current assets	370.4	292.9
Total current assets	3,248.4	2,953.9
Property, plant and equipment, net	1,443.4	1,325.4
Intangible assets, net	3,713.6	3,954.4
Goodwill	5,037.4	5,037.4
Other assets	400.8	312.2
Total assets	$13,843.6	$13,583.3
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$52.2	$70.8
Accrued expenses	539.8	639.4
Revolving credit facility	250.0	—
Current portion of long-term debt	61.2	167.4
Current portion of contingent consideration	95.8	—
Other current liabilities	28.4	74.9
Total current liabilities	1,027.4	952.5
Long-term debt, less current portion	2,533.3	2,720.7
Contingent consideration	179.4	168.9
Facility lease obligation	361.2	342.9
Deferred tax liabilities	442.8	365.0
Other liabilities	129.8	140.2
Total liabilities	4,673.9	4,690.2
Commitments and contingencies (Note 18)		
Stockholders' Equity:		
Common stock, $0.0001 par value; 290.0 shares authorized; 235.8 and 234.3 shares issued at September 30, 2018 and December 31, 2017, respectively	—	—
Additional paid-in capital	8,481.8	8,290.3
Treasury stock, at cost, 12.7 and 12.0 shares at September 30, 2018 and December 31, 2017, respectively	(1,689.9)	(1,604.9)
Accumulated other comprehensive income (loss)	6.9	(34.4)
Retained earnings	2,370.9	2,242.1
Total stockholders' equity	9,169.7	8,893.1
Total liabilities and stockholders' equity	$13,843.6	$13,583.3

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,	
	2018	2017	2018	2017
Net product sales	$1,026.5	$858.8	$3,001.6	$2,640.1
Other revenue	—	0.3	0.8	1.3
Total revenues	1,026.5	859.1	3,002.4	2,641.4
Cost of sales	90.6	157.0	277.5	309.6
Operating expenses:				
Research and development	174.8	195.7	524.8	613.4
Selling, general and administrative	258.7	270.6	793.1	798.0
Acquired in-process research and development	—	—	803.7	—
Amortization of purchased intangible assets	80.0	80.0	240.1	240.1
Change in fair value of contingent consideration	53.5	3.7	110.9	31.8
Restructuring expenses	10.3	72.0	26.4	98.7
Impairment of intangible assets	—	—	—	31.0
Total operating expenses	577.3	622.0	2,499.0	1,813.0
Operating income	358.6	80.1	225.9	518.8
Other income and expense:				
Investment income	5.9	4.5	119.4	12.9
Interest expense	(24.6)	(25.0)	(73.7)	(73.3)
Other income (expense)	2.2	(1.4)	3.5	0.1
Income before income taxes	342.1	58.2	275.1	458.5
Income tax expense (benefit)	11.2	(19.8)	152.5	45.2
Net income	$330.9	$78.0	$122.6	$413.3
Earnings per common share				
Basic	$1.48	$0.35	$0.55	$1.84
Diluted	$1.47	$0.35	$0.55	$1.83
Shares used in computing earnings per common share				
Basic	222.9	223.3	222.5	224.1
Diluted	224.6	225.0	224.2	225.5

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,	
	2018	2017	2018	2017
Net income	$330.9	$78.0	$122.6	$413.3
Other comprehensive income (loss), net of tax:				
Foreign currency translation	(1.7)	2.0	(6.0)	8.8
Unrealized gains (losses) on debt securities	0.1	0.2	(0.3)	1.1
Unrealized gains on pension obligation	—	—	0.7	0.3
Unrealized gains (losses) on hedging activities, net of tax of $2.9, $(14.0), $13.4 and $(59.3), respectively	11.4	(25.3)	46.9	(107.6)
Other comprehensive income (loss), net of tax	9.8	(23.1)	41.3	(97.4)
Comprehensive income	$340.7	$54.9	$163.9	$315.9

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,	
	2018	2017
Cash flows from operating activities:		
Net income	$122.6	$413.3
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	306.9	311.6
Impairment of assets	13.5	112.6
Change in fair value of contingent consideration	110.9	31.8
Payments of contingent consideration	—	(18.0)
Share-based compensation expense	150.9	172.3
Non-cash expense for acquired IPR&D	86.6	—
Deferred taxes	79.1	(57.3)
Unrealized foreign currency loss (gain)	8.6	(5.7)
Unrealized (gain) loss on forward contracts	(9.9)	8.1
Unrealized gain on equity investments	(100.5)	—
Other	(3.0)	4.4
Changes in operating assets and liabilities:		
Accounts receivable	(197.4)	(34.6)
Inventories	26.7	(69.1)
Prepaid expenses and other assets	(85.1)	(94.5)
Accounts payable, accrued expenses and other liabilities	(167.3)	82.6
Net cash provided by operating activities	342.6	857.5
Cash flows from investing activities:		
Purchases of available-for-sale debt securities	(771.4)	(1,580.0)
Proceeds from maturity or sale of available-for-sale debt securities	1,356.4	932.3
Purchases of mutual funds related to nonqualified deferred compensation plan	(9.0)	(8.1)
Proceeds from sale of mutual funds related to nonqualified deferred compensation plan	9.3	5.8
Purchases of property, plant and equipment	(170.6)	(268.8)
Other	3.6	0.1
Net cash provided by (used in) investing activities	418.3	(918.7)
Cash flows from financing activities:		
Debt issuance costs	(7.6)	—
Proceeds from revolving credit facility	250.0	—
Payments on term loan	(293.8)	(131.3)
Repurchases of common stock	(85.0)	(298.5)
Net proceeds from issuance of common stock under share-based compensation arrangements	41.4	76.0
Payments of contingent consideration	—	(7.0)
Other	(10.5)	(10.4)
Net cash used in financing activities	(105.5)	(371.2)
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(10.6)	16.5
Net change in cash and cash equivalents and restricted cash	644.8	(415.9)
Cash and cash equivalents and restricted cash at beginning of period	586.3	966.0
Cash and cash equivalents and restricted cash at end of period	$1,231.1	$550.1

Supplemental cash flow disclosures from investing and financing activities:		
Capitalization of construction costs related to facility lease obligations	$44.3	$109.6
Accrued expenses for purchases of property, plant and equipment	$10.2	$32.6

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

Alexion Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)
(amounts in millions, except per share amounts)

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

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

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, 2017. In our opinion, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of our financial statements for interim periods in accordance with accounting principles generally accepted in the United States. The condensed consolidated balance sheet data as of December 31, 2017 was derived from audited 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, 2017 included in our Annual Report on Form 10-K for the year ended December 31, 2017. The results of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the full year or any other future periods. In the current year, the Company’s rounding presentation of reported amounts have changed. The current year rounding presentation has been applied to all prior year amounts presented and, in certain circumstances, this change may adjust previously reported balances.

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, 2017. Updates to our accounting policies, including impacts from the adoption of new accounting standards, are discussed within Note 8, Marketable Securities, Note 9, Derivative Instruments and Hedging Activities, Note 10, Other Investments, and Note 14, Revenue Recognition.

Reclassifications

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

Alexion Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)
(amounts in millions, except per share amounts)

New Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) issued a new standard requiring that the rights and obligations arising from leases be recognized on the balance sheet by recording a right-of-use (ROU) asset and corresponding lease liability. The new standard also requires qualitative and quantitative disclosures to understand the amount, timing, and uncertainty of cash flows arising from leases, as well as significant management estimates utilized. The standard is effective for interim and annual periods beginning after December 15, 2018 and requires a modified retrospective adoption. In July 2018, the FASB issued an update with an optional transition method when adopting the new leases standard. Under this new transition method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption rather than recast the comparative periods presented in the year of adoption. We plan to elect this optional method. We have substantially completed the process of collecting and continue to analyze the Company's lease contracts and during the third quarter 2018, we started implementing our leasing software, including data upload and test procedures. Our lease accounting software implementation efforts are ongoing. While our assessment of the standard remains open, the standard may have a material impact on the Company's Condensed Consolidated Balance Sheets due to the requirement to recognize lease ROU assets and corresponding liabilities related to leases on the Company's Condensed Consolidated Balance Sheets.

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

In February 2018, the FASB issued a new standard that would permit entities to make a one time reclassification from accumulated other comprehensive income (AOCI) to retained earnings for the stranded tax effects resulting from the newly enacted corporate tax rates under the Tax Cuts and Jobs Act (the Tax Act), that was effective for the year ended December 31, 2017. The amount of the reclassification is calculated on the basis of the difference between the historical tax rate and newly enacted tax rate. The standard is effective for interim and annual periods beginning after December 15, 2018 with early adoption permitted. We are currently assessing the impact of this standard on our financial condition.

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

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five-step

framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We adopted the new standard on January 1, 2018.

In January 2017, the FASB issued a new standard that clarifies the definition of a business and determines when an integrated set of assets and activities is not a business. This framework requires that if substantially all of the fair value of gross assets acquired or disposed of is concentrated in a single asset or group of similar identifiable assets, the assets would not represent a business. We adopted the new standard on January 1, 2018 and will apply the new guidance prospectively to transactions occurring after adoption. We anticipate that the adoption of this new standard will likely result in more transactions, to the extent that such transactions are undertaken by the Company, being accounted for as asset acquisitions.

Alexion Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)
(amounts in millions, except per share amounts)

In January 2016, the FASB issued a new standard that changes accounting for equity investments, financial liabilities under the fair value option, and presentation and disclosure requirements for financial instruments. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. Equity investments with readily determinable fair values will be measured at fair value with changes in fair value recognized in net income. Companies have the option to either measure equity investments without readily determinable fair values at fair value, or at cost adjusted for changes in observable prices minus impairment. We adopted the new standard on January 1, 2018, and have elected to measure our current equity investments without readily determinable fair values at cost adjusted for changes in observable prices minus impairment. In connection with the adoption of the new standard, we reclassified an immaterial amount of unrealized gains on equity securities from other comprehensive income to retained earnings. The guidance related to equity investments without readily determinable fair values was applied prospectively to equity investments that existed as of the date of adoption. We will assess our equity investments without readily determinable fair values for observable price changes and impairment on a quarterly basis. Refer to Note 10, Other Investments, for further details.

In March 2017, the FASB issued a new standard that improves the presentation of net periodic pension cost and net periodic post retirement benefit cost by requiring the bifurcation of net benefit cost. Under the new standard, the service cost component of net benefit cost will be presented with other employee costs in operating expenses; while other components will be reported separately in other income and expense. We adopted the new standard on January 1, 2018. The adoption of this standard did not have a material impact on our condensed consolidated statements of operations.

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

In August 2017, the FASB issued a new standard intended to improve and simplify certain aspects of the accounting for hedges. The new standard is intended to more closely align hedge accounting with companies' risk management strategies, simplify the application of hedge accounting, and increase transparency as to the scope and results of hedging programs. It also amends the presentation and disclosure requirements and changes how companies assess effectiveness. The standard is effective for interim and annual periods beginning after December 15, 2018 with early adoption permitted. We early adopted the new standard in the second quarter 2018 using the modified retrospective method. The adoption of this standard did not have a material impact on our condensed consolidated financial statements.

Impacts of the New Revenue Standard

We adopted the new revenue standard by applying the modified retrospective method to all contracts that were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 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. We recorded a net increase to opening equity of $6.0 as of January 1, 2018 due to the cumulative impact of adopting this new standard.

The impact to net product sales for the three and nine months ended September 30, 2018 was an increase of $6.7 and $20.5, respectively, as a result of adopting the new standard. The resulting impact to net income for the three and nine months ended September 30, 2018 was an increase of $4.8 and $16.6, respectively. The impact of adopting the new

standard for the three and nine months ended September 30, 2018 is due primarily to the earlier recognition of revenue associated with customer arrangements for which control of the product has transferred to the customer prior to the shipment clearing customs in the respective country. Under prior revenue guidance, these amounts would have been deferred until risk of loss had transferred to the customer following customs clearance.

The new standard also resulted in a decrease of $32.2 in deferred revenue and an increase of $22.7 in retained earnings as of September 30, 2018. The adoption of the new revenue standard did not have a material impact on any other balances within the condensed consolidated financial statements as of and for the three and nine months ended September 30, 2018.

Alexion Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)
(amounts in millions, except per share amounts)

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 develops a novel therapy for patients with rare copper-mediated disorders, pursuant to a recommended public cash offer of SEK 232 for each share of stock of Wilson Therapeutics. As a result of the acquisition, we added WTX101, a highly innovative drug candidate that is currently in the early stages of Phase III clinical trials for the treatment of patients with Wilson disease, to our clinical pipeline.

The acquisition of Wilson Therapeutics is accounted for as an asset acquisition, as substantially all of the fair value of the gross assets acquired is concentrated in a single asset, WTX101. As of September 30, 2018, Alexion had acquired 99.8% of the outstanding shares of Wilson Therapeutics.

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, an early Phase III asset in development for the treatment of Wilson Disease. Due to the stage of development of this asset, significant risk remains and it is not yet probable that there is future economic benefit from this asset. Absent successful clinical results and regulatory approval for the asset, there is no alternative future use associated with WTX101. Accordingly, the value of this asset of $803.7 was expensed during the nine months ended September 30, 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 are 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 neonatal Fc receptor (FcRn). Syntimmune’s lead candidate, SYNT001, is a monoclonal antibody that inhibits the interaction of FcRn with Immunoglobulin G (IgG) and IgG immune complexes, and is being studied in Phase 1b/2a trials for the treatment of IgG-mediated autoimmune diseases. Under the terms of the agreement, Alexion will acquire Syntimmune for an upfront payment of $400.0, with the potential for additional milestone-dependent payments of up to $800.0, for a total

value of up to $1,200.0. The acquisition of Syntimmune, which is subject to the satisfaction of customary closing conditions (including approval from relevant regulatory agencies), is expected to close in the fourth quarter of 2018. We intend to finance the acquisition through cash on hand and account for the transaction as an asset acquisition.

Alexion Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
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(amounts in millions, except per share amounts)

4. Inventories

The components of inventory are as follows:

	September 30, 2018	December 31, 2017
Raw materials	$ 10.8	$ 4.7
Work-in-process	107.8	148.6
Finished goods	314.1	307.1
	$ 432.7	$ 460.4

5. Intangible Assets and Goodwill

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

		September 30, 2018			December 31, 2017		
	Estimated Life (years)	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Licensing rights	5-8	$31.0	$ (29.1)	$1.9	$31.0	$ (28.5)	$2.5
Patents	7	10.5	(10.5)	—	10.5	(10.5)	—
Purchased technology	6-16	4,710.5	(999.0)	3,711.5	4,710.5	(758.9)	3,951.6
Other intangibles	5	0.4	(0.2)	0.2	0.4	(0.1)	0.3
Total		$4,752.4	$ (1,038.8)	$3,713.6	$4,752.4	$ (798.0)	$3,954.4
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, 2018 and 2017 was $80.2 and $80.0, respectively. Amortization expense for the nine months ended September 30, 2018 and 2017 was $240.8 and $240.1, respectively. Assuming no changes in the gross cost basis of intangible assets, the total estimated amortization expense for finite-lived intangible assets is $80.2 for the three months ending December 31, 2018, and approximately $320.0 for each of the years ending December 31, 2019 through December 31, 2023.

In the second quarter 2017, we recognized an impairment charge of $31.0 related to our SBC-103 acquired in-process research and development asset due to clinical results.

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 amends and restates 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 amortization payments of 5.00% of the aggregate principal amount of the term loan facility annually, payable in equal quarterly installments.

Loans under the Credit Agreement bear interest, at our option, at either a base rate or a Eurodollar rate, in each case plus an applicable margin. Under the Credit Agreement, the applicable margins on base rate loans range from 0.25% to 1.00% and the applicable margins on Eurodollar loans range from 1.25% to 2.00%, in each case based on our consolidated net leverage ratio (as calculated in accordance with the Credit Agreement). Our obligations under the

Credit Agreement are guaranteed by certain of Alexion Pharmaceuticals, Inc.'s foreign and domestic subsidiaries and secured by liens on certain of our subsidiaries' equity interests, subject to certain exceptions. Under the terms of the Credit Agreement, we must maintain a ratio of total net debt to EBITDA of 3.50 to 1.00 (subject to certain limited adjustments) and EBITDA to cash interest expense ratio of at least 3.50 to 1.00, in each case as calculated in accordance with the Credit Agreement.

Alexion Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
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(amounts in millions, except per share amounts)

The Credit Agreement contains certain representations and warranties, affirmative and negative covenants and events of default. The negative covenants in the Credit Agreement restrict Alexion's and its subsidiaries' ability, subject to certain baskets and exceptions, to (among other things) incur liens or indebtedness, make investments, enter into mergers and other fundamental changes, make dispositions or pay dividends. The restriction on dividend payments includes an exception that permits us to pay dividends and make other restricted payments regardless of dollar amount so long as, after giving pro forma effect thereto, we have a consolidated net leverage ratio, as defined in the Credit Agreement, within predefined ranges, subject to certain increases following designated material acquisitions.
In connection with entering into the Credit Agreement and the Prior Credit Agreement, we paid an aggregate of $53.1 in financing costs. 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, 2018 and 2017 was $1.3 and $2.3, respectively, and amortization of deferred financing costs for the nine months ended September 30, 2018 and 2017 was $6.7 and $7.0 respectively. Remaining unamortized deferred financing costs as of September 30, 2018 and December 31, 2017 were $22.1 and $21.0, respectively.
As of September 30, 2018, we had $2,612.5 outstanding on the term loan and $250.0 of borrowings outstanding under the revolving credit facility. The $250.0 of proceeds on the revolving credit facility was used to refinance amounts outstanding under the Prior Credit Agreement. As of September 30, 2018, we had open letters of credit of $1.7 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.
The following table summarizes the calculation of basic and diluted EPS for the three and nine months ended September 30, 2018 and 2017:

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Net income used for basic and diluted calculation	$330.9	$78.0	$122.6	$413.3
Shares used in computing earnings per common share—basic	222.9	223.3	222.5	224.1
Weighted-average effect of dilutive securities:				
Stock awards	1.7	1.7	1.7	1.4
Shares used in computing earnings per common share—diluted	224.6	225.0	224.2	225.5
Earnings per common share:				
Basic	$1.48	$0.35	$0.55	$1.84
Diluted	$1.47	$0.35	$0.55	$1.83

We exclude from EPS the weighted-average number of securities whose effect is anti-dilutive. Excluded from the calculation of EPS for the three months ended September 30, 2018 and 2017 were 2.5 and 3.9 shares of common stock

because their effect was anti-dilutive. Similarly, we excluded 2.9 and 4.1 shares of common stock from the calculation of EPS for the nine months ended September 30, 2018 and 2017 because their effect was anti-dilutive.

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8. Marketable Securities

We invest our excess cash balances in marketable securities of highly rated financial institutions and investment-grade debt instruments. We classify these marketable securities as available-for-sale and, accordingly, record such securities at fair value. Unrealized gains and losses that are deemed temporary are included in accumulated other comprehensive income (loss) as a separate component of stockholders' equity in the accompanying balance sheets.

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, 2018 and December 31, 2017 were as follows:

	September 30, 2018			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Commercial paper	$196.1	$ —	$ —	$196.1
Corporate bonds	136.0	—	—	136.0
Other government-related obligations:				
U.S.	9.7	—	—	9.7
Foreign	2.6	—	—	2.6
Bank certificates of deposit	43.4	—	—	43.4
Total available-for-sale debt securities	$387.8	$ —	$ —	$387.8

	December 31, 2017			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Commercial paper	$16.0	$ —	$ —	$16.0
Repurchase agreements	27.0	—	—	27.0
Corporate bonds	432.2	0.5	(0.2)	432.5
Other government-related obligations:				
U.S.	—	—	—	—
Foreign	426.3	0.2	(0.2)	426.3
Bank certificates of deposit	11.8	—	—	11.8
Total available-for-sale debt securities	$913.3	$ 0.7	$ (0.4)	$913.6

The aggregate fair value of available-for-sale debt securities in an unrealized loss position as of September 30, 2018 and December 31, 2017 was $92.8 and $436.2, respectively. Investments that have been in a continuous unrealized loss position for more than 12 months were zero as of September 30, 2018 and $12.0 as of December 31, 2017. As of September 30, 2018, we believe that the cost basis of our available-for-sale debt securities is recoverable.

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

	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 100.5	$ 42.7

Marketable securities	287.3	870.9
	$ 387.8	$ 913.6

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The fair values of available-for-sale debt securities at September 30, 2018, by contractual maturity, are summarized as follows:

	September 30, 2018
Due in one year or less	$ 372.7
Due after one year through three years	15.1
	$ 387.8

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, 2018 and December 31, 2017, the fair value of these investments was $18.9 and $18.5, 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, 2018 and 2017.

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 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, 2018, we had open revenue related foreign exchange forward contracts with notional amounts totaling $994.4 that qualified for hedge accounting. As of September 30, 2018, we had open expense related foreign exchange forward contracts with notional amounts totaling $22.0 that qualified for hedge accounting.
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 our interest rate swap contracts as of September 30, 2018:

Type of Interest Rate Swap	Notional Amount	Effective Date	Termination Date	Fixed Interest Rate or Rate Range
Floating to Fixed	2,031.3	December 2016 - January 2018	December 2018 - December 2019	0.98% - 1.62%
Floating to Fixed	250.0	December 2018	December 2022	2.79%
Floating to Fixed	300.0	January 2019	December 2019	2.08%
Floating to Fixed	900.0	December 2019	December 2022	2.79% - 2.83%

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During the second quarter 2018, we adopted the new standard for accounting for hedges that is designed to simplify the application of hedge accounting and increase transparency as to the scope and results of hedging programs. The updated guidance no longer requires the separate measurement and reporting of hedge ineffectiveness. Following adoption, all unrealized gains and losses on derivatives that are designated and qualify for hedge accounting are reported in other comprehensive income (loss) and recognized in our condensed consolidated statements of operations when the underlying hedged transaction affects earnings.

The amount of gains and losses recognized in the condensed consolidated statements of operations for the three and nine months ended September 30, 2018 and 2017 from foreign exchange and interest rate swap contracts that qualified as cash flow hedges were as follows:

	Three months ended September 30, 2018		Three months ended September 30, 2017	
	Net Product Sales	Interest Expense	Net Product Sales	Interest Expense
Financial Statement Line Item in which the Effects of Cash Flow Hedges are Recorded	$1,026.5	$(24.6)	$858.8	$(25.0)
Impact of cash flow hedging relationships:				
Foreign Exchange Forward Contracts	$3.3	$—	$(1.3)	$—
Interest Rate Swap Contracts	$—	$4.0	$—	$(0.3)

	Nine months ended September 30, 2018		Nine months ended September 30, 2017	
	Net Product Sales	Interest Expense	Net Product Sales	Interest Expense
Financial Statement Line Item in which the Effects of Cash Flow Hedges are Recorded	$3,001.6	$(73.7)	$2,640.1	$(73.3)
Impact of cash flow hedging relationships:				
Foreign Exchange Forward Contracts	$(11.5)	$—	$30.7	$—
Interest Rate Swap Contracts	$—	$8.5	$—	$(1.6)

The impact on accumulated other comprehensive income (AOCI) from foreign exchange and interest rate swap contracts that qualified as cash flow hedges, for the three and nine months ended September 30, 2018 and 2017 were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017

Foreign Exchange Forward Contracts:				
Gain (loss) recognized in AOCI, net of tax	$9.8	$(27.6)	$26.3	$(89.3)
Gain (loss) reclassified from AOCI to net product sales, net of tax	$2.5	$(0.8)	$(8.9)	$19.8
Interest Rate Contracts:				
Gain (loss) recognized in AOCI, net of tax	$7.2	$1.2	$18.4	$0.4
Gain (loss) reclassified from AOCI to interest expense, net of tax	$3.1	$(0.2)	$6.7	$(1.0)

Assuming no change in foreign exchange rates from market rates at September 30, 2018, $7.5 of gains recognized in AOCI will be reclassified to revenue over the next 12 months. The amount of gains recognized in AOCI that will be reclassified to interest expense over the next 12 months is $22.6. Amounts recognized in AOCI for expense related foreign exchange forward contracts was not material at September 30, 2018.

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We enter into foreign exchange forward contracts, with durations up to seven 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, 2018, the notional amount of foreign exchange contracts where hedge accounting is not applied was $794.2.

We recognized a gain (loss) of $6.8 and $(2.5), in other income and expense, for the three months ended September 30, 2018 and 2017, respectively, associated with the foreign exchange contracts not designated as hedging instruments. We recognized a gain (loss) of $17.1 and $(11.7), for the nine months ended September 30, 2018 and 2017, 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, 2018 and December 31, 2017:

	September 30, 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	$10.0
Foreign exchange forward contracts	Other assets	0.7	Other liabilities	5.8
Interest rate contracts	Prepaid expenses and other current assets	22.6	Other current liabilities	—
Interest rate contracts	Other assets	14.1	Other liabilities	—
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	10.1	Other current liabilities	3.9
Total fair value of derivative instruments		$64.4		$19.7

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	December 31, 2017			
	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	$12.9	Other current liabilities	$34.8
Foreign exchange forward contracts	Other assets	4.1	Other liabilities	26.0
Interest rate contracts	Prepaid expenses and other current assets	9.3	Other current liabilities	—
Interest rate contracts	Other assets	12.5	Other liabilities	—
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	10.0	Other current liabilities	13.7
Total fair value of derivative instruments		$48.8		$74.5

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, 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	$64.4	$ —	$ 64.4	$ (16.7)	$ —	$ 47.7
Derivative liabilities	(19.7)	—	(19.7)	16.7	—	(3.0)

	December 31, 2017					
				Gross Amounts Not Offset in the		

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	$48.8	$ —	$ 48.8	$ (26.3)	$ —	$ 22.5
Derivative liabilities	(74.5)	—	(74.5)	26.3	—	(48.2)

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10. Other Investments

We invest in companies with securities that are not publicly traded and where fair value is not readily available. We have historically recorded these investments at cost, less impairments. As of January 1, 2018, we will continue to record these investments at cost, less impairments; however, we will also adjust the investment for any changes resulting from an observable price change in an orderly transaction for identical or similar investments of the same issuer. We assess relevant transactions that occur on or before the balance sheet date to identify observable price changes, and we regularly monitor these investments to evaluate whether there is an indication that the investment is impaired, based on the implied value of recent company financings, public market prices of comparable companies, and general market conditions.

During 2014, we purchased $37.5 of preferred stock of the non-public entity Moderna Therapeutics, Inc. (Moderna). During the first quarter 2018, Moderna announced the completion of a new round of financing. We considered this transaction and the rights of the preferred shares issued in the new round, compared to the rights of the preferred equity that we hold, and concluded that Moderna's new round of financing represents an observable price change in an orderly transaction for a similar investment. We further concluded, based on the respective rights of the stock and consideration of potential liquidity events, that the value of our preferred stock is equivalent to the value of the newly issued preferred stock. As a result, we recognized an unrealized gain of $100.8 in investment income during the first quarter 2018 to adjust our 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. The carrying value of this investment was $138.3 and $37.5 as of September 30, 2018 and December 31, 2017, respectively. The carrying value of this investment was not impaired as of September 30, 2018.

11. Stockholders' Equity

In February 2017, our Board of Directors authorized the future acquisition of shares with an aggregate value of up to $1,000.0 under our existing share repurchase program. The repurchase program does not have an expiration date, and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at our discretion. Under the program, for the three months ended September 30, 2017, we repurchased 0.5 shares at a cost of $59.6. During the nine months ended September 30, 2018 and 2017, we repurchased 0.7 and 2.6 shares of our common stock at a cost of $85.0 and $298.5, respectively. The Company did not repurchase any shares during the three months ended September 30, 2018. As of October 24, 2018, there is a total of $451.5 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, 2018 and 2017:

	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

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	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, 2016	$ (6.7)	$ (0.4)	$ 91.9	$ (24.3)	$ 60.5
Other comprehensive income (loss) before reclassifications	0.2	0.4	(88.9)	8.8	(79.5)
Amounts reclassified from other comprehensive income	0.1	0.8	(18.8)	—	(17.9)
Net other comprehensive income (loss)	0.3	1.2	(107.7)	8.8	(97.4)
Balances, September 30, 2017	$ (6.4)	$ 0.8	$ (15.8)	$ (15.5)	$ (36.9)

The table below provides details regarding significant reclassifications from AOCI during the three and nine months ended September 30, 2018 and 2017:

Details about Accumulated Other Comprehensive Income Components	Amount Reclassified From Accumulated Other Comprehensive Income during the three months ended September 30,		Amount Reclassified From Accumulated Other Comprehensive Income during the nine months ended September 30,		Affected Line Item in the Condensed Consolidated Statements of Operations
	2018	2017	2018	2017	
Unrealized Gains (Losses) from Hedging Activity					
Foreign exchange forward contracts	$ 3.3	$ (1.3)	$ (11.5)	$ 30.7	Net product sales
Interest rate swap contracts	4.0	(0.3)	8.5	(1.6)	Interest expense
	7.3	(1.6)	(3.0)	29.1	
	(1.7)	0.6	0.8	(10.3)	Income tax expense (benefit)
	$ 5.6	$ (1.0)	$ (2.2)	$ 18.8	

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, 2018 and December 31, 2017, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

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		Fair Value Measurement at September 30, 2018			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Money market funds	$503.2	$ —	$503.2	$—
Cash equivalents	Commercial paper	$96.1	$ —	$96.1	$—
Cash equivalents	Bank certificates of deposit	$1.6	$ —	$1.6	$—
Cash equivalents	Other government-related obligations	$2.8	$ —	$2.8	$—
Marketable securities	Mutual funds	$18.9	$ 18.9	$—	$—
Marketable securities	Commercial paper	$100.0	$ —	$100.0	$—
Marketable securities	Corporate bonds	$136.0	$ —	$136.0	$—
Marketable securities	Other government-related obligations	$9.5	$ —	$9.5	$—
Marketable securities	Bank certificates of deposit	$41.8	$ —	$41.8	$—
Prepaid expenses and other current assets	Foreign exchange forward contracts	$27.0	$ —	$27.0	$—
Other assets	Foreign exchange forward contracts	$0.7	$ —	$0.7	$—
Other current liabilities	Foreign exchange forward contracts	$13.9	$ —	$13.9	$—
Other liabilities	Foreign exchange forward contracts	$5.8	$ —	$5.8	$—
Prepaid expenses and other current assets	Interest rate contracts	$22.6	$ —	$22.6	$—
Other assets	Interest rate contracts	$14.1	$ —	$14.1	$—
Current portion of contingent consideration	Acquisition-related contingent consideration	$95.8	$ —	$—	$95.8
Contingent consideration	Acquisition-related contingent consideration	$179.4	$ —	$—	$179.4

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		Fair Value Measurement at December 31, 2017			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Commercial paper	$9.5	$ —	$9.5	$—
Cash equivalents	Reverse repurchase agreements	$27.0	$ —	$27.0	$—
Cash equivalents	Corporate bonds	$1.2	$ —	$1.2	$—
Cash equivalents	Other government-related obligations	$5.0	$ —	$5.0	$—
Marketable securities	Mutual funds	$18.5	$ 18.5	$—	$—
Marketable securities	Commercial paper	$6.5	$ —	$6.5	$—
Marketable securities	Corporate bonds	$431.3	$ —	$431.3	$—
Marketable securities	Other government-related obligations	$421.3	$ —	$421.3	$—
Marketable securities	Bank certificates of deposit	$11.8	$ —	$11.8	$—
Marketable securities	Equity securities	$0.3	$ 0.3	$—	$—
Prepaid expenses and other current assets	Foreign exchange forward contracts	$22.9	$ —	$22.9	$—
Other assets	Foreign exchange forward contracts	$4.1	$ —	$4.1	$—
Other current liabilities	Foreign exchange forward contracts	$48.5	$ —	$48.5	$—
Other liabilities	Foreign exchange forward contracts	$26.0	$ —	$26.0	$—
Prepaid expenses and other current assets	Interest rate contracts	$9.3	$ —	$9.3	$—
Other assets	Interest rate contracts	$12.5	$ —	$12.5	$—
Contingent consideration	Acquisition-related contingent consideration	$168.9	$ —	$—	$168.9

There were no securities transferred between Level 1, 2 and 3 during the nine months ended September 30, 2018.

Valuation Techniques
We classify mutual fund investments and equity securities, which are valued based on quoted market prices in active markets with no valuation adjustment, as Level 1 assets within the fair value hierarchy.
Cash equivalents and marketable securities classified as Level 2 within the valuation hierarchy consist of commercial paper, reverse repurchase agreements, 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.
Our derivative assets and liabilities include foreign exchange and interest rate derivatives that are measured at fair value using observable market inputs such as forward rates, interest rates, our own credit risk as well as an evaluation of our counterparties' credit risks. Based on these inputs, the derivative assets and liabilities are classified within Level 2 of the valuation hierarchy.

Contingent consideration liabilities related to acquisitions are classified as Level 3 within the valuation hierarchy and are valued based on various estimates, including probability of success, discount rates and amount of time until the conditions of the milestone payments are met.

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As of September 30, 2018, there has not been any impact to the fair value of our derivative liabilities due to our own credit risk. Similarly, there has not been any significant adverse impact to our derivative assets based on our evaluation of our counterparties' credit risks.

Contingent Consideration

In connection with prior 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 4.2% for developmental milestones and a weighted average cost of capital ranging from 9.0% to 21.0% 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, 2018, estimated future contingent milestone payments related to prior business combinations range from zero if no milestone events are achieved, to a maximum of $702.0 if all development, regulatory and sales-based milestones are reached. As of September 30, 2018, the fair value of acquisition-related contingent consideration was $275.2. The following table represents a roll-forward of our acquisition-related contingent consideration:

	Nine months ended September 30, 2018
Balance at December 31, 2017	$ 168.9
Amounts derecognized upon sale of asset	(4.6)
Changes in fair value	110.9
Balance at September 30, 2018	$ 275.2

In September 2018, we sold all our assets, rights and obligations related to the ALXN1101 program to a third party and, as a result, in the quarter ended September 30, 2018, derecognized $4.6 of contingent consideration due under our prior purchase agreement with Orphatec Pharmaceuticals GmbH, dated February 8, 2011. The definitive agreement related to our sale of ALXN1101 provides for contingent consideration payments to Alexion 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 contingent payments is deemed to be fully constrained as of September 30, 2018, and therefore has not been included in the transaction price. For the three and nine months ended September 30, 2018, we recognized an immaterial gain on the sale of ALXN1101 within operating income.

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 quarter ended September 30, 2018.

14. Revenue Recognition

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

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that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract, and determines those that are performance obligations. Revenue is recognized for the applicable performance element when each distinct performance obligation is satisfied.

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

Nature of Products

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

Our customers are primarily comprised of distributors, pharmacies, hospitals, hospital buying groups, and other healthcare providers. In some cases, we may also sell to governments and government agencies. In addition to sales in countries where our products are commercially available, we have also recorded revenue on sales for patients receiving treatment through named-patient programs. The relevant authorities or institutions in those countries have agreed to reimburse for product sold on a named-patient basis where our products have not received final approval for commercial sale.

Revenue is recognized at the amount to which we expect to be entitled in exchange for the sale of our products. This amount includes both fixed and variable consideration and excludes amounts that are collected from customers and remitted to governmental authorities, such as value-added taxes in foreign jurisdictions. Shipping and handling costs associated with outbound freight after control of a product has transferred to our customers are accounted for as a fulfilment cost and are included in operating expenses. The cost for any shipping and handling activities (including customs clearance activities) associated with transactions for which revenue has been recognized are accrued if not completed before the respective period end.

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

We evaluate the creditworthiness of customers on a regular basis. In certain European countries, sales by us are subject to payment terms that are statutorily determined. This is primarily the case in countries where the payer is government-owned or government-funded, which we consider to be creditworthy. The length of time from sale to receipt of payment in certain countries exceeds our credit terms. In countries in which collections from customers extend beyond normal payment terms, we seek to collect interest. We record interest on customer receivables as interest income when collected. Subsequent adjustments for further declines in credit rating are recorded as bad debt expense as a component of selling, general and administrative expense. We also use judgments as to our ability to collect outstanding receivables and provide allowances for the portion of receivables if and when collection becomes doubtful, and we also assess on an ongoing basis whether collectibility is probable at the time of sale. As of

September 30, 2018 and December 31, 2017, allowances on receivables were not material.

Variable Consideration

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

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refunded may differ from our estimates. If actual results in the future vary from our estimates, we adjust these estimates, which would affect net product sales and earnings in the period such variances become know.

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

Discounts and Rebates: We offer discounts and rebates to certain distributors and customers under our arrangements. In many cases, these amounts are fixed at the time of sale and the transaction price is reduced accordingly. We also provide for rebates under certain governmental programs, including Medicaid in the U.S. and other programs outside the U.S. which are payable based on actual claim data. We estimate these rebates based on an analysis of historical claim patterns and estimates of customer mix to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period and record any necessary adjustments, which may have an impact on revenue in the period in which the adjustment is made. Generally, the length of time between product sale and the processing and reporting of the rebates is three to six months.

Volume-Based Arrangements: We have entered into volume-based arrangements with governments in certain countries and other customers in which reimbursement is limited to a contractual amount. Under this type of arrangement, amounts billed in excess of the contractual limitation are repaid to the customer as a rebate. We estimate incremental discounts resulting from these contractual limitations, based on forecasted sales during the limitation period, and we apply the discount percentage to product shipments as a reduction of revenue. Our calculations related to these arrangements require estimation of sales during the limitation period, and adjustments in these estimates may have a material impact in the period in which these estimates change.

Distribution & Other Fees: We pay distribution and other fees to certain customers in connection with the sales of our products. We record distribution and other fees paid to our customers as a reduction of revenue, unless the payment is for a distinct good or service from the customer and we can reasonably estimate the fair value of the goods or services received. If both conditions are met, we record the consideration paid to the customer as an operating expense. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

Product Returns: Our contracts with customers generally provide for returns only if the product is damaged or defective upon delivery. We assess our sales transactions and arrangements with customers and monitor inventory within our sales channels to determine whether a provision for returns is warranted and a resulting adjustment to the transaction price is necessary. This assessment is based on historical experience and assumptions as of the date of sale and changes in these estimates could have an impact in the period in which the change occurs. Because of factors such as the price of our products, the limited number of patients, the short period from product sale to patient infusion and limited contractual return rights, our customers often carry limited inventory.

The amount of variable consideration included in the transaction price is constrained by the amount that is probable will not result in a significant reversal of revenue. We consider our experience with similar transactions and expectations regarding the contract in estimating the amount of variable consideration to which we expect to be entitled, and determining whether the estimated variable consideration should be constrained. We do not have any material constraints on the variable consideration included within the transaction price of our current revenue arrangements.

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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,	
	2018	2017	2018	2017
Soliris				
United States	$404.5	$307.6	$1,136.3	$913.5
Europe	262.1	248.4	766.3	738.3
Asia Pacific	98.2	81.8	277.3	241.4
Rest of World	123.2	117.6	406.4	459.0
Total	$888.0	$755.4	$2,586.3	$2,352.2
Strensiq				
United States	$86.6	$70.6	$275.7	$203.9
Europe	16.6	9.6	47.0	23.3
Asia Pacific	7.2	5.2	19.2	13.3
Rest of World	2.8	1.6	7.1	3.7
Total	$113.2	$87.0	$349.0	$244.2
Kanuma				
United States	$13.7	$11.4	$38.6	$31.2
Europe	4.7	3.6	16.4	8.7
Asia Pacific	0.8	0.7	2.9	1.8
Rest of World	6.1	0.7	8.4	2.0
Total	$25.3	$16.4	$66.3	$43.7

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 statements of operations.

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

	September 30, 2018	December 31, 2017
Receivables, which are included in "Trade accounts receivable, net"	$ 910.2	$ 726.5
Contract liabilities, which are included in "Other current liabilities"	$ 3.2	$ 15.9

Upon adoption of the new revenue recognition standard, on January 1, 2018, we reduced our deferred revenue balance by $10.4, with an offsetting increase of $6.0 in retained earnings due to the cumulative impact of adopting this new standard. The adjusted deferred revenue balance, as of January 1, 2018, was $5.5. We recognized this amount in revenue in the first quarter of 2018.

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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, 2018 and 2017:

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Income tax expense	$11.2	$(19.8)	$152.5	$45.2
Effective tax rate	3.3 %	(34.0)%	55.4 %	9.9 %

The income tax expense for the three and nine months ended September 30, 2018 and 2017 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. The increase in the effective tax rate for the three months ended September 30, 2018 as compared to the same period in the prior year is primarily attributable to the benefit of settling a routine Internal Revenue Service (IRS) examination in the prior year, offset by U.S. tax reform measurement period adjustments of $(53.1). The increase in the effective tax rate for the nine months ended September 30, 2018 as compared to the same period in the prior year is primarily attributable to the acquisition of Wilson Therapeutics, offset by U.S. tax reform measurement period adjustments and the benefit of settling a routine IRS examination in the prior year. 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 in acquired in-process research and development for the nine months ended September 30, 2018. No tax benefit has been recognized for this expense, which resulted in an increase to the effective tax rate of 41.3%. 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 for the nine months ended September 30, 2018 by approximately 1.4%.

In December 2017, the Tax Act was enacted into law. The Tax Act decreased the U.S. federal corporate tax rate to 21.0%, imposed a minimum tax on foreign earnings related to intangible assets (GILTI), a one-time transition tax on previously unremitted foreign earnings, and modified the taxation of other income and expense items. With regard to the GILTI minimum tax, foreign earnings are reduced by the profit attributable to tangible assets and a deductible allowance of up to 50.0%, subject to annual limitations. We have elected to account for the impact of the minimum tax in deferred taxes.

We incorporated the impact of the Tax Act in our results or calculated provisional amounts for the tax effects of the Tax Act for the year ended December 31, 2017. As of September 30, 2018 we have concluded our accounting for the Tax Act as follows:

(a) We calculated a reasonable estimate of the one-time transition tax on previously unremitted earnings, which resulted in an increase to U.S. Federal tax expense of $177.9 and an increase to taxes payable, net of tax credits, of $28.0 in the period ended December 31, 2017. Our initial accounting for the transition tax was not complete as of December 31, 2017 because there was uncertainty regarding the calculation of the amounts subject to the tax. We completed our analysis of the transition tax and related interpretive guidance during the third quarter 2018. No significant measurement period adjustment to our initial accounting was required.

(b) We calculated a reasonable estimate of the Tax Act's limits on deductions for employee remuneration, including remuneration in kind, which resulted in an insignificant impact to tax expense, taxes payable, and deferred taxes in the period ended December 31, 2017. Our initial accounting for these limits was incomplete because there was uncertainty regarding the value of the deduction-limited remuneration. We completed our analysis of the relevant employee remuneration arrangements during the third quarter 2018. No measurement period adjustment to our initial accounting was required.

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As of September 30, 2018, our initial accounting for the Tax Act is incomplete as follows:

(a) We calculated a reasonable estimate of the impact of the Tax Act to U.S. state income taxes, which resulted in an increase to tax expense, taxes payable, and deferred taxes of $2.9, $2.2, and $0.7, respectively, in the period ended December 31, 2017. We interpreted the effect of the Tax Act's changes to federal law on each U.S. state's system of taxation as of the date of enactment. However, additional analysis is required to determine the effect of modifications to federal deductions and income inclusions on these systems. No measurement period adjustment to our initial accounting was recorded for the three and nine months ended September 30, 2018.

(b) We calculated a reasonable estimate of the impact of the GILTI minimum tax on deferred taxes in the period ended December 31, 2017, which resulted in an increase to U.S. Federal tax expense and the deferred tax liability of $236.9. Our initial accounting for the minimum tax is incomplete because there is uncertainty regarding the calculation of the temporary differences that will be subject to the minimum tax. Additional analysis regarding the computation of these temporary differences and the expected timing and manner of their realization is required to complete our accounting. During the three months ended September 30, 2018 the Company recorded a measurement period adjustment of $(57.8) to income tax (benefit) as a result of analyzing the deductible allowance in deferred taxes.

(c) We calculated the deferred tax liability related to our foreign captive partnership in the period ended December 31, 2017 consistent with our calculation in periods prior to enactment of the Tax Act. As a result, the deferred tax liability we recorded as of December 31, 2017 of $533.4 related to our foreign captive partnership is provisional. Additional analysis of the direct and indirect effects of the Tax Act is required to complete our accounting for this item. We recorded a measurement period adjustment of $4.7 in U.S. state income tax expense and deferred taxes to this provisional estimate for the three months ended September 30, 2018.

In 2017, the 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.

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.

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, 2018 and 2017 was not material.

17. Facility Lease Obligations

New Haven Facility Lease Obligation

In November 2012, we entered into a lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. The term of the lease commenced in 2015 and will expire in 2030, with a renewal option of ten years. Although we do not legally own the premises, we are deemed to be the owner of the building due to the substantial

improvements directly funded by us during the construction period based on applicable accounting guidance for build-to-suit leases. Accordingly, the landlord's costs of constructing the facility during the construction period are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our consolidated balance sheets.

Construction of the facility was completed and the building was placed into service in the first quarter 2016. For each of the three and nine months ended September 30, 2018 and 2017, we recognized $3.5 and $10.6, respectively, of interest expense associated with this arrangement. As of September 30, 2018 and December 31,

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2017, our total facility lease obligation was $134.0 and $134.6, respectively, recorded within other current liabilities and facility lease obligation on our condensed consolidated balance sheets.

Lonza Facility Lease Obligation

During the third quarter 2015, we entered into a new agreement with Lonza Group AG and its affiliates (Lonza) whereby Lonza will construct a new manufacturing facility dedicated to Alexion at one of its existing facilities. The agreement requires us to make certain payments during the construction of the new manufacturing facility and annual payments for ten years thereafter. As a result of our contractual right to full capacity of the new manufacturing facility, a portion of the payments under the agreement are considered to be lease payments and a portion as payment for the supply of inventory. Although we will not legally own the premises, we are deemed to be the owner of the manufacturing facility during the construction period based on applicable accounting guidance for build-to-suit leases due to our involvement during the construction period. Accordingly, the landlord’s costs of constructing the facility during construction period are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our consolidated balance sheets. The completion of the facility, including obtaining regulatory approval, is expected in 2019. As of September 30, 2018 and December 31, 2017, we recorded a construction-in-process asset of $203.4 and $180.6, respectively, and an offsetting facility lease obligation of $156.1 and $159.1, respectively, within other current liabilities and facility lease obligation on our condensed consolidated balance sheets.

Payments to Lonza under the agreement are allocated to the purchases of inventory and the repayment of the facility lease obligation on a relative fair value basis. During the nine months ended September 30, 2018, we incurred $53.7 of payments to Lonza under this agreement, of which $7.0 was applied against the outstanding facility lease obligation and $46.7 was recognized as a prepayment of inventory. See Note 18 for minimum fixed payments due under Lonza agreements.

Boston Facility Lease Obligation

In September 2017, we entered into a lease agreement for approximately 150,000 square feet of office space that was constructed in Boston, Massachusetts. The term of the lease commenced upon the landlord's substantial completion of our premises in the second quarter of 2018 and will expire on the thirteenth anniversary of commencement, with an option to renew for up to an additional ten years. Although we will not legally own the premises, due to our involvement during the construction period, we are deemed to be the owner of the portion of the building that we will lease based on applicable accounting guidance for build-to-suit leases. Accordingly, the landlord's costs of constructing the facility during the construction period were capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our condensed consolidated balance sheets.

Construction of the facility was completed and the building was placed into service in the second quarter 2018. As of September 30, 2018 and December 31, 2017, our total facility lease obligation was $82.3 and $59.6, respectively, within facility lease obligation on our condensed consolidated balance sheets.

18. Commitments and Contingencies

Commitments

License Agreements

We have entered into a number of license agreements in order to advance and obtain technologies and services related to our business. License agreements generally require us to pay an initial fee and certain agreements call for future payments upon the attainment of agreed upon development and/or commercial milestones. These agreements may also require minimum royalty payments based on sales of products developed from the applicable technologies, if any.

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 $1,174.7. If we terminate certain supply

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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) prior to its sale and a payment with respect to sales of Soliris manufactured at Lonza facilities.

In addition to Lonza, we have non-cancellable commitments of approximately $63.6 through 2020 with other third party manufacturers.

Contingent Liabilities

We are currently involved in various claims, lawsuits and legal proceedings. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, we accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on our best estimates based on 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 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.

We have received, and may in the future receive, notices from third parties claiming that their patents may be infringed by the development, manufacture or sale of our products. Under the guidance of ASC 450, Contingencies, we record a royalty accrual based on our best estimate of the fair value percent of net sales of our products that we could be required to pay the owners of patents for technology used in the manufacture and sale of our products. A costly license, or inability to obtain a necessary license, could have a material adverse effect on our financial results.

In May 2015, we received a subpoena in connection with an investigation by the Enforcement Division of the 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 to enhance and remediate its business processes, structures, controls, training, talent and systems across Alexion’s global operations. For information concerning the risks associated with the investigation, see our Risk Factor - "If we fail to comply with laws or regulations, we may be subject to investigations and civil or criminal penalties and our business could be adversely affected."

As previously reported, on December 29, 2016, a shareholder filed a putative class action against the Company and certain former employees in the U.S. District Court for the District of Connecticut, alleging that defendants made misrepresentations and omissions about Soliris. On April 12, 2017, the court appointed a lead plaintiff. On July 14, 2017, the lead plaintiff filed an amended putative class action complaint against the Company and seven current or former employees. The complaint alleges that defendants made misrepresentations and omissions about Soliris, including alleged misrepresentations regarding sales practices, management changes, and related investigations, between January 30, 2014 and May 26, 2017, and that the Company's stock price dropped upon the purported disclosure of the misrepresentations. Defendants moved to dismiss the amended complaint on September 12, 2017. Plaintiffs filed an opposition to defendants' motion to dismiss on November 13, 2017, and defendants' filed

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a reply brief in further support of their motion on December 28, 2017. Defendants' motion to dismiss is now fully briefed and pending before the court. Given the early stages of this litigation, an estimate of the possible loss or range of loss cannot be made 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 501(c)(3) organizations that provide financial assistance to Medicare patients taking drugs sold by Alexion, Alexion's provision of free drug to Medicare patients, and Alexion compliance policies and training materials concerning the anti-kickback statute or payments to any 501(c)(3) organization that provides financial assistance to Medicare patients. We understand that the U.S. Attorney's Office and the DOJ are coordinating its inquiry with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services. Other companies have disclosed similar inquiries. We are cooperating with this inquiry. We are engaged in discussions with the DOJ about a potential resolution of this matter. There can be no assurance that any current or future discussions with the government to resolve these matters will be successful or that any potential settlement terms or amount will be agreed to or finalized. We are unable to predict when these matters will be resolved or what further action, if any, the government will take in connection with them.

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 was not determined to be a material amount. In October 2017, Alexion filed an application for judicial review of the PMPRB's decision in the Federal Court of Canada. A hearing is scheduled to take place in November 2018. At this time, we cannot predict the outcome of these judicial review proceedings or any appeals that may follow and cannot reasonably estimate the amount of any forfeitures that will be required to be made or the potential impact to future Soliris revenues in Canada relating to any potential future price reduction.

In October 2018, the Japanese Ministry of Health, Labor and Welfare conducted an administrative inspection of Alexion's Japanese operations. The MHLW inquiry has been primarily focused on our communication efforts regarding the proper use of Soliris in Japan for aHUS, among other matters. We have cooperated, and will continue to cooperate, with this inquiry. Given the early stages of this matter, an estimate of the possible loss or range of loss, or what further action, if any, the MHLW will take in connection with this matter, cannot be made at this time.

19. Restructuring and Related Expenses

In the first quarter of 2017, we initiated a company-wide restructuring designed to help position the Company for sustainable, long-term growth that we believe will further allow us to fulfill our mission of serving patients and

families with rare diseases. The initial restructuring activities primarily focused on a reduction of the Company's global workforce. In September 2017, we committed to an operational plan to re-align the global organization with its refocused corporate strategy. The re-alignment focuses investments in priority growth areas to maximize leadership in complement and grow the rare disease business. The re-alignment also included the relocation of the Company's headquarters to Boston, Massachusetts which was completed in the second quarter of 2018. Our New Haven, Connecticut site continues to support employees working in the research and process development laboratories, the clinical supply and quality teams, nurse case management and a number of important enterprise business services. The plan also reduced the Company's global workforce by approximately 20.0%. The restructuring is designed to result in cost savings by focusing the development portfolio, simplifying business structures and processes across the Company's global operations, and closing of multiple Alexion sites, including ARIMF and certain regional and country-based offices.

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The following table summarizes the total expenses recorded related to the restructuring activities by the type of activity and the locations recognized within the consolidated statements of operations:

	Three months ended September 30, 2018				Three months ended September 30, 2017			
	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total
Cost of Sales	$—	$ —	$ —	$—	$—	$ 83.0	$ —	$83.0
Research and Development	—	—	—	—	—	1.0	—	1.0
Selling, General and Administrative	—	7.9	—	7.9	—	6.4	—	6.4
Restructuring Expense	2.8	—	7.5	10.3	66.2	—	5.8	72.0
Other (Income) Expense	—	—	—	—	—	—	2.3	2.3
	$2.8	$ 7.9	$ 7.5	$18.2	$66.2	$ 90.4	$ 8.1	$164.7

	Nine months ended September 30, 2018				Nine months ended September 30, 2017			
	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total
Cost of Sales	$—	$ 5.8	$—	$5.8	—	83.0	—	$83.0
Research and Development	—	0.1	—	0.1	—	1.0	—	$1.0
Selling, General and Administrative	—	18.0	—	18.0	—	6.4	—	$6.4
Restructuring Expense	6.9	—	19.5	26.4	86.3	—	12.4	$98.7
Other (Income) Expense	—	—	(0.1)	(0.1)	—	—	2.3	$2.3
	$6.9	$ 23.9	$19.4	$50.2	$86.3	$ 90.4	$14.7	$191.4

The following table presents a reconciliation of the restructuring reserve recorded within accrued expenses on the Company's condensed consolidated balance sheet for the three and nine months ended September 30, 2018:

	Three months ended September 30, 2018				Nine months ended September 30, 2018			
	Employee Separation Costs	Asset Charges	Other Costs	Total	Employee Separation Costs	Asset Charges	Other Costs	Total
Liability, beginning of period	$17.5	$ —	$2.6	$20.1	$53.8	$ —	$4.4	$58.2
Restructuring and Related Expenses	1.1	7.9	7.0	16.0	5.9	23.9	19.7	49.5
Cash settlements	(9.8)	—	(6.3)	(16.1)	(50.2)	—	(20.0)	(70.2)
Adjustments to previous estimates	1.7	—	0.5	2.2	1.0	—	(0.3)	0.7
Asset impairments	—	(7.9)	—	(7.9)	—	(23.9)	—	(23.9)
Liability, end of period	$10.5	$ —	$3.8	$14.3	$10.5	$ —	$3.8	$14.3

The restructuring reserve of $14.3 and $58.2 is recorded in accrued expenses on the Company's condensed consolidated balance sheet as of September 30, 2018 and December 31, 2017, respectively. We currently estimate

incurring up to an additional $125.0 in restructuring and related expenses primarily related to contract termination and related charges. We expect approximately half of the remaining restructuring and related expenses will result in cash outlays and we expect to pay all accrued amounts related to this restructuring during the next fiscal year.

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Notes to Condensed Consolidated Financial Statements
(unaudited)
(amounts in millions, except per share amounts)

20. Subsequent Events

In October 2018, we entered into a collaboration agreement with Dicerna Pharmaceuticals, Inc. (Dicerna) that provides us with exclusive worldwide licenses and development and commercial rights for two pre-clinical RNA interference (RNAi) subcutaneously delivered molecules for complement-mediated diseases, as well as an exclusive option for other pre-clinical RNAi molecules for two additional targets within the complement pathway. In addition to the collaboration agreement, we made an equity investment in Dicerna. Under the terms of the agreements, we will make an upfront payment of $37.0 for the exclusive licenses and the equity investment. We could also be required to pay up to approximately $625.0 for option exercise fees and amounts due upon the achievement of specified research, development, regulatory and commercial milestones, as well as royalties on commercial sales.

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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 that are being made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "committed," variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such statements. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management's beliefs, and certain assumptions made by our management, and may include, but are not limited to, statements regarding:

- the potential benefits and commercial potential of Soliris®, Strensiq® and Kanuma® for approved indications and any expanded uses, timing and effect of sales of our products in various markets worldwide, pricing for our products, level of insurance coverage and reimbursement for our products, timing regarding development and regulatory approvals for additional indications or in additional territories;
- the medical and commercial potential of ALXN 1210, as well as Soliris for additional indications;
- Soliris will continue to contribute a significant percentage of total revenue for the next several years and that demand for Soliris will increase;
- future costs, expenses and capital requirements, interest rates, cash outflows, operating expenses, capital investment, cash from operations, investment in certain facilities, status of reimbursement, price approval and funding processes in various countries worldwide;
- adequacy of cash resources to fund operations, fund acquisitions, as well as pay future contingent consideration obligations and payments under license agreements (and expected impact on liquidity), acquisition agreements and to make principal and interest payments under our debt agreement;
- the safety and efficacy of our products and our product candidates;
- the date of completion of construction and the regulatory approval of certain manufacturing and fill/finish facilities;
- expected impact of delay in collecting accounts receivable;
- the planned closing of acquisitions and the timing of the completion of acquisitions;
- impact of currency fluctuations;
- the expected impact of regulatory and legislative programs and government reimbursement and coverage;
- status of our ongoing clinical trials for eculizumab, ALXN1210 and our other product candidates, commencement dates for new clinical trials, clinical trial results, evaluation of our clinical trial results by regulatory agencies, the adequacy of our pharmacovigilance and drug safety reporting processes, anticipated filing and prospects for regulatory approval of our products and our product candidates, need for additional research and testing, the uncertainties involved in the drug development process and manufacturing;
- performance and reliance on third party service providers;
- our future research and development activities, plans for acquired programs, business development actions, our ability to develop and commercialize products with our collaborators;
- assessment of competitors and potential competitors;
- anticipated completion of tax audits;
- recoverability of the cost basis of certain debt securities;
- periods of patent, regulatory and market exclusivity for our products;
- estimated amortization expense for certain intangible assets;
- the scope of our intellectual property and the outcome of any challenges or opposition to our intellectual property;
- assertion or potential assertion by third parties that the manufacture, use or sale of our products infringes their intellectual property;
- the impact of new accounting standards and the Tax Act on the Company's results of operations;

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- compliance program transformation and improvements;
- estimates of the capacity of manufacturing and other service facilities to support our products and our product candidates;
- the expected benefits and the estimates of additional restructuring and related expenses and the timing of the payment of such amounts; and
- potential costs resulting from product liability or other third party claims.

Such risks and uncertainties include, but are not limited to, the possibility that expected tax benefits will not be realized, assessment of impact of recent accounting pronouncements, potential declines in sovereign credit ratings or sovereign defaults in countries where we sell our products, delay of collection or reduction in reimbursement due to adverse economic conditions or changes in government and private insurer regulations and approaches to reimbursement, uncertainties surrounding legal proceedings, company investigations and government investigations, including our Securities and Exchange Commission (SEC) and U.S. Department of Justice (DOJ) investigations, the securities class action litigation filed in December 2016, the inquiry by the U.S. Attorney's Office for the District of Massachusetts requesting documents relating generally to our support of patient assistance programs, the investigation of our Brazilian operations by Brazilian authorities and the inspection of our Japanese operations by the MHLW, risks related to challenges to our intellectual property portfolio or claims that we infringe third party intellectual property rights, the short and long-term effects of other government healthcare measures, and the effect of shifting foreign exchange rates, as well as those risks and uncertainties discussed later in this report under the section entitled “Risk Factors.” Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in this and other reports or documents we file from time to time with the SEC.

Overview

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

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

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

Recent Developments

In the second quarter 2018, we completed the acquisition of more than 99% of the equity interests of Wilson Therapeutics AB (publ), a biopharmaceutical company based in Stockholm, Sweden (Wilson Therapeutics), pursuant to a recommended public cash offer to all Wilson Therapeutics AB shareholders. Wilson Therapeutics develops a novel therapy for patients with rare copper-mediated disorders and, pursuant to the acquisition, we added WTX101, a highly innovative drug candidate that is currently in the early stages of Phase III clinical trials for the treatment of patients with Wilson disease, to our clinical pipeline.

In June 2018, we submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for approval of Ultomiris™ (also referred to as ALXN1210), our investigational long-acting C5 complement inhibitor, for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) as well as a Marketing Authorization Application to the European Medicines Agency (EMA) for Ultomiris for the treatment of patients with PNH. In September 2018, ALXN1210 (PNH) was designated as an orphan drug in Japan. In September 2018, we also filed an application with Japan's Pharmaceuticals and Medical Devices Agency (PDMA) for the approval of Ultomiris for PNH.

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

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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 neonatal Fc receptor (FcRn). Syntimmune's lead candidate, SYNT001, is a monoclonal antibody that inhibits the interaction of FcRn with Immunoglobulin G (IgG) and IgG immune complexes, and is being studied in Phase 1b/2a trials for the treatment of IgG-mediated autoimmune diseases. Under the terms of the agreement, Alexion will acquire Syntimmune for an upfront payment of $400.0, with the potential for additional milestone-dependent payments of up to $800.0, for a total value of up to $1,200.0. The acquisition of Syntimmune, which is subject to the satisfaction of customary closing conditions (including approval from relevant regulatory agencies), is expected to close in the fourth quarter of 2018. We intend to finance the acquisition through cash on hand and account for the transaction as an asset acquisition.

Products and Development Programs

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

Marketed Products

Our marketed products consist of the following:

Product	Development Area	Indication
	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)
	Hematology/Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)
	Neurology	Generalized Myasthenia Gravis (gMG)
	Metabolic Disorders	Hypophosphatasia (HPP)
	Metabolic Disorders	Lysosomal Acid Lipase Deficiency (LAL-D)

Soliris (eculizumab)

Soliris is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation associated with chronic disorders in several therapeutic areas, including hematology, nephrology and neurology. Soliris is a humanized monoclonal antibody that effectively blocks terminal complement activity at the doses currently prescribed. The initial indication for which we received approval for Soliris is PNH.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

PNH is a debilitating and life-threatening, ultra-rare genetic blood disorder defined by chronic uncontrolled complement activation leading to the destruction of red blood cells (hemolysis). The chronic hemolysis in patients with PNH may be associated with life-threatening thrombosis, recurrent pain, kidney disease, disabling fatigue, impaired quality of life, severe anemia, pulmonary hypertension, shortness of breath and intermittent episodes of dark-colored urine

(hemoglobinuria). We continue to work with researchers to expand the base of knowledge in PNH and the utility of Soliris to treat patients with PNH. Soliris is approved for the treatment of PNH in the U.S., Europe, Japan and in several other countries. We are sponsoring a multinational registry to gather information regarding the natural history of patients with PNH and the longer term outcomes during Soliris treatment. In addition, Soliris has been granted orphan drug designation for the treatment of PNH in the U.S., Europe, Japan and several other countries.

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Atypical Hemolytic Uremic Syndrome (aHUS)

aHUS is a severe and life-threatening, ultra-rare genetic disease characterized by chronic uncontrolled complement activation and thrombotic microangiopathy (TMA), the formation of blood clots in small blood vessels throughout the body, causing a reduction in platelet count (thrombocytopenia) and life-threatening damage to the kidney, brain, heart and other vital organs. Soliris is approved for the treatment of pediatric and adult patients with aHUS in the U.S., Europe, Japan and in several other countries. We are sponsoring a multinational registry to gather information regarding the natural history of patients with aHUS and the longer-term outcomes during Soliris treatment. In addition, the U.S. Food and Drug Administration (FDA) and European Commission (EC) have granted Soliris orphan drug designation for the treatment of patients with aHUS.

Generalized Myasthenia Gravis (gMG)

Myasthenia Gravis (MG) is a debilitating, complement-mediated neuromuscular disease in which patients suffer profound muscle weakness throughout the body, resulting in slurred speech, impaired swallowing and choking, double vision, upper and lower extremity weakness, disabling fatigue, shortness of breath due to respiratory muscle weakness and episodes of respiratory failure. Soliris has received orphan drug designation for the treatment of patients with MG in the U.S. and Europe, and for the treatment of patients with refractory gMG, a subset of MG, in Japan.

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

Strensiq (asfotase alfa)

Hypophosphatasia (HPP)

HPP is an ultra-rare genetic and progressive metabolic disease in which patients experience devastating effects on multiple systems of the body, leading to debilitating or life-threatening complications. HPP is characterized by defective bone mineralization that can lead to deformity of bones and other skeletal abnormalities, as well as systemic

complications such as profound muscle weakness, seizures, pain, and respiratory failure leading to premature death in infants.

Strensiq, a targeted enzyme replacement therapy, is the first and only approved therapy for patients with HPP and is designed to directly address underlying causes of HPP by aiming to restore the genetically defective metabolic process, thereby preventing or reversing the severe and potentially life-threatening complications in patients with HPP. In 2015, the FDA approved Strensiq for patients with perinatal-, infantile- and juvenile-onset HPP, the EC granted marketing authorization for Strensiq for the treatment of patients with pediatric-onset HPP, and the MHLW approved Strensiq for the treatment of patients with HPP. We are sponsoring a multinational registry to gather information regarding the natural history of patients with HPP and the longer-term outcomes during Strensiq treatment.

Kanuma (sebelipase alfa)

Lysosomal Acid Lipase Deficiency (LAL Deficiency or LAL-D)

LAL-D is a serious, life-threatening ultra-rare disease associated with premature mortality and significant morbidity. LAL-D is a chronic disease in which genetic mutations result in decreased activity of the LAL enzyme that leads to marked accumulation of lipids in vital organs, blood vessels, and other tissues, resulting in progressive and systemic organ damage including hepatic fibrosis, cirrhosis, liver failure, accelerated atherosclerosis, cardiovascular disease, and other devastating consequences.

Kanuma, a recombinant form of the human LAL enzyme, is the only enzyme-replacement therapy that is approved for the treatment for patients with LAL-D. In 2015, the FDA approved Kanuma for the treatment of patients with LAL-D and the EC granted marketing authorization of Kanuma for long-term enzyme replacement therapy in patients of all

ages with LAL-D. In 2016, the MHLW approved Kanuma for the treatment of patients of all ages in Japan with LAL-D. We are sponsoring a multinational registry to gather information regarding the natural history of patients with LAL-D and the longer-term outcomes during Kanuma treatment.

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Clinical Development Programs
Our clinical development programs include the following:

Product	Development Area	Indication	Phase I	Phase II	Phase III	Filed
	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)				1
ALXN1210 (IV)	Hematology/Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)			1	
	Neurology	Generalized Myasthenia Gravis (gMG)			1	
ALXN1210 (Subcutaneous)	Hematology/Nephrology	PNH/aHUS			1	
ALXN1810 (Subcutaneous)	Next Generation Subcutaneous Complement Inhibitor		1			
Soliris (eculizumab)	Neurology	Relapsing Neuromyelitis Optica Spectrum Disorder (NMOSD)			1	
WTX101	Metabolics	Wilson disease			1	

ALXN1210
ALXN1210 is an innovative, long-acting C5 inhibitor discovered and developed by Alexion that works by inhibiting the C5 protein in the terminal complement cascade. In early studies, ALXN1210 demonstrated rapid, complete, and sustained reduction of free C5 levels.
Paroxysmal Nocturnal Hemoglobinuria (PNH)
Chronic hemolysis in patients with PNH may be associated with life-threatening thrombosis, 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).
In May 2016 and January 2017, the Committee for Orphan Medicinal Products and the FDA, respectively, granted orphan drug designation to ALXN1210, for the treatment of patients with PNH.
In February 2018, we began enrolling in a Phase III, open-label, single-arm multicenter study to evaluate the PK/PD, safety, and efficacy of ALXN1210 administered by IV infusion to pediatric patients with PNH, including patients who have never received treatment with a complement inhibitor and those who enter the study stabilized on Soliris.
In March 2018, we announced that the pivotal Phase III, open-label, randomized, active-controlled multicenter study to evaluate the safety and efficacy of ALXN1210 versus Soliris administered by intravenous (IV) infusion every 8 weeks to adult patients with PNH who have never received treatment with a complement inhibitor demonstrated non-inferiority to Soliris in complement inhibitor treatment-naïve patients with PNH based on the co-primary endpoints of transfusion avoidance and normalization

of LDH levels, a direct marker of complement-mediated hemolysis in PNH. The study also demonstrated non-inferiority on all four key secondary endpoints: percentage change from baseline in LDH levels, change from baseline in quality of life as assessed by the Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue scale, proportion of patients with breakthrough hemolysis, and proportion of patients with stabilized hemoglobin levels. In addition, numeric results for all six endpoints favored ALXN1210. There were no notable differences in the

safety profiles for ALXN1210 and Soliris in the study.

In April 2018, we announced the results of a Phase III study of ALXN1210 to evaluate the safety and efficacy of ALXN1210 versus Soliris in patients with PNH who have been treated with Soliris for at least the past 6 months. The study demonstrated non-inferiority of ALXN1210 to Soliris in patients with PNH who had been stable on Soliris based on the primary endpoint of change in LDH levels, a direct marker of complement-mediated hemolysis in PNH. The study also demonstrated non-inferiority on all four key secondary endpoints: the proportion of patients with breakthrough hemolysis, the change from baseline in quality of life as assessed via the FACIT-Fatigue Scale, the proportion of patients avoiding transfusion, and the proportion of patients with stabilized hemoglobin levels. In addition, numeric results for all five endpoints favored ALXN1210. In the study, ALXN1210 had a safety profile that is consistent with that for Soliris.

In June 2018, we submitted a BLA to the FDA for approval of ALXN1210 for the treatment of patients with PNH. The submission uses a rare disease priority review voucher, which designates the BLA for an expedited eight-month review by the FDA instead of the standard twelve-month review. The FDA set a Prescription Drug User Fee Act (PDUFA) date of

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February 18, 2019, as part of this expedited eight-month review.
In June 2018, we submitted an MAA to the EMA for approval of ALXN1210 for the treatment of patients with PNH and in July 2018 the MAA was accepted in the EU and the review procedure started.
In September 2018, ALXN1210 (PNH) was designated as an orphan drug in Japan and we also filed an application with the PDMA for the approval of ALXN1210 for PNH.
Atypical Hemolytic Uremic Syndrome (aHUS)
In patients with aHUS, complement-mediated TMA leads to life-threatening damage to the kidney, brain, heart and other vital organs.
Enrollment was completed in late May 2018 in a Phase III, single arm, multicenter study to evaluate the safety and efficacy of ALXN1210 administered by IV infusion every 8 weeks to adult patients with aHUS who have never been treated with a complement inhibitor. A second Phase III, single arm, multicenter study to evaluate the safety, efficacy, pharmacokinetics (PK), and pharmaco-dynamics of ALXN1210 administered by IV infusion every 8 weeks in pediatric patients (including adolescents) with aHUS who have never been treated with a complement inhibitor is ongoing.
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.
Alexion plans to initiate a study with ALXN1210 administered by intravenous (IV) infusion every 8 weeks to adult patients for the treatment of gMG, a debilitating, chronic and progressive autoimmune neuromuscular disease, in 2019.
Subcutaneous (SC) Delivery
In late 2018, Alexion plans to initiate a single, PK-based Phase III study of ALXN1210 delivered subcutaneously once per week to PNH patients to support registration in both PNH and aHUS.
In October 2017, the FDA granted orphan drug designation to the subcutaneous formulation of ALXN1210 for the treatment of aHUS.

ALXN1810 Subcutaneous (SC) Delivery
ALXN1810 combines ALXN1210 with recombinant human hyaluronidase enzyme (rHuPH20) from Halozyme Therapeutics, Inc. to potentially further extend the dosing interval for ALXN1210 SC to once every two weeks or once per month. A SC healthy volunteer study with ALXN1810 was initiated in August 2018.
Soliris (eculizumab)
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 spinal cord. Each relapse of the disorder results in a stepwise accumulation of disability, including blindness and paralysis, and sometimes premature death. In September 2018, we announced the results of the Phase III global, randomized, double-blind, placebo-controlled study to evaluate eculizumab as a treatment for patients with relapsing NMOSD. The study met its primary endpoint of time to first adjudicated on-trial relapse, demonstrating that treatment with Soliris reduced the risk of NMOSD relapse by 94.2 percent compared to placebo. At 48 weeks, 97.9 percent of patients receiving Soliris were free of relapse compared to 63.2 percent of patients receiving placebo. Soliris had a safety profile consistent with that seen in previous clinical studies. The FDA, EC, and MHLW have each granted orphan designation for eculizumab as a treatment for patients with relapsing NMOSD.
WTX101
Wilson's 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. 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.

WTX101 is in Phase III development as a treatment for Wilson disease. In addition, WTX101 has received Fast Track designation in the U.S. and Orphan Drug Designation for the treatment of Wilson disease in the U.S. and EU.

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Manufacturing

We currently rely on internal manufacturing facilities and third party contract manufacturers, including Lonza Group AG and its affiliates (Lonza), to supply clinical and commercial quantities of our commercial products and product candidates. Our internal manufacturing facilities include our Ireland manufacturing facilities, and facilities in Massachusetts and Georgia. We also utilize third party contract manufacturers for other manufacturing services including purification, product filling, finishing, packaging, and labeling.

We have various agreements with Lonza through 2028, with remaining total non-cancellable commitments of approximately $1,174.7. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangements. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris that was manufactured at our Rhode Island Manufacturing Facility (ARIMF) and a payment with respect to sales of Soliris manufactured at Lonza facilities. During 2015, we entered into a new supply agreement with Lonza whereby Lonza will construct a new manufacturing facility dedicated to Alexion manufacturing at one of its existing facilities. While we sold the ARIMF facility in the third quarter of 2018, we continue to pay royalties to Lonza as the product manufactured at the facility while we were owner is still being sold.

In addition, we have non-cancellable commitments of approximately $63.6 through 2020 with other third party manufacturers.

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

In May 2015, we announced plans to construct a new biologics manufacturing facility on our existing property in Dublin, Ireland, which is expected to be completed and receive regulatory approval in 2020.

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, 2017. Under accounting principles generally accepted in the U.S., we are required to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingent assets and liabilities in our financial statements. Actual results could differ 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, 2017. Updates to our critical accounting policy for revenue recognition, including impacts from the adoption of the new revenue accounting standard, are discussed within Note 14, Revenue Recognition.

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New Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) issued a new standard requiring that the rights and obligations arising from leases be recognized on the balance sheet by recording a right-of-use (ROU) asset and corresponding lease liability. The new standard also requires qualitative and quantitative disclosures to understand the amount, timing, and uncertainty of cash flows arising from leases, as well as significant management estimates utilized. The standard is effective for interim and annual periods beginning after December 15, 2018 and requires a modified retrospective adoption. In July 2018, the FASB issued an update with an optional transition method when adopting the new leases standard. Under this new transition method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption rather than recast the comparative periods presented in the year of adoption. We plan to elect this optional method. We have substantially completed the process of collecting and continue to analyze the Company's lease contracts and during the third quarter 2018, we started implementing our leasing software, including data upload and test procedures. Our lease accounting software implementation efforts are ongoing. While our assessment of the standard remains open, the standard may have a material impact on the Company's Condensed Consolidated Balance Sheets due to the requirement to recognize lease ROU assets and corresponding liabilities related to leases on the Company's Condensed Consolidated Balance Sheets.

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

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

enacted tax rate. The standard is effective for interim and annual periods beginning after December 15, 2018 with early adoption permitted. We are currently assessing the impact of this standard on our financial condition.

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

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five-step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We adopted the new standard on January 1, 2018.

In January 2017, the FASB issued a new standard that clarifies the definition of a business and determines when an integrated set of assets and activities is not a business. This framework requires that if substantially all of the fair value

of gross assets acquired or disposed of is concentrated in a single asset or group of similar identifiable assets, the assets would not represent a business. We adopted the new standard on January 1, 2018 and will apply the new guidance prospectively to transactions occurring after adoption. We anticipate that the adoption of this new standard will likely result in more transactions, to the extent that such transactions are undertaken by the Company, being accounted for as asset acquisitions.

In January 2016, the FASB issued a new standard that changes accounting for equity

investments, financial liabilities under the fair value option, and presentation and disclosure requirements for financial instruments. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. Equity investments with readily determinable fair values will be measured at fair value with changes in fair value recognized in net income. Companies have the option to either measure equity investments without readily determinable fair values at fair value, or at cost adjusted for changes in observable prices minus impairment. We adopted the new standard on January 1, 2018, and have elected to measure our current equity investments without readily determinable fair values at cost adjusted for changes in observable prices minus impairment. In connection with the adoption of the new standard, we reclassified an immaterial amount of unrealized gains on equity securities from other comprehensive income to retained earnings. The guidance related to equity investments without readily determinable fair values was applied prospectively to equity investments that existed as of the date of adoption. We will assess our equity investments without readily determinable fair values for observable price changes and impairment on a quarterly basis. Refer to Note 10, Other Investments, for further details.

In March 2017, the FASB issued a new standard that improves the presentation of net periodic pension cost and net periodic post retirement benefit cost by requiring the bifurcation of net benefit cost. Under the new standard, the service cost component of net benefit cost will be presented with other employee costs in operating expenses; while other components will be reported separately in other income and expense. We adopted the new standard on January 1, 2018. The adoption of this standard did not have a material impact on our condensed consolidated statements of operations.

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

In August 2017, the FASB issued a new standard intended to improve and simplify certain aspects of the accounting for hedges. The new standard is intended to more closely align hedge accounting with companies' risk management strategies, simplify the

application of hedge accounting, and increase transparency as to the scope and results of hedging programs. It also amends the presentation and disclosure requirements and changes how companies assess effectiveness. The standard is effective for interim and annual periods beginning after December 15, 2018 with early adoption permitted. We early adopted the new standard in the second quarter 2018 using the modified retrospective method. The adoption of this standard did not have a material impact on our condensed consolidated financial statements.

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Results of Operations

Net Product Sales

Net product sales by significant geographic region for the three and nine months ended September 30, 2018 and 2017 are as follows:

	Three months ended September 30,		%	Nine months ended September 30,		%
	2018	2017	Change	2018	2017	Change
Soliris						
United States	$404.5	$307.6	31.5 %	$1,136.3	$913.5	24.4 %
Europe	262.1	248.4	5.5 %	766.3	738.3	3.8 %
Asia Pacific	98.2	81.8	20.0 %	277.3	241.4	14.9 %
Rest of World	123.2	117.6	4.8 %	406.4	459.0	(11.5)%
Total	$888.0	$755.4	17.6 %	$2,586.3	$2,352.2	10.0 %
Strensiq						
United States	$86.6	$70.6	22.7 %	$275.7	$203.9	35.2 %
Europe	16.6	9.6	72.9 %	47.0	23.3	101.7 %
Asia Pacific	7.2	5.2	38.5 %	19.2	13.3	44.4 %
Rest of World	2.8	1.6	75.0 %	7.1	3.7	91.9 %
Total	$113.2	$87.0	30.1 %	$349.0	$244.2	42.9 %
Kanuma						
United States	13.7	11.4	20.2 %	38.6	31.2	23.7 %
Europe	4.7	3.6	30.6 %	16.4	8.7	88.5 %
Asia Pacific	0.8	0.7	14.3 %	2.9	1.8	61.1 %
Rest of World	6.1	0.7	**	8.4	2.0	**
Total	$25.3	$16.4	54.3 %	$66.3	$43.7	51.7 %
Total Net Product Sales	$1,026.5	$858.8	19.5 %	$3,001.6	$2,640.1	13.7 %

** Percentages not meaningful

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Net Product Sales
United States Asia Pacific
Europe Rest of World

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

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

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

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The components of the increase in revenues are as follows:
The increase in net product sales for the three and nine months ended September 30, 2018, as compared to the same periods in 2017, was primarily due to an increase in unit volumes of 25.8% and 16.4%, respectively. This increase in unit volumes is primarily due to increased global demand for Soliris therapy including sales to patients with gMG, which received regulatory approval in the second half of 2017. Additional unit volume increases were due to increased sales of Strensiq and Kanuma during 2018 as a result of our continuing efforts to identify and reach more patients with HPP and LAL-D globally.
The volume increase for the three months ended September 30, 2018 was also driven by an increase within rest of world for Soliris therapy for patients in Latin America related to the timing of ordering patterns in the third quarter 2018 as compared to the same period in 2017.
The increase in net product sales for the three and nine months ended September 30, 2018, as compared to the same periods in 2017, was offset by price decreases of 5.3% and 3.2%, respectively, resulting primarily from price changes in Turkey and Brazil resulting from formalized reimbursement agreements, subsequent to marketing authorization, in the third quarter of 2018 and the fourth quarter of 2017, respectively.
As discussed above, we adopted the new revenue recognition guidance in the first quarter of 2018. The adoption of this standard did not have a material impact on the sales recognized in the three

and nine months ended September 30, 2018 as compared to the three and nine months ended September 30, 2017.
Cost of Sales
Cost of sales includes manufacturing costs as well as actual and estimated royalty expenses associated with sales of our products.
The following table summarizes cost of sales and cost of sales as a percent of net product sales for the three and nine months ended September 30, 2018 and 2017:

2018 Cost of Sales
2017 Cost of Sales
Cost of sales as a percentage of net product sales
The decrease in cost of sales as a percentage of net product sales for the three and nine months ended September 30, 2018 is primarily attributable to charges of $83.0 in the third quarter 2017 associated with the closure of the ARIMF facility that was announced in the third quarter of 2017 as part of our restructuring activities.
Exclusive of these charges, cost of sales as a percentage of net product sales were 8.8% and 8.6% for the three months ended September 30, 2018 and 2017, respectively and 9.2% and 8.6% for the nine months ended September 30, 2018 and 2017, respectively.

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.

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R&D expenses are comprised of costs paid for clinical development, product development and discovery research, as well as costs associated with certain strategic licensing agreements we have entered into with third parties. Clinical development costs are comprised of costs to conduct and manage clinical trials related to eculizumab, ALXN1210 and other product candidates. Product development costs are those incurred in performing duties related to manufacturing development and regulatory functions, including manufacturing of material for clinical and research activities, milestone expenses related to our licensing agreements and collaborations and other administrative costs incurred during product development. Discovery research costs are incurred in conducting laboratory studies and performing preclinical research for other uses of our products and other product candidates. Upfront payments include upfront payments related to licenses and collaborations. Clinical development costs have been accumulated and allocated to each of our programs, while product development and discovery research costs have not been allocated.
Other R&D expenses consist of costs to compensate personnel, to maintain our facilities and equipment, and other occupancy costs associated with our research and development efforts. These costs relate to efforts on our clinical and preclinical products, our product development and our discovery research efforts. These costs have not been allocated directly to each program.

The following graph provides information regarding research and development expenses:

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

For the three months ended September 30, 2018, the decrease of $20.9 in R&D expense, as compared to the same period in the prior year, was primarily related to the following:

- Decrease of $5.9 in external clinical development expenses related primarily to decreases in various eculizamab clinical studies (see graph below).
- Decrease of $6.3 in external product development expenses driven by de-prioritized programs as a result of the September 2017 restructuring activities and a decrease in costs associated with the manufacturing of material for ALXN1210 as compared to the same period in 2017.

For the nine months ended September 30, 2018, the decrease of $88.6 in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Decrease of $42.2 in external clinical development expenses related primarily to decreases in various eculizamab clinical studies, partially offset by an expansion of clinical studies for ALXN1210 (see graph below).
- Decrease of $26.6 in payroll and benefits primarily related to headcount reductions

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resulting from restructuring activities initiated in 2017.

- Decrease of $15.0 in discovery primarily related to decreases in external research expenses associated with our collaboration agreements.
- Decrease of $10.0 in facilities and other related expenses primarily related to decreased facilities expenses resulting from restructuring activities initiated in 2017.
- Decrease of $8.9 in upfront payment expenses due to the upfront payments on licensing arrangements made in the second quarter 2017. No upfront payments related to licensing arrangements were made for the nine months ended 2018.

Partially offset by the following:

- Increase of $14.1 in external product development expenses related primarily to an increase in costs associated with the manufacturing of material for ALXN1210 further driven by an increase 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 each of these programs:

2018 2017

2018 2017

The successful development of our drug candidates is uncertain and subject to a number of risks. We cannot guarantee that results of clinical trials will be favorable or sufficient to support regulatory approvals for our development programs, even after we expend significant technical and financial resources. We could decide to abandon development or be required to spend considerable resources not otherwise contemplated. For additional discussion regarding the risks and uncertainties regarding our development programs, please refer to Item 1A "Risk Factors" in this 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.

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The graph below provides information regarding selling, general and administrative expense:
Salary, benefits and other labor expense
External selling, general and administrative expense
For the three months ended September 30, 2018, the decrease of $11.9 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to the following:

- Decrease in salary, benefits and other labor expenses of $7.5. The decrease was primarily related to headcount reductions resulting from restructuring activities initiated in 2017. These decreases were partially offset by an increase in commercial activities to support the launch of Soliris for gMG.

For the nine months ended September 30, 2018, the decrease of $4.9 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to the following:

- Decrease in salary, benefits and other labor expenses of $12.4. The decrease was primarily related to headcount reductions resulting from restructuring activities initiated in 2017. These decreases were partially offset by an increase in commercial activities to support the launch of Soliris for gMG.

Partially offset by the following:

- Increase in net external selling, general and administrative expenses of $7.5. The increase was primarily due to an increase in professional services and asset related charges associated with the previously announced restructuring programs. These increases were offset by decreased distribution expenses as compared to the same period in 2017 and gain on sale of intangibles.

Acquired In-Process Research and Development
For the nine months ended September 30, 2018 we recorded acquired in-process research and development (IPR&D) expense of $803.7. The increase in acquired IPR&D for the nine months ended September 30, 2018, as compared to 2017, is due 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 both the three and nine months ended September 30, 2018 and 2017 we recorded amortization expense of $80.0 and $240.1, respectively, 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.

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Change in Fair Value of Contingent Consideration

For the three and nine months ended September 30, 2018, the change in fair value of contingent consideration expense associated with our prior business combinations was $53.5 and $110.9, respectively, as compared to $3.7 and $31.8 for the three and nine months ended September 30, 2017, respectively.

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 expense associated with the fair value of contingent consideration for the three and nine months ended September 30, 2018, as compared the same periods in 2017, was primarily due to increases in the likelihood and anticipated timing of payments for contingent consideration.

Restructuring Expenses

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

For the three and nine months ended September 30, 2018, we recorded $10.3 and $26.4 of restructuring expenses, respectively, compared to $72.0 and $98.7 for the three and nine months ended, September 30, 2017, respectively. The decrease in restructuring expenses for the three and nine months ended September 30, 2018 as compared to the same time periods in 2017 was primarily related to the decrease in employee separation costs associated with the 2017 restructuring activities period over period. We currently estimate incurring up to an additional $125.0 in restructuring and related expenses primarily related to contract termination and related charges. We expect approximately half of the remaining restructuring and related expenses will result in cash outlays.

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Impairment of Intangible Assets

In the second quarter 2017, we recognized an impairment charge of $31.0 related to our SBC-103 acquired IPR&D asset due to clinical results. No impairments of acquired in-process research and development were recognized for the three and nine months ended September 30, 2018.

Other Income and Expense

The following table provides information regarding other income and expense:

Investment Income
Interest Expense
Other Income

For the nine months ended September 30, 2018 and 2017, we recognized investment income of $119.4 and $12.9, respectively. The increase in investment income in 2018 results from the recognition in the first quarter 2018 of an unrealized gain of $100.8 on our investment in Moderna Therapeutics, Inc. following it's completion of a new round of equity financing.

Income Taxes

2018 Income Tax Expense
2017 Income Tax Expense
Effective tax rate

During the three and nine months ended September 30, 2018, we recorded income tax expense of $11.2 and $152.5 and had an effective tax rate of 3.3% and 55.4%, respectively, compared to income tax expense of $(19.8) and $45.2 and an effective tax rate of (34.0)% and 9.9% for the three and nine months ended September 30, 2017, respectively. The increase in the effective tax rate for the three months ended September 30, 2018 as compared to the same period in the prior year is primarily attributable to the benefit of settling a routine IRS examination in the prior year, offset by U.S. tax reform measurement period adjustments of $(53.1). The increase in the effective tax rate for the nine months ended September 30, 2018 as compared to the same period in the prior year is primarily attributable to the acquisition of Wilson Therapeutics, offset by U.S. tax reform measurement period adjustments and the benefit of settling a routine IRS examination in the prior year. 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 in acquired IPR&D during the nine months ended September 30, 2018. No tax benefit has been recognized for this expense, which resulted in an increase to the effective tax rate of 41.3%. 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 for the nine months ended September 30, 2018 by approximately 1.4%.

In addition, 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.

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Financial Condition, Liquidity and Capital Resources

The following table summarizes the components of our financial condition as of September 30, 2018 and December 31, 2017:

	September 30, 2018	December 31, 2017	$ Change
Cash and cash equivalents	$ 1,228.9	$ 584.4	$644.5
Marketable securities	$ 306.2	889.7	(583.5)
Long-term debt (includes current portion & revolving credit facility)	$ 2,862.5	2,906.3	(43.8)
Current assets	$ 3,248.4	2,953.9	294.5
Current liabilities	1,027.4	952.5	74.9
Working capital	$ 2,221.0	2,001.4	219.6

The aggregate increase in cash and cash equivalents and marketable securities as compared to December 31, 2017 was primarily attributable lower repurchases of shares, payments on our credit facility, and purchases of property, plant. This increase was offset primarily by cash utilized for the purchase of Wilson Therapeutics in the second quarter of 2018.

Excluding the impact of our asset acquisitions, we expect our annual operating expenses to decrease as a percentage of sales in 2018. We also expect reduced capital investment in 2018 as compared to 2017. We anticipate that cash generated from operations and our existing available cash, cash equivalents and marketable securities should provide us adequate resources to fund our operations as currently planned 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 credit facility and contingent payments from our acquisitions principally through our cash flows from operations. We may, from time to time, also seek additional funding through a combination of equity or debt financings or from other sources, if necessary for future acquisitions or other strategic purposes. 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.

In connection with the pending acquisition of Syntimmune, we expect to make an upfront payment of $400.0 in the fourth quarter 2018, with the

potential for additional milestone-dependent payments of up to $800.0. We intend to finance the acquisition through cash on hand.

In October 2018, we entered into a collaboration agreement and equity investment with Dicerna Pharmaceuticals, Inc. (Dicerna). Under the terms of the agreements, we will make an upfront payment of $37.0 for the exclusive licenses and the equity investment. We could also be required to pay up to an additional $625.0 for option exercise fees and amounts due upon the achievement of specified development, regulatory and commercial milestones, as well as royalties on commercial sales.

Financial Instruments

Until required for use in the business, we may invest our cash reserves in money market funds, bank deposits, reverse repurchase agreements, and marketable securities in accordance with our investment policy. The stated objectives of our investment policy are to preserve capital, provide liquidity consistent with forecasted cash flow requirements, maintain appropriate diversification and generate returns relative to these investment objectives and prevailing market conditions.

Financial instruments that potentially expose us to concentrations of credit risk are cash equivalents, marketable securities, accounts receivable and our derivative contracts. As of September 30, 2018, three customers accounted for an aggregate of 47.0% of our accounts receivable balance, with these individual customers ranging from 13.2% to 18.8% of the accounts receivable balance. At December 31, 2017, four customers accounted for an aggregate of

57.7% of the accounts receivable balance, with these individual customers ranging from 10.2% to 18.9% of the accounts receivable balance. For the three months ended September 30, 2018, three customers accounted for 41.1% of our net product sales and 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 11.3% to 16.7% and 10.0% to 16.3% of our net product sales, respectively. For the three and nine months ended September 30, 2017, three customers accounted for 39.0% and 36.7% of our net product sales, respectively, with these individual customers accounting for 11.2% to 15.4% and 10.8% to 14.8% of our net product sales, respectively.

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

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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, 2018, we had foreign exchange forward contracts with notional amounts totaling $1,810.6. These outstanding foreign exchange forward contracts had a net fair value of $8.0, of which $27.7 is included in other current assets and noncurrent assets and $19.7 included in other current liabilities and noncurrent liabilities. As of September 30, 2018, we had interest rate swap contracts with notional amounts totaling $3,481.3. These outstanding interest rate swap contracts had a net fair value of $36.7 which is included in other current assets and noncurrent assets. The counterparties to these contracts are large domestic and multinational commercial banks, and we believe the risk of nonperformance is not material.
As of September 30, 2018, our financial assets and liabilities were recorded at fair value. We have classified our financial assets and liabilities as Level 1, 2 or 3 within the fair value hierarchy. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Our Level 1 assets consist of mutual fund investments and equity securities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, but substantially the full term of the financial instrument. Our Level 2 assets consist primarily of commercial paper, reverse repurchase agreements, U.S. and foreign government-related debt, corporate debt securities, certificates of deposit and derivative contracts. Our Level 2 liabilities consist also of derivative contracts. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. Our Level 3 liabilities consist of contingent consideration related to acquisitions.
Business Combinations and Contingent Consideration Obligations
The purchase agreements for our business combinations include contingent payments totaling up to $702.0 that will become payable if and when certain development and commercial milestones are achieved. Of these milestone amounts, $367.0 and

$335.0 of the contingent payments relate to development and commercial milestones, respectively. As of September 30, 2018, we do not expect these amounts to have an impact on our liquidity in the near-term, and, during the next 12 months, we expect to make milestone payments of approximately $100.0, associated with our prior business combinations. As additional future payments become probable, we will evaluate methods of funding payments, which could be made from available cash and marketable securities, cash generated from operations or proceeds from other financing.
License Agreements
Our license agreements include contingent payments that will become payable if and when certain development, regulatory and commercial milestones are achieved. As of September 30, 2018, we do not expect the payments associated with these milestones to have a significant impact on our liquidity in the near-term. During the next 12 months, we expect to make milestone payments related to our license agreements of approximately $21.5.
Financing Lease Obligations
In November 2012, we entered into a lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. The term of the lease commenced in 2015 and will expire in 2030, with a renewal option of ten years. Although we do not legally own the premises, we are deemed to be the owner of the building due to the substantial improvements directly funded during the construction period based on applicable accounting guidance for build-to-suit leases. Accordingly, the landlord's costs of constructing the facility during the construction period are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our condensed consolidated balance sheets. Construction of the new facility was completed and the building was placed into service in the first quarter 2016. For each of the three and nine months ended September 30, 2018 and 2017, we recognized $3.5 and $10.6, respectively, of interest expense associated with this arrangement. As of September 30,

2018 and December 31, 2017, our total facility lease obligation was $134.0 and $134.6, respectively, recorded within other current liabilities and facility lease obligation on our condensed consolidated balance sheets.

During the third quarter 2015, we entered into an agreement with Lonza whereby Lonza will construct a new manufacturing facility dedicated to Alexion at one of its existing facilities. As a result of our contractual right to full capacity of the new manufacturing facility, a portion of the payments under the agreement are considered to be lease payments and a portion as payment for the supply of

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inventory. Although we will not legally own the premises, we are deemed to be the owner of the manufacturing facility during the construction period based on applicable accounting guidance for build-to-suit leases due to our involvement during the construction period. Accordingly, the landlord’s costs of constructing the facility during the construction period are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our condensed consolidated balance sheets. The completion of the facility, including obtaining regulatory approval, is expected in 2019. As of September 30, 2018 and December 31, 2017, we recorded a construction-in-process asset of $203.4 and $180.6 respectively, and an offsetting facility lease obligation of $156.1 and $159.1 respectively, within other current liabilities and facility lease obligation on our condensed consolidated balance sheets.

In September 2017, we entered into a lease agreement for approximately 150,000 square feet of office space in Boston, Massachusetts. The term of the lease commenced upon the landlord's substantial completion of our premises in the second quarter of 2018 and will expire on the thirteenth anniversary of commencement, with an option to renew for up to an additional ten years. Although we will not legally own the premises, due to our involvement during the construction period, we are deemed to be the owner of the portion of the building that we will lease based on applicable accounting guidance for build-to-suit leases. Accordingly, the landlord's costs of constructing the facility during the construction period are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our condensed consolidated balance sheets. Construction of the facility was completed and the building was placed into service in the second quarter 2018. As of September 30, 2018 and December 31, 2017, our total facility lease obligation was $82.3 and $59.6, respectively, within facility lease obligation on our condensed consolidated balance sheets.

Long-term Debt

On June 7, 2018, we entered into an Amended and Restated Credit Agreement (the Credit Agreement) with Bank of America, N.A. as Administrative Agent. The Credit Agreement amends and restates 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. Borrowings can be used for working capital requirements, acquisitions and other general corporate purposes.

As of September 30, 2018, we had $2,612.5 outstanding on the term loan and $250.0 of borrowings outstanding under the revolving credit facility. The $250.0 of proceeds on the revolving credit facility was used to refinance amounts outstanding under the Prior Credit Agreement. As of September 30, 2018, we had open letters of credit of $1.7 that offset our availability in the revolving facility.

Manufacturing Obligations

We have supply agreements with Lonza relating to the manufacture of Soliris and Strensiq, which requires payments to Lonza at the inception of contract and upon the initiation and completion of product manufactured. On an ongoing basis, we evaluate our plans for future levels of manufacturing by Lonza, which depends upon our commercial requirements, the progress of our clinical development programs and the sale of any remaining product manufactured at ARIMF prior to its sale in the third quarter of 2018.

We have various agreements with Lonza, with remaining total non-cancellable commitments of approximately $1,174.7 through 2028. Certain commitments may be canceled only in limited circumstances. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris that was manufactured at ARIMF and a payment with respect to sales of Soliris manufactured at Lonza facilities.

In addition to Lonza, we have non-cancellable commitments of approximately $63.6 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 tax.

Common Stock Repurchase Program

In February 2017, our Board of Directors authorized the future acquisition of shares with an aggregate value of up to $1,000.0 under our existing share repurchase program. The repurchase program does not have an expiration date, and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at our discretion. Under the program, for the three months ended September 30, 2017, we repurchased 0.5 shares at a cost of $59.6. For the nine months ended September 30, 2018 and 2017,

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

we repurchased 0.7 and 2.6 shares of our common stock at a cost of $85.0 and $298.5, respectively. The Company did not repurchase any shares during the third quarter 2018. As of October 24, 2018, there

is a total of $451.5 remaining for repurchases under the repurchase program.

Cash Flows

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

	Nine months ended September 30, 2018		$
	2018	2017	Change
Net cash provided by operating activities	$342.6	$857.5	$(514.9)
Net cash provided by (used in) investing activities	418.3	(918.7)	1,337.0
Net cash used in financing activities	(105.5)	(371.2)	265.7
Effect of exchange rate changes on cash	(10.6)	16.5	(27.1)
Net change in cash and cash equivalents	$644.8	$(415.9)	$1,060.7

Operating Activities

Cash flows provided by operations for the nine months ended September 30, 2018 was $342.6 compared to $857.5 for the nine months ended September 30, 2017. The decrease in cash provided by operating activities was primarily due to the acquisition of Wilson Therapeutics and higher cash payments for restructuring and incentive compensation, as well as the impact of the timing of cash receipts and other payments for the nine months ended September 30, 2018 as compared to the same period in the prior year. This decrease was partially offset by an increase in operating income, excluding the impact of the IPR&D change associated with the Wilson acquisition.

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

Investing Activities

Cash provided by (used in) investing activities for the nine months ended September 30, 2018 was $418.3 compared to $(918.7) for the nine months ended September 30, 2017. The increase in cash provided by investing activities was primarily attributable to purchases and sales of available-for-sale debt securities, which resulted in a net cash inflow of $585.0 for the nine months ended September 30, 2018, compared to net cash outflow of $647.7 for the nine months ended September 30, 2017. We utilized some of the cash received from the sale of available-for-sale debt securities during the nine months ended September 30, 2018 to fund the acquisition of Wilson Therapeutics.

Purchases of property, plant and equipment also decreased $98.2 during the nine months ended

September 30, 2018 as compared to the same period in the prior year.

Financing Activities

Cash used for financing activities for the nine months ended September 30, 2018 was $105.5 compared to $371.2 for the nine months ended September 30, 2017. The decrease in cash used for financing activities was primarily due to a decrease in share repurchase activity of $213.5. There was an additional decrease in cash used of $87.5 due to lower net payments against our credit facility, as well as a reduction in proceeds received from the issuance of stock for share-based compensation arrangements of $34.6.

Contractual Obligations

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, 2017, in the section titled “Management's Discussion and Analysis of Financial Condition and Results of Operations” under the caption “Contractual Obligations.”

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Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

(amounts in millions, except
percentages)

Interest Rate Risk

As of September 30, 2018, we invested our cash in a variety of financial instruments, principally money market funds, corporate bonds, commercial paper and government-related obligations. Most of our interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate. Our investment portfolio is comprised of marketable securities of highly rated financial institutions and investment-grade debt instruments, and we have guidelines to limit the term-to-maturity of our investments. Based on the type of securities we hold, we do not believe a change in interest rates would have a material impact on our financial statements. If interest rates were to increase or decrease by 1%, the fair value of our investment portfolio would increase (decrease) by approximately $(1.1) and $1.1, respectively.

On June 7, 2018, we entered into the Credit Agreement, which bears interest at a rate per annum equal to either a base rate or a Eurodollar rate plus, in each case, an applicable margin. The applicable margins on base rate loans range from 0.25% to 1.00% and the applicable margins on Eurodollar loans range from 1.25% to 2.00%, in each case based on Alexion's 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 through December 31, 2022 that qualified for and are designated as cash flow hedges. We currently have cash flow hedges with aggregate notional amounts of approximately 79.0% 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 $5.3, based on the unhedged portion of our outstanding term loan during that period.

Foreign Exchange Market Risk

Our operations include activities in many countries outside the U.S. As a result, our financial results are impacted by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets where we operate. We have exposure to movements in foreign currency exchange rates, the most significant of which are the Euro, the Ruble and Japanese Yen, against the

U.S. dollar. We are a net receiver of many foreign currencies, and our consolidated financial results benefit from a weaker U.S. dollar and are adversely impacted by a stronger U.S. dollar relative to foreign currencies in which we sell our product.

Our monetary exposures on our balance sheet arise primarily from cash, accounts receivable, and payables denominated in foreign currencies. Approximately 48.0% and 49.0% of our net product sales were denominated in foreign currencies for the three and nine months ended September 30, 2018, 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 in fluctuations in foreign currency exchange rates which may also impact the timing and amount of our revenue.

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

We currently have a derivative program in place to achieve the following: 1) limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet, using contracts with durations of approximately 7 months and 2) hedge a portion of our forecasted product sales (in some currencies), including intercompany sales, using contracts with durations of up to 60 months. The 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, 2018 and December 31, 2017, we held foreign exchange forward contracts with notional amounts totaling $1,810.6 and $2,708.1, respectively. As of September 30, 2018 and December 31, 2017, our

outstanding foreign exchange forward contracts had a net fair value of $8.0 and $(47.5), respectively.

We do not use derivative financial instruments for speculative trading purposes. The counterparties to these foreign exchange forward contracts are large domestic and multinational commercial banks. We believe the risk of counterparty nonperformance is not material.

Based on our foreign currency exchange rate exposures as of September 30, 2018, a hypothetical

10% adverse fluctuation in exchange rates would decrease the fair value of our foreign exchange forward contracts that are designated as cash flow hedges by approximately $101.6 as of September 30, 2018. The resulting loss on these forward contracts would be offset by the gain on the underlying transactions and therefore would have minimal impact on future anticipated earnings and cash flows. Similarly, adverse fluctuations in exchange rates that would decrease the fair value of our foreign exchange forward contracts that are not designated as hedge instruments would be offset by a positive impact of the underlying monetary assets and liabilities.

Credit Risk

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

Item 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 under the Securities Exchange Act of 1934, as amended (Exchange Act), as of September 30, 2018. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2018, 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, 2018 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.

In May 2015, we received a subpoena in connection with an investigation by the Enforcement Division of the SEC requesting information related to our grant-making activities and compliance with the FCPA in various countries. In addition, in October 2015, we received a request from the DOJ for the voluntary production of documents and other information pertaining to Alexion’s compliance with FCPA. The SEC and DOJ also seek information related to Alexion’s recalls of specific lots of Soliris and related securities disclosures. Alexion is cooperating with these investigations.

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

At this time, Alexion is unable to predict the duration, scope or outcome of these investigations. While it is possible that a loss related to these matters may be incurred, given the ongoing nature of these investigations, management cannot reasonably estimate the potential magnitude of any such loss or range of loss, or the cost of the ongoing investigation. Any determination that our operations or activities are not 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 to enhance and remediate its business processes, structures, controls, training, talent and systems across Alexion’s global operations. For information concerning the risks associated with the investigation, see our Risk Factor - "If we fail to comply with laws or regulations, we may be subject to investigations and civil or criminal penalties and our business could be adversely affected."

As previously reported, on December 29, 2016, a shareholder filed a putative class action against the Company and certain former employees in the U.S. District Court for the District of Connecticut, alleging that defendants made misrepresentations and omissions about Soliris. On April 12, 2017, the court appointed a lead plaintiff. On July 14, 2017, the lead plaintiff filed an amended putative class action complaint against the Company and seven current or former employees. The complaint alleges that

defendants made misrepresentations and omissions about Soliris, including alleged misrepresentations regarding sales practices, management changes, and related investigations, between January 30, 2014 and May 26, 2017, and that the Company's stock price dropped upon the purported disclosure of the misrepresentations. Defendants moved to dismiss the amended complaint on September 12, 2017. Plaintiffs filed an opposition to defendants’ motion to dismiss on November 13, 2017, and defendants’ filed a reply brief in further support of their motion on December 28, 2017. Defendants’ motion to dismiss is now fully briefed and pending before the court. Given the early stages of this litigation, an estimate of the possible loss or range of loss cannot be made 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 501(c)(3) organizations that provide financial assistance to Medicare patients taking drugs sold by Alexion, Alexion’s provision of free drug to Medicare patients, and Alexion compliance policies and training materials concerning the anti-kickback statute or payments to any 501(c)(3) organization that provides financial assistance to Medicare patients. We understand that the U.S. Attorney’s Office and the DOJ are coordinating its inquiry with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services. Other companies have disclosed similar inquiries. We are cooperating with this inquiry. We are engaged in discussions with the DOJ about a potential resolution of this matter. There can be no assurance that any current or future discussions with the government to resolve these matters will be successful or that any potential settlement terms or amount will be agreed to or finalized. We are unable to predict when these matters will be resolved or what further action, if any, the government will take in connection with them.

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 was not determined to be a material amount. In October 2017, Alexion filed an application for judicial review of the PMPRB's decision in the Federal Court of Canada. A hearing is scheduled to take place in November 2018. At this time, we cannot predict the outcome of these judicial review proceedings or any appeals that may follow and cannot reasonably estimate the amount of any forfeitures that will be required to be made or the potential impact to future Soliris revenues in Canada relating to any potential future price reduction.

In October 2018, the Japanese Ministry of Health, Labor and Welfare conducted an administrative inspection of Alexion's Japanese operations. The MHLW inquiry has been primarily focused on our communication efforts regarding the proper use of Soliris in Japan for aHUS, among other matters. We have cooperated, and will continue to cooperate, with this inquiry. Given the early stages of this matter, an estimate of the possible loss or range of loss, or what further action, if any, the MHLW will take in connection with this matter, cannot be made at this time.

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

Risks Related to Our Products

We depend heavily on the success of our lead product, Soliris. If sales of Soliris are adversely affected, our business may be materially harmed.

Currently, our ability to generate revenues depends primarily on the commercial success of Soliris and whether physicians, patients and healthcare payers view Soliris as therapeutically effective and safe relative to cost. Since we launched Soliris in the U.S. in 2007, substantially all of our revenue has been attributed to sales of Soliris. In 2015, we received marketing approval in the U.S., the EU and Japan, of our second marketed product, Strensiq, for the treatment of HPP. We also received marketing approval in 2015 in the U.S. and the EU for our third product, Kanuma, for the treatment of LAL-D. However, we anticipate that Soliris product sales will continue to contribute a significant percentage of our total revenue over the next several years.

The commercial success of Soliris and our ability to generate revenues depends on several factors, as discussed in greater detail below, including safety and efficacy of Soliris, coverage or reimbursement by government or third-party payers, pricing, manufacturing and uninterrupted supply, the introduction of and success of competing products, the size of patient populations and the number of patients diagnosed who may be treated with Soliris, adverse legal, administrative, regulatory or legislative developments, and our ability to develop, register and commercialize Soliris for new indications.

While Soliris has been studied for indications beyond PNH, aHUS and gMG there is no guarantee that we can obtain regulatory approve or achieve any commercial sales of Soliris for other indications. For example, in September 2018, we announced positive topline results from the Phase 3 PREVENT study of Soliris in patients with anti-aquaporin-4 (AQP4) auto antibody-positive neuromyelitis optica spectrum disorder (NMOSD). NMOSD is a rare, devastating, complement-mediated disorder of the central nervous system characterized by relapses. Despite these positive results, we may not be able to obtain regulatory approval to sell Soliris as a treatment for NMOSD due to, among other potential issues, the failure of our clinical studies to meet regulatory requirements, failure of our manufacturing facilities to meet regulatory requirements or other reasons. Additionally, even if we were to obtain regulatory approval, physicians and patients may not accept Soliris as a treatment for NMOSD. In these instances, we may generate limited or no revenue from Soliris as a potential treatment of NMOSD.

If we are not able to maintain revenues from sales of Soliris, or our Soliris revenues do not grow, our results of operations and stock price could be adversely affected.

If we do not obtain marketing approval for our ALXN1210 product or if ALXN1210 is not broadly accepted by the market, our future operating results may be adversely impacted and, if ALXN1210 is approved for use and accepted by the market, we expect our Soliris revenues may be adversely impacted.

We recently submitted applications to the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and the Ministry of Health, Labour and Welfare (MHLW) in Japan for approval of ALXN1210 in the U.S., EU and Japan, respectively, for patients with PNH. There is no guarantee that the FDA, the EMA or the MHLW will timely approve the use of ALXN1210 in PNH patients or that they will approve the use of ALXN1210 in PNH patients at all. The FDA, EMA or MHLW could reject our applications 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 money to generate prior to a decision on approval. We anticipate that, in the future, we will seek approval of ALXN1210 in other jurisdictions and for other indications.

If ALXN1210 is not approved for use in the U.S., the EU, Japan or elsewhere, if approval is delayed, or if use is not approved for PNH or indications in addition to PNH, we would expect that our future business and results of operations may be harmed. If the use of ALXN1210 is authorized in the U.S., EU, Japan and elsewhere and for indications beyond PNH, we anticipate that certain customers currently on Soliris may transition to ALXN1210, which would result in a reduction of Soliris revenue. Alternatively, patients and providers may determine that ALXN1210 is not a preferred alternative to Soliris for PNH (or other potential indications) and our ALXN1210 revenues and operating results may be adversely

impacted and we may not gain any return in our investment in the ALXN1210 development program.

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

Our long-term success and revenue growth will depend upon the successful development and commercialization of new products and technologies from our research and development activities, including ALXN1210, those licensed or acquired from third parties and approval of additional indications for our existing products and products under development. Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. The process for obtaining regulatory approval to market a biologic is expensive, often takes many years, and can vary substantially based on the type, complexity, the novelty of the product candidates involved and the indications to be treated. Our ability to maintain or grow revenues would be adversely affected if we are delayed or unable to successfully develop the products in our pipeline, including ALXN1210 for PNH and additional indications, Soliris for additional indications, obtain marketing approval for Strensiq and Kanuma in additional territories, obtain approval for additional delivery systems for our therapies (such as subcutaneous delivery), obtain marketing approval for ALXN1210 or acquire or license products and technologies from third parties.

We dedicate significant resources to the worldwide development, manufacture and commercialization of our products. We cannot guarantee that any marketing application for our product candidates, including ALXN1210 for PNH or Soliris for NMOSD, will be approved or maintained in any country where we seek marketing authorization. If we do not obtain regulatory approval of new products or additional indications for existing products or additional delivery systems, or are significantly delayed or limited in doing so, our revenue will be adversely affected, we may experience surplus inventory, be required to write down certain assets, our business may be materially harmed and we may need to significantly curtail operations.

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

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

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

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

We may not be able to sell our products on a profitable basis or our profitability may be reduced if we are required to sell our products at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. Our products are significantly more expensive than traditional drug treatments and almost all patients require some form of third party coverage to afford their cost. We depend, to a significant extent, on governmental payers, such as Medicare and Medicaid in the U.S. or country specific governmental organizations in foreign countries, and private third-party payers to defray the cost of our products to patients. These entities may refuse to provide coverage and reimbursement, determine to provide a lower level of coverage and reimbursement than anticipated, or reduce previously approved levels of coverage and reimbursement, including in the form of higher mandatory rebates or modified pricing terms.

In certain countries where we sell or are seeking or may seek to commercialize our products, pricing, coverage and level of reimbursement or funding of prescription drugs are subject to governmental control. We may be unable to timely or successfully negotiate coverage, pricing and reimbursement on terms that are favorable to us (or 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. The requirements

governing drug pricing vary widely from country to country, which may include a combination of distinct potential payers, including private insurance and governmental payers as well as a HTA assessment of medicinal products for pricing and reimbursement methodologies. Therefore, we may not successfully conclude the necessary processes and commercialize our products in every, or even most countries in which we seek to sell our products.

A significant reduction in the amount of reimbursement or pricing for our products in one or

more countries may reduce or eliminate our profitability and adversely affect our financial condition. Certain countries establish pricing and reimbursement amounts by reference to the price of the same or similar products in other countries. Therefore, if coverage or the level of reimbursement is limited in one or more countries, we may be unable to obtain or maintain anticipated pricing or reimbursement in other countries or in new markets. In Canada, for example, the Patented Medicine Prices Review Board (PMPRB) issued a decision in an administrative pricing matter that we had excessively priced Soliris in a manner inconsistent with the Canadian pricing rules and guidelines and ordered that the price be decreased to no higher than the lowest price in seven comparator countries (we filed an application for judicial review of the PMPRB's decision in the Federal Court of Canada, but we are unable to determine the outcome of this review). In the U.S., the EU Member States, and elsewhere, there have been, and we expect there will continue to be, efforts to control and reduce healthcare costs. In the U.S. for example, the price of drugs has come under intense scrutiny by the presidential administration and U.S. Congress. Third party payers decide which drugs they will pay for and establish reimbursement and co-payment levels. Government and other third-party payers are increasingly challenging the prices charged for healthcare products, examining the cost effectiveness of drugs in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement for prescription drugs. See additional discussion below under the heading "Changes in healthcare 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."

The potential increase in the number of patients receiving Soliris may cause third-party payers to modify or limit coverage or reimbursement for Soliris for the treatment of PNH, aHUS, gMG or all indications (including NMOSD, if approved by regulatory authorities). In 2017, Soliris was approved in the U.S., EU and Japan as a treatment for adult patients with gMG who are anti-acetylcholine receptor antibody-positive and we intend to request regulatory approval for Soliris as a treatment for NMOSD. The potential increase in the number of patients receiving Soliris may cause third-party payers to refuse or limit coverage or reimbursement for Soliris for the treatment of PNH, aHUS or gMG (or, potentially NMOSD if approved for such indication by the regulatory authorities), or provide a lower level of coverage or reimbursement than anticipated or currently in effect. We are subject to the same risks with respect to Strensiq and Kanuma.

Health insurance programs may restrict coverage of some products by using payer formularies under which only selected drugs are covered, variable co-payments that make drugs that are not preferred by the payer more expensive for patients, and by using utilization management controls, such as requirements for prior authorization or failure first on another type of treatment. Payers may especially impose these obstacles to coverage for higher-priced drugs, and consequently our products may be subject to payer-driven restrictions. Additionally, U.S. payers are increasingly considering new metrics as the basis for reimbursement rates and if our products do not meet or surpass these metrics, these payers may not reimburse for use of our products and we expect revenue from such product would decrease.

In countries where patients have access to insurance, their insurance co-payment amounts or other benefit limits may represent a barrier to obtaining or continuing Soliris or adoption of new treatment options, such as ALXN1210. We have financially supported non-profit organizations that assist patients in accessing treatment for PNH and aHUS, including Soliris. Such organizations assist patients whose insurance coverage imposes prohibitive co-payment amounts or other expensive financial obligations. Such organizations' ability to provide assistance to patients is dependent on funding from external sources, and we cannot guarantee that such funding will be provided at adequate levels, if at all. We have also provided our products without charge to patients who have no insurance (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.

Our commercial success depends on obtaining and maintaining reimbursement at anticipated levels for our products. It may be difficult to project the impact of evolving reimbursement mechanics on the willingness of payers to cover our products. If we are unable to obtain or maintain coverage for our products, or coverage is reduced in one or more countries, our pricing may be affected or our product sales, results of operations or financial condition could be harmed.

We may not be able to maintain market acceptance of our products among the medical community or patients, or gain market acceptance of our products in the future, which could prevent us from maintaining profitability or growth. We cannot be certain that our products will maintain market acceptance in a particular country among physicians, patients, healthcare payers, and others. Although we have received regulatory approval

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 relative to their cost. Nor can we predict whether patients, physicians or payers will continue use of Soliris or elect to switch to ALXN1210 (if and when approved for use by appropriate regulatory authorities) or alternative treatments that may be available. Physicians' willingness to prescribe, and patients' willingness to accept, our products, depends on many factors, including prevalence and severity of adverse side effects in both clinical trials and commercial use, the timing of the market introduction of competitive drugs, lower demonstrated clinical safety and efficacy compared to other drugs, perceived lack of cost-effectiveness and negative evaluations in health technology assessments, pricing and lack of availability of reimbursement from third-party payers, convenience and ease of administration, effectiveness of our marketing strategy, publicity concerning the product, our other product candidates and availability of alternative treatments, including bone marrow transplant as an alternative treatment for PNH. The likelihood of physicians to prescribe Soliris for patients with aHUS may also depend on how quickly Soliris can be delivered to the hospital or clinic and our distribution methods may not be sufficient to satisfy this need. In addition, we are aware that medical doctors have determined not to continue Soliris treatment for some patients with aHUS.

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

Manufacturing issues at our facilities or the facilities of our third party service providers could cause product shortages, stop or delay commercialization of our products, disrupt or delay our clinical trials or regulatory approvals, and adversely affect our business.

The manufacture of our products and our product candidates is highly regulated, complex and difficult, requiring multi-step controlled processes and even minor problems or deviations could result in defects or failures. We have limited experience manufacturing commercial quantities of Strensiq and Kanuma, and we have no experience manufacturing commercial quantities of ALXN1210 (if approved for use in PNH patients in the U.S., EU, Japan and other jurisdictions). Only a small number of companies have the ability and capacity to manufacture our products

for our development, clinical and commercialization needs. Due to the highly technical requirements of manufacturing our products and the strict quality and control specifications, we and our third party providers may be unable to manufacture or supply our products despite our and their efforts. Failure to produce sufficient quantities of our products and product candidates could result in lost revenue, diminish our profitability, delay the development of our product candidates, delay regulatory approval or result in the rejection of our product candidates (including ALXN1210) 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.

The manufacture of our products and product candidates is at high risk of product loss due to contamination, equipment malfunctions, human error, or raw material shortages. Deviations from established manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or manufacturing facilities, we may need to close our manufacturing facilities for an extended period of time to investigate and remediate the contaminant. The occurrence of any such event could adversely affect our ability to satisfy demand for any of our products, which could materially and adversely affect our operating results.

Many additional factors could cause production interruptions at our facilities or at the facilities of our third party providers, including natural disasters, labor disputes, acts of terrorism or war. The occurrence of any such event could adversely affect our ability to satisfy demand for Soliris and our other products, and due to the fact that we rely on a limited number of facilities to produce our products and product candidates (as noted below), any of the foregoing could materially and adversely affect our operating results.

We expect that the demand for Soliris will increase. We may underestimate demand for Soliris or any of our products, or experience product interruptions at Alexion's internal manufacturing facilities or a facility of a third party provider, including as a result of risks and uncertainties described in this report.

We and our third party providers are required to maintain compliance with current good manufacturing practice regulations (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. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our

facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to supply our products and product candidates. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.

We rely on one to two facilities to manufacture each of our products. We are authorized to sell Soliris that is manufactured by Lonza in the U.S., the EU, Japan and certain other territories. In September 2017, we announced our intention to close ARIMF which has now been closed and no longer performs any manufacturing operations for us. Manufacturing Soliris for commercial sale in certain other territories may only be performed at a single facility in some cases until such time as we have received the required regulatory approval for an additional facility, if ever, however in certain territories only a single manufacturing facility may be registered and we will continue to rely on a single manufacturing facility in such instances. Governmental authorities will generally not permit products manufactured at any facility that is not registered by the applicable government agency to enter into the country and such products may be returned for this reason, which may decrease or delay sales and result in the loss of inventory. We also depend entirely on one facility to manufacture Strensiq and on one facility for the purification of Kanuma for commercial sale. Regarding Kanuma, we rely on two animal facilities to produce the starting material, and a single manufacturing facility to manufacture the drug product. Any interruption or halt in manufacturing at any one of these facilities may, therefore, have a material adverse impact on our operations.

We depend on a very limited number of third party providers for supply chain services with respect to our clinical and commercial product requirements, including product filling, finishing, packaging, and labeling. Our third party providers operate as independent entities and we do not have control over any third party provider’s compliance with our internal or external specifications or the rules and regulations of regulatory agencies, including the FDA, competent authorities of the EU Member States, or any other applicable regulations or standards.

Any difficulties or delays in our third party manufacturing, or any failure of our third party providers to comply with our internal and external specifications or any applicable rules, regulations and standards could increase our costs, constrain our ability to satisfy demand for our products from customers, cause us to lose revenue or incur penalties for failure to deliver product, make us postpone or cancel clinical trials, or cause our products to be recalled or withdrawn, such as the

voluntary recalls that we initiated in 2013 and 2014 due to the presence of visible particles in a limited number of vials in specific Soliris lots. Even if we are able to find alternatives, they may ultimately be insufficient for our needs. No guarantee can be made that regulators will approve additional third party providers in a timely manner or at all, or that any third party providers will be able to perform services for sufficient product volumes for any country or territory. Further, due to the nature of the current market for third-party commercial manufacturing, many arrangements require substantial penalty payments by the customer for failure to use the manufacturing capacity for which it contracted. Penalty payments under these agreements typically decrease over the life of the agreement, and may be substantial initially and de minimis or non-existent in the final period. The payment of a substantial penalty could harm our financial condition and may restrict our ability to transition to internal manufacturing or manufacturing by other third parties.

It can take longer than five years to build and validate a new manufacturing facility and it can take longer than three years to qualify and validate a new contract manufacturer. We have completed the build-out of a fill-finish facility in Ireland to support global drug product manufacture or vial fill finish of Soliris and Alexion’s other clinical and commercial products. We cannot guarantee that this facility will receive all the necessary global regulatory approvals in a timely manner and we will continue to rely on appropriate third parties to supplement our fill finish operations until that time. We also completed construction of a new facility in Dublin, Ireland in the fourth quarter of 2015, which is comprised of laboratories, packaging and warehousing operations and we intend to make significant further investment in this facility for the manufacture of our products. We cannot guarantee that we will be able to successfully and timely complete the appropriate validation processes or obtain the necessary regulatory approvals, or that we will be able to perform the intended supply chain services at either of these facilities for commercial or clinical use.

Certain of the raw materials required in the manufacture and the formulation of our products are derived from biological sources. Such raw materials are difficult to procure and may be subject to contamination or recall. Access

to and supply of sufficient quantities of raw materials which meet the technical specifications for the production process is challenging, and often limited to single-source suppliers. Finding an alternative supplier could take a significant amount of time and involve significant expense due to the nature of the products and the need to obtain regulatory approvals. The failure of these single-source suppliers to supply adequate quantities of raw materials for the production process

in a timely manner may impact our ability to produce sufficient quantities of our products for clinical or commercial requirements. A material shortage, contamination, recall, or restriction on the use of certain biologically derived substances or any raw material used in the manufacture of our products could adversely impact or disrupt manufacturing.

In addition, Kanuma is a transgenic product. It is produced in the egg whites of genetically modified chickens who receive copies of the human lysosomal acid lipase gene to produce recombinant human lysosomal acid lipase. The facilities on which we rely to produce raw material for recombinant lysosomal acid lipase are the only animal facilities in the world that produces the necessary egg whites from transgenic chickens. Natural disasters, disease, such as exotic Newcastle disease or avian influenza, or other catastrophic events could have a significant impact on the supply of unpurified Kanuma, or destroy Alexion's animal operations altogether. If our animal operations are disrupted or destroyed, it will be extremely difficult to set up another animal facility to supply the unpurified Kanuma. This would adversely affect our ability to satisfy demand for Kanuma, which could materially and adversely affect our operating results.

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

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

We and our current and future partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by governmental authorities around the world, including the FDA, EMA, the competent authorities of the EU Member States, and MHLW. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or in the case of Kanuma, problems

with animal operations, a regulatory agency may impose restrictions on that product, the manufacturing facility or us. For example, in March 2013, we received a Warning Letter from the FDA relating to compliance with FDA's cGMP requirements at ARIMF. In October 2017, the FDA notified Alexion that the Warning Letter has been resolved. If we had failed to address the FDA's concerns or if we 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, withdrawal of FDA approval, and/or criminal prosecution.

If we or our third-party providers, including our product fill-finish providers, packagers and labelers, fail to comply fully with applicable regulations, then we may be required to initiate a recall or withdrawal of our products. Like our contract manufacturers' manufacturing operations, our animal operations will also be subject to FDA inspection to evaluate whether our animal husbandry, containment, personnel, and record keeping practices are sufficient to ensure safety and security of our transgenic chickens and animal products (e.g., eggs, waste, etc.). Our animal operations may also be subject to inspection by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA APHIS), the agency responsible for administering the Animal Welfare Act. Any failure to ensure safety and security of our transgenic chickens and/or animal products could result in regulatory action by the FDA or another regulatory body, including USDA APHIS.

The safety profile of any product continues to be closely monitored by the FDA and other foreign regulatory authorities after approval. Regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, finishing, filling, labeling, advertising, promotion, risk mitigation, adverse event reporting requirements, and export of biologics. For example, the risk management program established in 2007 upon the FDA's approval of Soliris for the treatment of PNH was replaced with a Risk Evaluation and Mitigation

Strategy (REMS) program, approved by the FDA in 2010, and further revised in December 2015 concerning prescribing information regarding the level of fever needed to seek medical attention and reporting adverse events. Future changes to the Soliris REMS could be costly and burdensome to implement.

We are required to report any serious and unexpected adverse experiences and certain quality problems with our products to the FDA, the EMA, the MHLW and other health agencies. Non-compliance with safety reporting requirements could result in

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

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

We also agreed to set up an observational, longitudinal, prospective, long-term registry of patients with HPP to collect information on the epidemiology of the disease, including clinical outcomes and quality of life, and to evaluate safety and effectiveness data in patients treated with Strensiq.

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

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 ALXN1210 for the treatment of PNH or Soliris for the treatment of NMOSD, in each case, if approved for use by the FDA and such agencies).

Failure to comply with the laws and requirements, including statutes and regulations, administered by the FDA, the EC, the competent authorities of the EU Member States, the MHLW or other agencies, could result in:

- a product recall;
- a product withdrawal;
- significant administrative and judicial sanctions, including, warning letters or untitled letters;
- significant fines and other civil penalties;
- suspension, variation or withdrawal of a previously granted approval for our products;
- interruption of production;
- operating restrictions, such as a shutdown of production facilities or production lines, or new manufacturing requirements;
- suspension or termination of ongoing clinical trials;
- delays in approving or refusal to approve our products including pending BLAs or BLA supplements for our products or a facility that manufactures our products;
- seizing or detaining product;
- requiring us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- injunctions; and/or
- criminal prosecution.

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

The testing, manufacturing, marketing and sale of drugs for use in humans exposes us to product liability risks. Side effects and other problems from using our products could include, among others, (1) decrease in the frequency with which physicians decide to prescribe our products, (2) encouraging physicians to stop prescribing our products to their patients who previously had been prescribed our products, (3) causing serious adverse events and give rise to product liability claims against us, and (4) result in our need to withdraw or recall our products from the marketplace. Some of these risks are unknown at this time.

Our products and our product candidates treat patients with rare diseases. We generally test our

products in only a small number of patients. For example, the FDA marketing approval for the treatment of patients with aHUS was based on two prospective studies in a total of 37 adult and adolescent patients, together with a retrospective study that included 19 pediatric patients. As more patients use our products, including more children and adolescents, new risks and side effects may be discovered, the rate of known risks or side effects may increase, and risks previously viewed as less significant could be determined to be significant. Previously unknown risks and adverse effects may also be discovered in connection with unapproved uses of our products, which may include administration of our products under acute emergency conditions, such as the Enterohemorrhagic E. coli health crisis in Europe, primarily Germany, which began in May 2011. We have instituted procedures that are designed to ensure that we do not promote, or in any way support or encourage the promotion of our products for unapproved uses in violation of applicable law, but physicians are permitted to use products for unapproved purposes and we are aware of such uses of Soliris. In addition, we are studying and expect to continue to study Soliris in diseases other than PNH, aHUS and gMG in controlled clinical settings (for example, we recently completed a Phase III trial for Soliris as a treatment for NMOSD), and independent investigators are doing so as well. We are also studying and expect to continue to study ALXN1210 in diseases other than PNH (for which we have not yet received regulatory approval in any jurisdiction) in controlled clinical settings and we are also reviewing a subcutaneous delivery method. In the event of any new risks or adverse effects discovered as new patients are treated for approved indications, or as our products are studied in or used by patients for other indications, regulatory authorities may delay or revoke their approvals, we may be required to conduct additional clinical trials and safety studies, make changes in labeling, reformulate our products or make changes and obtain new approvals for our and our suppliers' manufacturing facilities. We may also experience a significant drop in potential sales, experience harm to our reputation and the reputation of our products in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales or substantially increase the costs and expenses of commercializing and marketing our products.

We may be sued by people who use our products, whether as a prescribed therapy, during a clinical trial, during an investigator initiated study, or otherwise. Many patients who use our products are already very ill. Any informed consents or waivers obtained from people who enroll in our trials or use our products may not protect us from liability or litigation. Our product liability insurance may not cover

all potential types of liabilities or may not cover certain liabilities completely. Moreover, we may not be able to maintain our insurance on acceptable terms, or at all. In addition, negative publicity relating to the use of our products or a product candidate, or to a product liability claim, may make it more difficult, or impossible, for us to market and sell our products. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Patients who use our products already often have severe and advanced stages of disease and known as well as unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our products. Some patients treated with our products, including patients who have participated in our clinical trials, have died or suffered potentially life-threatening diseases either during or after ending their treatments. Patients who delay or miss a dose or discontinue treatment may also experience complications, including death. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time consuming or inconclusive. These investigations may interrupt our sales efforts, delay or result in the withdrawal or revocation of our regulatory approval process in other countries, or impact and limit the type of regulatory approvals that our products receive or maintain.

For example, use of C5 Inhibitors, such as Soliris, is associated with an increased risk for certain types of infection, including meningococcal infection. Under controlled settings, patients in our eculizumab trials all receive vaccination against meningococcal infection prior to first administration of Soliris and patients who are prescribed Soliris in most countries are required by prescribing guidelines to be vaccinated prior to receiving their first dose. A physician may not have the opportunity to timely vaccinate a patient in the event of an acute emergency episode, such as in a patient presenting with aHUS or during the health crisis that began in May 2011 in Europe, principally in Germany, due to

the epidemic of infections from Enterohemorrhagic E. coli. Vaccination does not, however, eliminate all risk of meningococcal infection. Additionally, in some countries there may not be any vaccine approved for general use or approved for use in infants and

children. Some patients treated with Soliris who had been vaccinated have nonetheless experienced meningococcal infection, including patients who have suffered serious illness or death. Each such incident is required to be reported to appropriate regulatory agencies in accordance with relevant regulations.

Clinical evaluations of outcomes in the post-marketing setting are required to be reported to appropriate regulatory agencies in accordance with relevant regulations. Determination of significant complications associated with the delay or discontinuation of our products could have a material adverse effect on our ability to sell our products.

If we are unable to establish and maintain effective sales, marketing and distribution capabilities, or to enter into agreements with third parties to do so, we will be unable to successfully commercialize our products.

We are marketing and selling our products ourselves in the U.S., Europe, Japan and several other territories. Strensiq and Kanuma were approved in 2015 and are the second and third product launches in Alexion's history. Soliris for the treatment of gMG was approved in 2017 and is in the early stages of commercial launch. If we are unable to establish and/or expand our capabilities to sell, market and distribute our products, either through our own capabilities or by entering into agreements with others, or to maintain such capabilities in countries where we have already commenced commercial sales, we will not be able to successfully sell our products. In that event, we will not be able to maintain or increase revenues. We cannot guarantee that we will be able to establish and maintain our own capabilities or enter into and maintain any marketing or distribution agreements with third-party providers on acceptable terms, if at all. Even if we hire the qualified sales and marketing personnel we need to support our objectives, or enter into marketing and distribution agreements with third parties on acceptable terms, we may not do so in an efficient manner or on a timely basis. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell our products. Establishing and maintaining sales, marketing and distribution capabilities are competitive, expensive and time-consuming. In addition, if and when the products we acquire in connection with acquisitions and development agreements with third parties move closer to regulatory approval, we will likely have a larger product portfolio and the foregoing risks will continue to apply and may even increase.Our expenses associated with building up and maintaining the sales force and distribution capabilities around the world may be disproportionate compared to the revenues we may

be able to generate on sales. We cannot guarantee that we will be successful in commercializing any of our products for the above referenced or other reasons.

If we fail to comply with laws or regulations, we may be subject to investigations and civil or criminal penalties and our business could be adversely affected.

In addition to FDA and related regulatory requirements, we are subject to healthcare "fraud and abuse" laws, such as the False Claim Act (FCA), the anti-kickback provisions of the federal Social Security Act, and other related federal and state laws and regulations. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind to induce, or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs. Liability may be established without a person or entity having actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. A conviction for violation of the Anti-kickback Statute requires mandatory exclusion from participation in federal healthcare programs. The majority of states also have statutes similar to the federal Anti-Kickback Statute and false claims laws that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. We seek to comply with the anti-kickback laws and with the available statutory exemptions and safe harbors. However, our practices may not in all cases fit within the safe harbors, and our practices may therefore be subject to scrutiny on a case-by-case basis. The FCA prohibits any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim. Pharmaceutical companies have been investigated and have reached substantial financial settlements with the Federal government under the FCA for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for uses that the FDA has not approved, or "off-label" uses; and submitting inflated best price information to

the Medicaid Rebate Program. We seek to comply with the FCA laws, but we cannot assure that our compliance program, policies and procedures will always protect Alexion from acts committed by its employees or third-party distributors or service

providers. Other related federal and state laws and regulations that may affect our ability to operate include, among others, the federal False Statements Statute, the federal Civil Monetary Penalties Law, HIPAA, the federal Open Payments program, state anti-kickback and false claims acts, and state and local disclosure requirements and marketing restrictions. Additional information about the scope of these requirements is offered in the “Fraud and Abuse” section of our Annual Report on Form 10-K for the year ended December 31, 2017.

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 against us for violation of these laws, even if we successfully defend against it, could require the expenditure of significant resources and generate negative publicity, which could materially adversely affect our ability to operate our business and our financial results.

Although physicians in the U.S. are permitted to, based on their medical judgment, prescribe products for indications other than those cleared or approved by the FDA, manufacturers are prohibited from promoting their products for such off-label uses. In the U.S., we market our products for their approved uses. Although we believe our marketing materials and training programs for physicians do not constitute improper promotion, the FDA, the U.S. Justice Department, or other federal or state government agencies may disagree. If the FDA or other government agencies determine that our promotional materials, training or other activities constitute improper promotion of any of our products, it could request that we modify our training or promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal or state enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false or fraudulent claims for payment of government funds.

The EU and EU Member States and the MHLW impose similar strict restrictions on the promotion and marketing of drug products. The off-label promotion of medicinal products is prohibited in the EU, Japan and in other territories. The promotion of medicinal products that are not subject to a marketing authorization is also prohibited in the EU and other

jurisdictions. Violations of the rules governing the promotion of medicinal products in the EU, Japan and in other territories could be penalized by administrative measures, fines and imprisonment. For information regarding a recent MHLW inspection, see "Legal Proceedings" elsewhere in this Quarterly Report on Form 10-Q.

We are subject to FCPA, the U.K. Bribery Act, and other anti-corruption laws and regulations that generally prohibit companies and their intermediaries from making improper payments to government officials and/or other persons for the purpose of obtaining or retaining business and we operate in countries that are recognized as having a greater potential for governmental and commercial corruption. We cannot assure that our compliance program, policies and procedures will always protect Alexion from acts committed by its employees or third-party distributors or service providers.

In May 2015, we received a subpoena in connection with an investigation by the Enforcement Division of the SEC requesting information related to our grant-making activities and compliance with the FCPA in various countries. The SEC also seeks information related to Alexion’s recalls of specific lots of Soliris and related securities disclosures. In addition, in October 2015, Alexion received a request from the DOJ for the voluntary production of documents and other information pertaining to Alexion’s compliance with the FCPA, and in December 2016, we received a subpoena from the U.S. Attorney’s Office for the District of Massachusetts requesting documents relating generally to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients, Alexion’s provision of free drug to Medicare patients and Alexion’s related compliance policies and training materials. We understand that the U.S. Attorney's Office is coordinating its inquiry with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services. In May 2017, Brazilian authorities seized records and data from our Sao Paulo, Brazil offices as part of an investigation being conducted into Alexion's Brazilian operations. In October 2018, the MHLW conducted an inspection of the Company's Japanese operations. Alexion is cooperating with these investigations. At this time, Alexion is unable to predict the duration, scope or outcome of these investigations.

Any determination that our operations or activities are not, or were not, in compliance with existing U.S. or foreign laws or regulations, including by the ongoing investigations of our compliance with the FCPA, Medicare patient assistance rules, regulations in Brazil or Japan, and other matters, could result in the imposition of a broad range of civil and criminal sanctions against Alexion and certain of

our directors, officers and/or employees, including injunctive relief, disgorgement, substantial fines or penalties, imprisonment, and other legal or equitable sanctions, including exclusion from Medicare, Medicaid, and other governmental healthcare programs. Any attempts to resolve some or all of these matters may not be successful and/or may result in monetary or other penalties materially stricter or greater than the terms or amounts that we proposed in discussions. 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. 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.

Completion of preclinical studies or clinical trials does not guarantee advancement to the next phase of development.

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

successfully achieving the primary endpoint in scientifically similar indications.

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

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

We rely on a small number of clinical research organizations to carry out our clinical trial related activities, and one 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.

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;
- slow patient enrollment, including, for example, due to the rarity of the disease being studied;
- delay or failure in having patients complete a trial or return for post-treatment follow-up;
- long treatment time required to demonstrate effectiveness;
- lack of sufficient supplies of the product candidate;
- disruption of operations at the clinical trial sites;
- adverse medical events or side effects in treated patients, and the threat of legal claims and litigation alleging injuries;
- failure of patients taking the placebo to continue to participate in our clinical trials;
- insufficient clinical trial data to support safety and effectiveness of the product candidates;
- lack of effectiveness or safety of the product candidate being tested;
- lack of sufficient funds;
- inability to meet required specifications or to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner;
- decisions by regulatory authorities, the IRB, ethics committee, or us, or recommendation by a data safety monitoring board, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- failure to obtain the necessary regulatory approvals for the product candidate or the approvals for the facilities in which such product candidate is manufactured; and
- decisions by competent authorities, IRBs or ethics committees to demand variations in protocols or conduct of clinical trials.

Risks Related to Intellectual Property

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

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

obtaining patent and trade secret protection for significant new technologies, products and processes.

We have and may in the future obtain patents or the right to practice patents through ownership or license. Our patent applications may not result in the issue of patents in the U.S. or other countries. Even in our patents are issued, those patents may not afford adequate protection for our products. Third parties may challenge our patents, and have challenged our patents in the past. If any of our patents are narrowed, invalidated or become unenforceable, competitors may develop and market products similar to ours that do not conflict with or infringe our patents rights, which could have a material adverse effect on our financial condition. We may also finance and collaborate in research conducted by government organizations, hospitals, universities or other educational or research institutions. Such research partners may be unwilling to grant us exclusive rights to technology or products developed through such collaborations. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties. Our products and product candidates are expensive and time-consuming to test and develop. Even if we obtain and maintain patents, our business may be significantly harmed if the patents are not broad enough to protect our products from copycat products.

Significant legal questions exist concerning the extent and scope of patent protection for biopharmaceutical products and processes in the U.S. and elsewhere. Accordingly, there is no certainty that patent applications owned or licensed by us will issue as patents, or that our issued patents will afford meaningful protection against competitors. Once issued, patents are subject to challenge through both administrative and judicial proceedings in the U.S. and other countries. Such proceedings include re-examinations, inter partes reviews, post-grant reviews and interference proceedings before the U.S. Patent and Trademark Office, as well as opposition proceedings before the European Patent Office and other non-U.S. patent offices. 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. 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 would likely help our competitors and adversely affect our business prospects.

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

Parts of our technology, techniques, proprietary compounds and potential product candidates, including those which are or may be in-licensed, may be found to infringe patents owned by or granted to others. We previously reported that certain third parties filed civil lawsuits against us claiming infringement of their intellectual property rights. Each of those matters was resolved. However, additional third parties may claim that the manufacture, use or sale of our products or product candidates infringes patents owned or granted to such third parties. We have received, and may in the future receive, notices from third parties claiming that their patents may be infringed by the development, manufacture or sale of our products or product candidates. We are aware of patents owned by third parties that might be claimed by such third parties to be infringed by the development and commercialization of our products or investigational compounds. In respect to some of these patents, we have obtained licenses, or expect to obtain licenses. However, with regard to other patents, we have determined in our judgment that:

- our products and investigational compounds do not infringe the patents; and/or
- 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 can be costly and time consuming to defend. Prior to launch of a new product (or an existing product for a new indication), for various reasons, a patent owner may not be able to assert its patent rights so it is likely that any potential challenges to our products will be made after a product has been commercialized and not while the product is in development, in clinical trials or during the regulatory review process. If we cannot successfully defend against any future actions or conflicts, if they arise, we may incur substantial legal costs and may be liable for damages, be required to obtain costly licenses or need to stop manufacturing, using or selling our products, which would adversely affect our business. We may seek to obtain a license prior to or during legal actions in order to reduce the risks in connection with product launches 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 would be of limited value and the same technology could be utilized by competitors.

There can be no assurance that we would prevail in a patent infringement action or that we would be able to obtain a license to any third-party patent on commercially reasonable terms or any terms at all; successfully develop non-infringing alternatives on a timely basis; or license alternative non-infringing technology, if any exists, on commercially reasonable terms 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 would harm our competitive position.

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

substantial decline in the innovative product's sales.

Market exclusivity for our products is based upon patent rights and certain regulatory forms of exclusivity. The scope of our product patent rights vary from country to country and is dependent on the availability of meaningful legal remedies in each country. The failure to obtain patent and other

intellectual property rights, or limitations on the use, or loss of such rights, could be material to our business. In some countries, patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents or we did not file patents in those markets. Also, the patent environment is unpredictable and the validity and enforceability of patents cannot be predicted with certainty. Absent relevant patent protection for a product, once regulatory exclusivity periods expire, biosimilar or generic versions of the product can be approved and marketed. Even prior to the expiration of regulatory exclusivity, a competitor could seek to obtain marketing approval by submitting its own clinical trial data.

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

Risks Related to Our Operations

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

From June 30, 2008 to June 30, 2018, we had maintained profitability on a consecutive quarterly

basis and we have maintained profitability on an annual basis beginning with the year ended December 31, 2008. Our quarterly revenues, expenses and net income (loss) may fluctuate, even significantly, due to the risks described in these “Risk Factors” as well as the timing of charges and expenses that we may take and acquisitions (such as the Wilson Therapeutics acquisition and the proposed acquisition of Syntimmmune). We believe that we formulate our annual operating budgets with reasonable assumptions and targets, however we may not generate sufficient revenues or control expenses to achieve our financial goals, including continued profitability. We may not be able to sustain or increase profitability on a quarterly or annual basis. You should not consider our financial performance, including our revenue growth, in recent periods as indicative of our future performance. We may not accurately forecast demand for our products, especially Strensiq, Kanuma, Soliris for the treatment of gMG and ALXN1210 for PNH (if ALXN1210 is approved by the regulatory authorities for patients with PNH in the U.S., EU and Japan). Strensiq and Kanuma are in the early stages of commercial launch having each received marketing approval in 2015, and both products treat rare diseases for which there was no existing therapy in a new therapeutic area. Soliris for the treatment of gMG was approved in 2017 and we intend to file for regulatory approval for Soliris as a treatment for NMOSD in the near future). Product demand is dependent on a number of factors. Our investors and investment analysts may have widely varying expectations that may be materially higher or lower than actual revenues and if our revenues are different from these expectations, our stock price may experience significant volatility. Our revenues are also subject to foreign exchange rate fluctuations due to the global nature of our operations and our results of operations could be adversely affected due to unfavorable foreign exchange rates. Although we use derivative instruments to manage foreign currency risk, our efforts to reduce currency exchange losses may not be successful.

In addition, we have provided financial guidance for future periods and if our 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.

We have significant debt service obligations as a result of the debt we incurred to finance the acquisition of Synageva. Changes in interest rates related to this debt could significantly increase our annual interest expense. As we attempt to advance our pipeline and continue to launch our second and third products and our third indication for Soliris worldwide and as we seek to obtain regulatory approval for ALXN1210 as a treatment for PNH in the U.S., EU and Japan, and as we move towards filing for

regulatory approval for Soliris as a treatment for NMOSD, we will have substantial expenses as we continue our research and development efforts, continue to conduct clinical trials and continue to develop manufacturing, sales, marketing and distribution capabilities worldwide, some of which could be delayed, scaled-back or eliminated to achieve our financial objectives.

We have also recorded, or may be required to record, charges that include inventory write-downs for failed quality specifications or recalls, impairments with respect to investments 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.

Other than Soliris for the treatment of gMG, each of our products is currently the only approved drug for the disease(s) the product treats. If a competitive product is approved for sale, including a biosimilar or generic product, our market share and our revenues could decline, particularly if the competitive product is perceived to be more effective or is less expensive than our product.

We operate in a highly competitive environment. Soliris is currently the only approved therapy for the treatment of PNH and aHUS, and is the only approved complement inhibition therapy for the treatment of AChR antibody-positive gMG. If ALXN1210 is approved as a treatment for PNH, it would be the second approved therapy for PNH (in addition to Soliris). We have completed Phase III clinical studies of Soliris for the treatment of NMOSD, and there are currently no approved drugs for this indication. Strensiq is currently the only product approved to treat HPP and Kanuma is the only product approved to treat LAL-D. In the future, Soliris and ALXN1210 (if approved by the FDA, EMA and MHLW for use in the U.S., EU and Japan for PNH patients) may compete with new drugs currently in development, and Strensiq and Kanuma may also experience competition. Other companies have initiated clinical studies for the treatment of PNH, aHUS, MG and NMOSD, and we are aware of companies that are planning to initiate studies for diseases that we are also targeting. Our revenues could be negatively affected if patients or potential patients enroll in our clinical trials or clinical trials of other companies with respect to diseases that we also target with approved therapies.

Pharmaceutical companies have publicly announced intentions to establish or develop rare disease programs and these companies may introduce products that are competitive with ours. These and other companies, many of which have significantly greater financial, technical and marketing resources than us, may commercialize products that

are cheaper, more effective, safer, or easier to administer than our products. In the future, our products may also compete with biosimilars or generics. We experience competition in drug development from universities and other research institutions, and pharmaceutical companies compete with us to attract universities and academic research institutions as drug development partners, including for licensing their proprietary technology. If our competitors successfully enter into such arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may not be able to find equivalent opportunities elsewhere.

If a company announces successful clinical trial results for a product that may be competitive with one of our products or product candidates, receives marketing approval of a competitive product, or gets to the market before we do with a competitive product, our business may be harmed or our stock price may decline.

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

We undertook broad corporate restructuring activities in 2017 to re-align our global organization with the Company's re-focused strategy, reduce costs, and realize operational efficiencies. These activities, including a work force reduction of more than 20.0% and plans to close certain operational sites, subject the Company to many risks, including loss of business continuity, unanticipated costs, and higher than usual employee turnover. The expected cost savings and operational efficiencies from the restructuring activities are based on assumptions and expectations, which 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 the restructuring, we must execute on our re-focused strategy, including growing and maximizing our rare disease business and pursuing disciplined business development to expand our pipeline. If we are unable to

effectively execute with fewer human resources and/or attract, retain or motivate key employees, our business may be adversely affected.

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

The success of our business is dependent in large part on our continued ability to attract and retain our senior management, and other highly qualified personnel in our scientific, clinical, manufacturing and commercial organizations. There is intense competition in the biopharmaceutical industry for these types of personnel. In March 2017, our Board appointed a new Chief Executive Officer (CEO) and we have experienced other recent management changes. In addition, in the second quarter of 2018, we completed the relocation of our global headquarters from New Haven, Connecticut to Boston, Massachusetts and in 2017 we began a company-wide restructuring to re-align our global organization with the Company's re-focused strategy. We continue to fill many open positions as a result of employees who did not relocate to Boston. The relocation and restructuring have the potential to adversely impact our ability to recruit and/or retain key employees as well as to disrupt our business operations, financial conditions, programs, plans and strategies.

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

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

In June 2015, we acquired Synageva and used a substantial portion of our cash on hand and incurred significant debt under the terms of a senior secured credit facility to finance the acquisition. In June 2018 we amended and restated this 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.

In addition, we have substantial contingent liabilities, including milestone and royalty obligations under acquisitions and strategic transactions, and we are currently 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 the credit facilities and require us to use cash flow from operations to satisfy our debt obligations, which would reduce the availability of our cash flow for other purposes, including business development efforts, research and development and mergers and acquisitions;
- limit our ability to incur additional debt or access the capital markets; and
- limit our flexibility in planning for, or reacting to changes in, our business.

The Amended and Restated Credit Agreement requires us to comply with certain financial covenants and additional 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 would increase and the administrative agent would be entitled to take various actions, including the acceleration of amounts due under the Amended and Restated Credit Agreement. 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 will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

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

We may need to raise additional capital to supplement our existing funds and cash generated from operations for working capital, capital expenditure and debt service requirements, and other business activities. Funding needs may

shift and the amount of capital we may need depends on many factors, including, the cost of any acquisition or any new collaborative, licensing or other commercial relationships that we may establish, the time and cost necessary to build our manufacturing facilities or enhance our manufacturing operations, 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 extreme volatility and disruption. We may not receive additional funding when we need it or funding may only be available on unfavorable terms. If we cannot raise adequate funds to satisfy our capital requirements and debt repayment obligations, we may have to delay, scale-back or eliminate certain research, development, manufacturing, acquisition or commercial activities.

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

As a biopharmaceutical company, our business involves the use of certain hazardous materials in our research, development, manufacturing, and other activities. We and our third party providers are subject to various federal, state and local 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. If an accident or environmental discharge occurs, or if we discover contamination caused by prior owners and operators of properties we acquire, we could be liable for remediation obligations, damages and fines that could exceed our insurance coverage and financial resources. Such obligations and liabilities, which to date have not been material, could have a material impact on our business and financial condition. Additionally, the cost of compliance with environmental and safety laws and regulations may increase in the future, and we may be required dedicate more resources, including substantial financial resources, to comply with such developments 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 strategic initiatives. 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, we currently rely on one product for a substantial portion of our revenue and we expect that there may be potential increased competition to Soliris from, among other products and therapies, biosimilars. As a result, we have identified rebuilding our product pipeline as a key strategic objective and, in order to achieve this objective, we expect we will purchase businesses and acquire, co-develop or license technologies from third parties in the future. 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, including Wilson Therapeutics and Complement Pharma, Dicerna and the pending acquisition of Syntimmune, may involve numerous risks, including:

- substantial cash expenditures;
- potentially dilutive issuance of equity securities;
- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- difficulties in assimilating the operations of the acquired companies;
- failure of any acquired businesses or products or in-licensed products or technologies to achieve the scientific, medical, commercial or other results anticipated;
- 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 markets in which we have limited or no direct experience.

A substantial portion of our strategic efforts are focused on opportunities for rare disorders and life-saving therapies, but the availability of such opportunities is limited. We may not be able to identify opportunities that satisfy our strategic criteria or are acceptable to us or our stockholders. Several companies have publicly announced intentions to establish or develop rare disease programs and we may compete with these companies for the same opportunities. For these and other reasons, we may not be able to acquire the rights to additional product

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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 product pipeline and any future revenue would remain largely dependent on our existing products which, as noted above, may be subject to increasing competition from biosimilars and other therapies.
Even if we are able to successfully identify and complete acquisitions and other strategic transactions, we may not be able to integrate them or take full advantage of them. An acquisition or other strategic transaction may not result in short-term or long-term benefits to us. We may also incorrectly judge the value or worth of an acquired company or business or an acquired or in-licensed product.
To effectively manage our current and future potential growth, we must continue to effectively enhance and develop our global employee base, and our operational and financial processes. Supporting our growth strategy will require significant capital expenditures and management resources, including investments in research, development, sales and marketing, manufacturing and other areas of our operations. The development or expansion of our business, any acquired business or any acquired or in-licensed products may require a substantial capital investment by us. We may not have the necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our capital stock, which could dilute current stockholders' ownership interest in our company, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest in Alexion upon conversion.
We may be required to recognize impairment charges for our goodwill and other intangible assets, and such charges may be material in amount and have an adverse impact on our financial results in the period such charges are incurred.

As of September 30, 2018, the net carrying value of our goodwill and other intangible assets, net totaled $8,751.0. As required by generally accepted accounting principles, we periodically assess these assets to determine if there are indicators of impairment. Impairment of intangible assets may be triggered by developments both within and outside our control. Deteriorating economic conditions, technological changes, disruptions to our business, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in 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, 2018 and determined that there were no indicators of impairment. We will continue to review the related valuation and accounting of this asset in future quarters as new information becomes available to us. Changes to assumptions used in our net cash flow projections may result in impairment charges in subsequent periods. The net book value of the Kanuma intangible asset as of September 30, 2018 is $3,317.7.
Our business could be affected by litigation, government investigations and enforcement actions.
We operate in many jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the U.S. or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, Qui Tam, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment, and other claims and legal proceedings which may arise from conducting our business. As previously disclosed, in May 2015, we received a subpoena in connection with an investigation by the Enforcement Division of the SEC requesting information related to our grant-making activities and compliance with the FCPA in various countries. The SEC also seeks information related to Alexion's recalls of specific lots of Soliris and related securities disclosures. In October 2015, Alexion received a request from the DOJ for the voluntary production of documents and other information pertaining to Alexion's compliance with the FCPA. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief, and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations. In addition, we are subject to other government investigations and litigation including those described in PART II - Item 1. Legal Proceedings elsewhere in this Quarterly Report on Form 10-Q. Legal proceedings, government investigations, including the SEC and DOJ investigations, and enforcement actions have been and we expect will continue to be expensive and time consuming. Any future litigation or investigation

would also likely be expensive and time consuming. An adverse outcome on any current of future matter could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations.

The 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 our corporate structure, the manner in which we develop and use our intellectual property, and our intercompany transactions between our affiliates in a way that is intended to enhance our operational and financial efficiency and increase our overall profitability. The application of the tax laws and regulations of various countries in which we operate and to our global operations is subject to interpretation. We also must operate our business in a manner consistent with our corporate structure to realize such efficiencies. The tax authorities of the countries in which we operate may challenge our methodologies for valuing developed technology or for transfer pricing. If tax authorities determine that the manner in which we operate results in our business not achieving the intended tax consequences, our effective tax rate could increase (and 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 and planned expansion 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 import our products and we may be required to pay additional duties or fines;
- difficulties enforcing contractual and intellectual property rights;
- compliance with complex import and export control laws;
- trade restrictions and restrictions on direct investments by foreign entities;
- compliance with tax, employment and labor laws;
- costs and difficulties in recruiting and retaining qualified managers and employees to manage and operate the business in local jurisdictions;

- costs and difficulties in managing and monitoring international operations; and
- longer payment cycles.

Additionally, our business and marketing methods are subject to the laws and regulations of the countries in which we operate, which may differ significantly from country to country and may conflict with U.S. laws and regulations. The FCPA and anti-bribery laws and regulations in the locations in which we operate our business are extensive and far-reaching, and we must maintain accurate records and control over the activities of our distributors and third party service providers in countries where we operate. We have policies and procedures, and we are currently implementing an enhanced company-wide compliance program and effort, designed to help ensure that we and our representatives, including our employees and

our vendors and distributors, comply with such laws, however we cannot guarantee that these policies and procedures will protect us against liability under the FCPA or other anti-bribery laws for actions taken by 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 an 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. Failure 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, Swiss Franc, and Russian Ruble. As the U.S. dollar strengthens against these foreign currencies, the relative value of sales made in the respective foreign currencies decrease. When the U.S. dollar weakens against these currencies, the relative value of such sales increase. We manage 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 hedges of revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. Further, we enter into foreign exchange forward contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results. Gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures.

While we attempt to hedge certain currency risks, currency fluctuations between the U.S. dollar and the currencies in which we do business have, in the past, caused foreign currency transaction gains and losses and have also impacted the amounts of revenues and expenses calculated in U.S. dollars and will do so in the future. Likewise, past currency fluctuations have at times resulted in foreign currency transaction gains, and there can be no assurance that these gains can be reproduced. Any significant foreign currency exchange rate fluctuations could adversely affect our financial condition and results of operations.

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

In the U.S., there have been a number of legislative and regulatory initiatives focused on containing the cost of healthcare. The Patient Protection and Affordable Care Act (PPACA) was enacted in the U.S. in March 2010. This law substantially changes the way healthcare is financed by both governmental and private insurers in the U.S., and significantly impacts the pharmaceutical industry. PPACA contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under health insurance exchanges, expansion of the 340B program, expansion of state Medicaid programs, fraud and abuse enforcement and rules governing the approval of biosimilar products. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. In early 2016, the Centers for Medicare and Medicaid Services (CMS) issued final regulations to implement the changes to the Medicaid Drug Rebate Program under PPACA. These regulations became effective on April 1, 2016. Moreover, in the future, Congress could enact legislation that further increases Medicaid drug

rebates or other costs and charges associated with participating in the Medicaid Drug Rebate Program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate Program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

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

Governments in countries where we operate have adopted or have also shown significant interest in pursuing legislative initiatives to reduce costs of healthcare. We expect that the implementation of current laws and policies, the amendment of those laws and policies in the future, as well as the adoption of new laws and policies, could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales or successfully commercialize our product candidates, or could limit or eliminate our future spending on development projects. In many cases, these government initiatives, even if enacted into law, are subject to future rulemaking by regulatory agencies. Although we have evaluated these government initiatives and the expected impact on our business, we cannot know with certainty whether any such law, rule or regulation will adversely affect coverage and reimbursement of our products, or to what extent, until such laws, rules and regulations are promulgated, implemented and enforced, which could sometimes take many years. The announcement or adoption of regulatory or legislative proposals could delay or prevent our entry into new markets, affect our reimbursement or sales in the markets where we are already selling our products and materially harm our business, financial condition and results of operations.

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

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate Program and we have obligations to report the average sales price under the Medicare program. Under the Medicaid Drug Rebate Program, we are required to pay a rebate to each state Medicaid program for quantities of our products that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our products under Medicaid and Medicare Part B. Those rebates are based on pricing

data reported by us on a monthly and quarterly basis to CMS. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug. Any failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. PPACA expanded the 340B program to include additional types of covered entities but exempts "orphan drugs"-those designated under section 526 of the Federal Food, Drug, and Cosmetic Act, such as our products-from the ceiling price requirements for these newly-eligible entities. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Any changes to the definition of average manufacturer price and the Medicaid rebate amount also could affect our 340B ceiling price calculation for our products and could negatively impact our results of operations.

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

regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The effective date of the regulation has been delayed until July 1, 2019. Implementation of this final rule and the issuance of any other final regulations and guidance

could affect our obligations under the 340B pricing program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B pricing program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting. Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due, and CMS may request or require restatements for earlier periods as well. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B pricing program.

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

Federal law requires that a company must participate in the 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, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA. Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. EU Member States and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EC adopted the EU Data Protection Directive, as implemented into national laws by the EU Member States, which imposes strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from different EU Member States have interpreted the privacy laws differently, which adds to the complexity of processing personal data in the EU, and guidance on implementation and compliance practices are often updated or otherwise revised. Any failure to comply with the rules arising from the EU Data

Protection Directive and related national laws of EU Member States could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

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

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

We are increasingly dependent on our information technology systems and infrastructure for our business. We collect, store, and transmit sensitive information including intellectual property, proprietary business information and personal information in connection with business operations. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack by third parties with a wide range of motives and expertise, including organized criminal groups, “hacktivists,” patient groups, disgruntled current or former employees, and others. Cyber-attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance. We have implemented information security measures to protect patients’ personal information against the risk of inappropriate and unauthorized external use and disclosure. However, despite these measures, and due to the ever changing information cyber-threat landscape, we may be subject to data breaches through cyber-attacks. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. If our systems become compromised, we may not promptly discover the intrusion. Like other companies in our industry, we have experienced attacks to our data and systems, including malware and computer viruses. If our systems failed or were breached or disrupted, we could lose product sales, and suffer reputational damage and loss of customer confidence. Such incidents would 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 would be adversely impacted.

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

Risks Related to Our Common Stock

Our stock price is extremely volatile.

The trading price of our common stock has been extremely volatile and may continue to be volatile in the future. Many factors could have an impact on our stock price, including fluctuations in our or our competitors’ operating results, clinical trial results or adverse events associated with our products, product development by us or our competitors, changes in laws, including healthcare, tax or intellectual property laws, intellectual property developments, changes in reimbursement or drug pricing, the existence or outcome of litigation or government proceedings, including the SEC/DOJ investigation, acquisitions or other strategic transactions, and the perceptions of our investors that we are not performing or meeting expectations. The trading price of the common stock of many biopharmaceutical companies, including ours, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of the companies whose stocks were affected.

Anti-takeover provisions in our charter and bylaws and under Delaware law could make a third-party acquisition of us difficult and may frustrate any attempt to remove or replace our current management.

Our corporate charter and by-law provisions may discourage certain types of transactions involving an actual or potential change of control that might be beneficial to us or our stockholders. Our bylaws provide that special meetings of our stockholders may be called only by the Chairman of the Board of

Directors, the President, the Secretary, or a majority of the Board of Directors, or upon the written request of stockholders who together own of record 25.0% of the outstanding stock of all classes entitled to vote at such meeting. Our bylaws also specify that the authorized number of directors may be changed only by resolution of the Board of Directors. Our charter does not include a provision for cumulative voting for directors, which may have enabled a minority stockholder holding a sufficient percentage of a class of shares to elect one or more directors. Under our charter, our Board of Directors has the authority, without further action by stockholders, to designate up to 5 shares of preferred stock in one or more series. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any class or series of preferred stock that may be issued in the future.

Because we are a Delaware corporation, the anti-takeover provisions of Delaware law could make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to stockholders. We are subject to the provisions of Section 203 of the Delaware General Laws, which prohibits a person who owns in excess of 15.0% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15.0% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Item 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 of 2018:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Dollar Value of Shares that May Yet Be Purchased Under the Program
July 1-31, 2018	—	$ ——		$ 451.5
August 1-31, 2018	—	$ ——		$ 451.5
September 1-30, 2018	—	$ ——		$ 451.5
Total	—	$ ——		

In February 2017, our Board of Directors authorized the future acquisition of shares with an aggregate value of up to $1,000.0 under our existing share repurchase program. The repurchase program does not have an expiration date, and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at our discretion. The Company did not repurchase any shares during the third quarter 2018.

Item 5. OTHER INFORMATION.
None.

Item 6. EXHIBITS.

(a)Exhibits:

10.1	Agreement and Plan of Merger, dated as of September 25, 2018, by and among Alexion Pharmaceuticals, Inc., Syracuse Merger Sub, Inc., Syntimmune, Inc. and Shareholder Representative Services LLC *
10.2	Agreement, dated as of September 7, 2018, by and between Alexion Pharma Holding Unlimited Company, Shareholder Representative Services LLC, Fonds de Solidarité des Travailleurs du Québec F.T.Q, Capital Régional et Coopératif Desjardins, CTI Life Sciences Fund, L.P., OrbiMed Private Investments III, LP and OrbiMed Associates III, LP (in connection with the Agreement and Plan of Merger, dated December 28, 2011 pursuant to which Alexion acquired Enobia Pharma Corp.)
10.3	Alexion Pharmaceuticals, Inc. Amended and Restated 2015 Employee Stock Purchase Plan **
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, 2018 formatted in eXtensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017, (ii) the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2018 and 2017, (iii) the Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2018 and 2017, (iv) the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and 2017, and (v) Notes to Condensed Consolidated Financial Statements.

* Alexion has applied for confidential treatment of certain provisions of this exhibit with the Securities and Exchange Commission (SEC). The confidential portions of this exhibit are marked by an asterisk and have been omitted and filed separately with the SEC pursuant to Alexion’s request for confidential treatment.

** 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.
Ludwig N. Hantson, Ph.D.
Date: October 24, 2018 Chief Executive Officer (principal executive officer)

By: /s/ Paul J. Clancy
Paul J. Clancy
Date: October 24, 2018 Executive Vice President and Chief Financial Officer
(principal financial officer)