ALEXION PHARMACEUTICALS INC
Form 10-Q
July 29, 2016

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 June 30, 2016
or
¨Transition report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934
For the transition period from to
Commission file number: 0-27756

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

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

100 College Street, New Haven Connecticut 06510
(Address of Principal Executive Offices) (Zip Code)
203-272-2596
(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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. Check One:
Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨ (Do not check if a smaller reporting company)
Smaller reporting company ¨
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	224,247,998
Class	Outstanding as of July 27, 2016

Alexion Pharmaceuticals, Inc.
Contents

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

	June 30, 2016	December 31, 2015
Assets		
Current Assets:		
Cash and cash equivalents	$597,550	$1,010,111
Marketable securities	582,501	374,904
Trade accounts receivable, net	609,297	532,832
Inventories	329,847	289,874
Prepaid expenses and other current assets	242,014	208,993
Total current assets	2,361,209	2,416,714
Property, plant and equipment, net	825,301	697,025
Intangible assets, net	4,547,762	4,707,914
Goodwill	5,037,444	5,047,885
Other assets	257,631	228,343
Total assets	$13,029,347	$13,097,881
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$28,978	$57,360
Accrued expenses	407,289	403,348
Deferred revenue	53,422	20,504
Current portion of long-term debt	79,136	166,365
Other current liabilities	89,637	62,038
Total current liabilities	658,462	709,615
Long-term debt, less current portion	3,171,092	3,254,536
Facility lease obligation	196,439	151,307
Contingent consideration	109,565	121,424
Deferred tax liabilities	570,074	528,990
Other liabilities	124,376	73,393
Total liabilities	4,830,008	4,839,265
Commitments and contingencies (Note 17)		
Stockholders' Equity:		
Common stock, $0.0001 par value; 290,000 shares authorized; 231,403 and 230,498 shares issued at June 30, 2016 and December 31, 2015, respectively	23	23
Additional paid-in capital	7,852,432	7,726,560
Treasury stock, at cost, 7,179 and 4,851 shares at June 30, 2016 and December 31, 2015, respectively	(1,041,314)	(710,663)
Accumulated other comprehensive income	694	62,301
Retained earnings	1,387,504	1,180,395
Total stockholders' equity	8,199,339	8,258,616
Total liabilities and stockholders' equity	$13,029,347	$13,097,881

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

Alexion Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(amounts in thousands, except per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Net product sales	$752,546	$635,983	$1,452,971	$1,236,316
Other revenue	570	227	1,183	227
Total revenues	753,116	636,210	1,454,154	1,236,543
Cost of sales	60,627	52,007	119,613	121,406
Operating expenses:				
Research and development	179,311	131,693	355,601	352,773
Selling, general and administrative	231,802	221,383	464,363	408,499
Amortization of purchased intangible assets	80,055	—	160,149	—
Change in fair value of contingent consideration	5,186	4,044	(9,614)	16,023
Acquisition-related costs	974	29,777	2,313	29,777
Restructuring expenses	455	16,224	1,177	23,276
Total operating expenses	497,783	403,121	973,989	830,348
Operating income	194,706	181,082	360,552	284,789
Other income and expense:				
Investment income	1,872	2,226	3,423	5,110
Interest expense	(23,793)	(3,971)	(47,683)	(4,622)
Foreign currency loss	(2,820)	(2,045)	(2,729)	(1,040)
Income before income taxes	169,965	177,292	313,563	284,237
Income tax provision	55,022	7,077	106,454	22,699
Net income	$114,943	$170,215	$207,109	$261,538
Earnings per common share				
Basic	$0.51	$0.84	$0.92	$1.30
Diluted	$0.51	$0.83	$0.92	$1.29
Shares used in computing earnings per common share				
Basic	224,089	202,234	224,593	200,806
Diluted	225,756	204,546	226,328	203,302

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

Alexion Pharmaceuticals, Inc.
Condensed Consolidated Statements of Comprehensive Income
(unaudited)
(amounts in thousands)

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Net income	$114,943	$170,215	$207,109	$261,538
Other comprehensive income (loss), net of tax:				
Foreign currency translation	125	1,170	2,121	(4,218)
Unrealized gains (losses) on marketable securities	1,965	(803)	3,463	254
Unrealized (losses) gains on pension obligation	(911)	(7,193)	1,210	(7,445)
Unrealized (losses) gains on hedging activities, net of tax of $(1,712), $(27,623), $(37,362) and $11,010, respectively	(4,300)	(50,147)	(68,401)	17,140
Other comprehensive (loss) income, net of tax	(3,121)	(56,973)	(61,607)	5,731
Comprehensive income	$111,822	$113,242	$145,502	$267,269

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 thousands)

	Six months ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net income	$207,109	$261,538
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	194,579	23,141
Change in fair value of contingent consideration	(9,614)	16,023
Share-based compensation expense	104,868	109,797
Deferred taxes	76,154	(3,565)
Change in excess tax benefit from stock options	(479)	(10,763)
Unrealized foreign currency gain	(4,073)	(10,434)
Other	9,088	6,094
Changes in operating assets and liabilities, excluding the effect of acquisitions:		
Accounts receivable	(65,223)	(108,984)
Inventories	(39,041)	4,722
Prepaid expenses and other assets	(88,125)	(48,069)
Accounts payable, accrued expenses and other liabilities	(6,702)	(10,761)
Deferred revenue	33,376	32,517
Net cash provided by operating activities	411,917	261,256
Cash flows from investing activities:		
Purchases of available-for-sale securities	(495,206)	(187,416)
Proceeds from maturity or sale of available-for-sale securities	294,370	1,030,825
Purchases of trading securities	(4,421)	(3,769)
Purchases of property, plant and equipment	(131,031)	(130,171)
Payment for acquisition of business, net of cash acquired	—	(3,939,268)
Other	(52)	1,410
Net cash used in investing activities	(336,340)	(3,228,389)
Cash flows from financing activities:		
Debt issuance costs	—	(45,492)
Proceeds from revolving credit facility	—	200,000
Proceeds from term loan	—	3,500,000
Payments on revolving credit facility	—	(200,000)
Payments on term loan	(175,000)	(57,500)
Equity issuance costs for shares issued in connection with acquisition of business	—	(3,864)
Change in excess tax benefit from stock options	479	10,763
Repurchase of common stock	(330,651)	(83,563)
Net proceeds from issuance of common stock under share-based compensation arrangements	19,595	31,684
Other	(4,773)	(613)
Net cash (used in) provided by financing activities	(490,350)	3,351,415
Effect of exchange rate changes on cash	2,212	(6,158)
Net change in cash and cash equivalents	(412,561)	378,124
Cash and cash equivalents at beginning of period	1,010,111	943,999
Cash and cash equivalents at end of period	$597,550	$1,322,123

Supplemental cash flow disclosures from investing and financing activities:		
Common stock issued in acquisition of business	$—	$4,917,849
Capitalization of construction costs related to facility lease obligations	$49,895	$19,065
Accrued expenses for purchases of property, plant and equipment	$26,238	$21,299

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 thousands, except per share amounts)

1. Business

Alexion Pharmaceuticals, Inc. (Alexion, the Company, we, our or us) is a biopharmaceutical company focused on serving patients with devastating and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products.

In our complement franchise, Soliris® (eculizumab) is the first and only therapeutic approved for patients with either paroxysmal nocturnal hemoglobinuria (PNH), a life-threatening and ultra-rare genetic blood disorder, or atypical hemolytic uremic syndrome (aHUS), a life-threatening and ultra-rare genetic disease. PNH and aHUS are two disorders resulting from chronic uncontrolled activation of the complement component of the immune system.

In our metabolic franchise, we commercialize Strensiq® (asfotase alfa) for the treatment of patients with hypophosphatasia (HPP) and Kanuma® (sebelipase alfa) for the treatment of patients with lysosomal acid lipase deficiency (LAL-D). HPP is a genetic ultra-rare disease characterized by defective bone mineralization that can lead to deformity of bones and other skeletal abnormalities. LAL-D is a serious, life threatening ultra-rare disease in which genetic mutations result in decreased activity of the LAL enzyme leading to marked accumulation of lipids in vital organs, blood vessels and other tissues.

We are also evaluating additional potential indications for eculizumab in other severe and devastating diseases in which uncontrolled complement activation is the underlying mechanism, and we are progressing in various stages of development with additional product candidates as potential treatments for patients with severe and life-threatening rare disorders.

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, 2015. In our opinion, the accompanying unaudited 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, 2015 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, 2015 included in our Annual Report on Form 10-K. The results of operations for the three and six months ended June 30, 2016 are not necessarily indicative of the results to be expected for the full year.

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, 2015.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2017 and allows for adoption using a full retrospective method, or a modified retrospective method. Entities may elect to early adopt the standard for annual periods beginning after December 15, 2016. We are currently assessing the method of adoption and the expected impact the new standard has on our financial position and results of operations.

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

In April 2015, the FASB issued a new standard simplifying the presentation of debt issuance costs. The new standard aligns the treatment of debt issuance costs with debt discounts and premiums and requires debt issuance costs be presented as a direct deduction from the carrying amount of the related debt. We adopted the provisions of this standard in the first quarter 2016 and reclassified $8,635 of deferred financing costs from other current assets to the current portion of long term debt and $26,714 from other non current assets to long-term debt, less current portion in our consolidated balance sheets as of December 31, 2015.

In April 2015, the FASB issued a new standard clarifying the accounting for a customer's fees paid in a cloud computing arrangement. Under this standard, if a cloud computing arrangement includes a software license, the customer would account for the software license consistent with other software licenses. If a cloud computing arrangement does not include a software license, the customer would account for the arrangement as a service contract. We adopted the provisions of this standard in the first quarter 2016. The adoption did not have a material effect on our financial condition or results of operations.

In February 2016, the FASB issued a new standard requiring that the rights and obligations arising from leases be recognized on the balance sheet by recording a right-of-use asset and corresponding lease liability. The new standard also requires qualitative and quantitative disclosures to understand the amount, timing, and uncertainty of cash flows arising from leases, as well as significant management estimates utilized. The standard is effective for interim and annual periods beginning after December 15, 2018 and requires a modified retrospective adoption. We are currently assessing the impact of this standard on our financial condition and results of operations.

In March 2016, the FASB issued a new standard simplifying aspects of the accounting for employee share-based payments, including the accounting for income taxes, forfeitures, statutory withholding requirements, and classification on the statement of cash flows. The standard is effective for interim and annual periods beginning after December 15, 2016, with early adoption permitted. We are currently assessing the impact of this standard on our financial condition and results of operations.

3. Acquisitions

On May 6, 2015, we announced that we entered into a definitive agreement to acquire Synageva BioPharma Corp. (Synageva), a publicly-held clinical-stage biotechnology company based in Lexington, Massachusetts for per share consideration of $115 in cash and 0.6581 shares of Alexion stock. At this date, the announced purchase consideration was estimated at approximately $8,400,000, net of Synageva cash, based on the closing price of Alexion stock on May 5, 2015 of $168.55.

On June 22, 2015, we completed the acquisition of Synageva, in a transaction accounted for under the acquisition method of accounting for business combinations. Under the acquisition method of accounting, the assets acquired and liabilities assumed from Synageva were recorded as of the acquisition date at their respective fair values. Synageva's results of operations are included in the consolidated financial statements from the date of acquisition. The acquisition furthers our objective to develop and commercialize life-transforming therapies to an increasing number of patients with devastating and rare diseases. Synageva's lead product candidate was Kanuma, an enzyme replacement therapy for patients suffering with LAL-D, a life-threatening, ultra-rare disease for which there are no approved treatments. We acquired all of the outstanding shares of common stock of Synageva for $4,565,524 in cash and 26,125 shares of common stock. At closing of the business combination on June 22, 2015, the purchase consideration was approximately $8,860,000, net of Synageva cash, based on Alexion's closing share price on the date of acquisition of $188.24. We financed the cash consideration with existing cash and proceeds from our new credit facility described further in Note 6.

The aggregate consideration to acquire Synageva consisted of:

Stock consideration	$4,917,810
Cash consideration	4,565,524
Total purchase price	$9,483,334

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

The following table summarizes the estimated fair values of assets acquired and liabilities assumed:

Cash	$626,217
Inventory	23,880
In-process research and development (IPR&D)	4,236,000
Deferred tax liabilities, net	(159,991)
Other assets and liabilities	(26,143)
Net assets acquired	4,699,963
Goodwill	4,783,371
Total purchase price	$9,483,334

The fair value of the assets acquired and liabilities assumed were initially based upon preliminary calculations, and our estimates and assumptions were subject to change as we obtained additional information for our estimates during the measurement period (up to one year from the acquisition date). During the six months ended June 30, 2016, we recorded fair value adjustments of $10,441, primarily due to tax related items.

We acquired $23,880 of Kanuma inventory. The estimated fair value of work-in-process and finished goods inventory was determined utilizing the comparative sales method, based on the expected selling price of the inventory, adjusted for incremental costs to complete the manufacturing process and for direct selling efforts, as well as for a reasonable profit allowance. The estimated fair value of raw material inventory was valued at replacement cost, which is equal to the value a market participant would pay to acquire the inventory.

Intangible assets associated with IPR&D projects primarily relate to Kanuma. The estimated fair value of IPR&D assets of $4,236,000 was determined using the multi-period excess earnings method, a variation of the income approach. The multi-period excess earnings method estimates the value of an intangible asset equal to the present value of the incremental after-tax cash flows attributable to that intangible asset. The fair value using the multi-period excess earnings method was dependent on an estimated weighted average cost of capital for Synageva of 10%, which represents a rate of return that a market participant would expect for these assets.

The excess of purchase price over the fair value amounts of the assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. The goodwill, which is not tax-deductible, has been recorded as a noncurrent asset and is not amortized, but is subject to an annual review for impairment. The goodwill represents future economic benefits arising from other assets acquired that could not be individually identified and separately recognized and expected synergies that are specific to our business and not available to market participants, including our unique ability to commercialize therapies for rare diseases, our existing relationships with specialty physicians who can identify patients with LAL-D, a global distribution network to facilitate drug delivery and other benefits that we believe will result from combining the operations of Synageva within our operations.

We recorded a net deferred tax liability of $159,991. This amount was primarily comprised of $602,887 of deferred tax liabilities related to the IPR&D and inventory acquired, offset by $442,896 of deferred tax assets related to net operating loss carryforwards (NOLs), tax credits, and other temporary differences, which we expect to utilize.

For the three and six months ended June 30, 2015, we recorded $4,862 of operating expenses associated with the continuing operations of Synageva in our condensed consolidated statements of operations.

Pro forma financial information (unaudited)

The following unaudited pro forma information presents the combined results of Alexion and Synageva as if the acquisition of Synageva had been completed on January 1, 2014, with adjustments to give effect to pro forma events that are directly attributable to the acquisition. The unaudited pro forma results do not reflect operating efficiencies or potential cost savings which may result from the consolidation of operations. Accordingly, the unaudited pro forma

financial information is not necessarily indicative of the results of operations that would have had we completed the transaction on January 1, 2014.

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

	Three months ended June 30, 2015	Six months ended June 30, 2015
Pro forma revenue	$637,491	$1,238,751
Pro forma net income	98,568	130,289
Earnings per common share		
Basic	$0.44	$0.58
Diluted	$0.43	$0.57

The unaudited pro forma consolidated results include the following pro forma adjustments related to non-recurring activity:

- Alexion and Synageva expenses of $33,150 and $127,290, respectively, associated with the accelerated vesting of stock based compensation as a result of the acquisition, were excluded from net income for the three and six months ended June 30, 2015.

- Alexion and Synageva acquisition-related and restructuring costs of $40,099 and $62,071, respectively, were excluded from income for the three and six months ended June 30, 2015.

Acquisition-Related Costs
Acquisition-related costs associated with our business combinations for the three and six months ended June 30, 2016 and 2015 include the following:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Transaction costs [1]	$—	$26,799	$375	$26,799
Integration costs	974	2,978	1,938	2,978
	$974	$29,777	$2,313	$29,777

(1) Transaction costs include investment advisory, legal, and accounting fees

For the three and six months ended June 30, 2015, the acquisition of Synageva resulted in $10,322 of restructuring related charges. Synageva restructuring related charges were not material for the three and six months ended June 30, 2016. See Note 18 for additional details.

4. Inventories
Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of inventory on a standard cost basis, which approximates average costs.
The components of inventory are as follows:

	June 30,	December 31,

	2016	2015
Raw materials	$19,780	$ 17,924
Work-in-process	157,097	180,324
Finished goods	152,970	91,626
	$329,847	$ 289,874

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

5. Intangible Assets and Goodwill

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

		June 30, 2016			December 31, 2015		
	Estimated Life (years)	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Licenses	6-8	$28,507	$ (28,507)	$—	$28,507	$ (28,504)	$3
Patents	7	10,517	(10,517)	—	10,517	(10,517)	—
Purchased technology	6-16	4,708,495	(276,733)	4,431,762	4,708,495	(116,584)	4,591,911
Acquired IPR&D	Indefinite	116,000	—	116,000	116,000	—	116,000
Total		$4,863,519	$ (315,757)	$4,547,762	$4,863,519	$ (155,605)	$4,707,914
Goodwill	Indefinite	$5,040,345	$ (2,901)	$5,037,444	$5,050,786	$ (2,901)	$5,047,885

Amortization expense for the three and six months ended June 30, 2016 was $80,055 and $160,152, respectively. Amortization expense was not material for the three and six months ended June 30, 2015. Total estimated amortization expense for finite-lived intangible assets is $160,070 for the six months ending December 31, 2016, and $320,142 for each of the years ending December 31, 2017 through December 31, 2021.

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

Balance at December 31, 2015	$5,047,885
Change in goodwill associated with prior acquisition	(10,441)
Balance at June 30, 2016	$5,037,444

6. Debt

In June 2015, Alexion entered into a credit agreement (Credit Agreement) with a syndicate of banks, which provides for a $3,500,000 term loan facility and a $500,000 revolving credit facility maturing in five years. Borrowings under the term loan are payable in quarterly installments equal to 1.25% of the original loan amount, beginning December 31, 2015. Final repayment of the term loan and revolving credit loans are due on June 22, 2020. In addition to borrowings in which prior notice is required, the revolving credit facility includes a sublimit of $100,000 in the form of letters of credit and borrowings on same-day notice, referred to as swingline loans, of up to $25,000. Borrowings can be used for working capital requirements, acquisitions and other general corporate purposes. With the consent of the lenders and the administrative agent, and subject to satisfaction of certain conditions, we may increase the term loan facility and/or the revolving credit facility in an amount that does not cause our consolidated net leverage ratio to exceed the maximum allowable amount.

In connection with entering into the Credit Agreement, we paid $45,492 in financing costs which are being amortized as interest expense over the life of the debt. Amortization expense associated with deferred financing costs for the three and six months ended June 30, 2016 was $2,382 and $4,895, respectively. Amortization expense associated with deferred financing costs for the three and six months ended June 30, 2015 was not material.

We made principle payments of $175,000 during the six months ended June 30, 2016. As of June 30, 2016, we had $3,281,250 outstanding on the term loan. As of June 30, 2016, we had open letters of credit of $13,829, and our borrowing availability under the revolving facility was $486,171.

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

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

The following table summarizes the calculation of basic and diluted EPS for the three and six months ended June 30, 2016 and 2015:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Net income used for basic and diluted calculation	$114,943	$170,215	$207,109	$261,538
Shares used in computing earnings per common share—basic	224,089	202,234	224,593	200,806
Weighted-average effect of dilutive securities:				
Stock awards	1,667	2,312	1,735	2,496
Shares used in computing earnings per common share—diluted	225,756	204,546	226,328	203,302
Earnings per common share:				
Basic	$0.51	$0.84	$0.92	$1.30
Diluted	$0.51	$0.83	$0.92	$1.29

We exclude from EPS the weighted-average number of securities whose effect is anti-dilutive. Excluded from the calculation of EPS for the three and six months ended June 30, 2016 were 4,345 and 4,156 shares of common stock, respectively, because their effect was anti-dilutive. Similarly, we excluded 2,435 and 2,387 shares from the calculation of EPS for the three and six months ended June 30, 2015, respectively, because their effect was anti-dilutive.

8. Marketable Securities

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and estimated fair value of available-for-sale investments by type of security at June 30, 2016 and December 31, 2015 were as follows:

	June 30, 2016			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Commercial paper	$147,523	$ —	$ —	$147,523
Corporate bonds	209,816	596	(31)	210,381
Municipal bonds	91,884	88	—	91,972
Other government-related obligations:				
U.S.	33,144	44	(59)	33,129
Foreign	148,035	393	(8)	148,420
Bank certificates of deposit	13,001	—	—	13,001
Total available-for-sale debt securities	$643,403	$ 1,121	$ (98)	$644,426
Equity securities	—	2,888	—	2,888
Total available-for-sale securities	$643,403	$ 4,009	$ (98)	$647,314

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	December 31, 2015			
	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Commercial paper	$254,396	$ —	$ —	$254,396
Corporate bonds	133,062	23	(336)	132,749
Municipal bonds	87,173	1	(63)	87,111
Other government-related obligations:				
U.S.	25,244	—	(94)	25,150
Foreign	163,403	—	(504)	162,899
Bank certificates of deposit	27,000	—	—	27,000
Total available-for-sale securities	$690,278	$ 24	$ (997)	$689,305

The aggregate fair value of available-for-sale securities in an unrealized loss position as of June 30, 2016 and December 31, 2015 were $97,047 and $293,947, respectively. Investments that have been in a continuous unrealized loss position for more than 12 months were not material. As of June 30, 2016, we believe that the cost basis of our available-for-sale investments is recoverable.

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

	June 30, 2016	December 31, 2015
Cash and cash equivalents	$76,891	$ 323,218
Marketable securities	570,423	366,087
	$647,314	$ 689,305

The fair values of available-for-sale debt securities at June 30, 2016, by contractual maturity, are summarized as follows:

	June 30, 2016
Due in one year or less	$394,939
Due after one year through three years	249,487
	$644,426

As of June 30, 2016 and December 31, 2015, the fair value of our trading securities was $12,078 and $8,817, respectively.

We utilize the specific identification method in computing realized gains and losses. Realized gains and losses on our available-for-sale and trading securities were not material for the three and six months ended June 30, 2016 and 2015.

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 our outstanding term loan debt. 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, that are denominated in currencies other than the U.S.

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dollar. The purpose of these hedges is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. These hedges are designated as cash flow hedges upon contract inception. At June 30, 2016, we had open foreign exchange forward contracts with notional amounts totaling $1,987,340 that qualified for hedge accounting.

To achieve a desired mix of floating and fixed interest rates on our term loan, we entered into two interest rate swap agreements in June 2016 that qualified for and are designated as cash flow hedges. The first agreement has a notional amount of $3,281,250 and is effective from June 30, 2016 through December 30, 2016. This agreement hedges the contractual floating interest rate of our term loan. As a result of this agreement, the interest rate for our term loan has been fixed at 0.535%, plus the borrowing spread, until December 30, 2016. The second agreement has a notional amount of $656,250 and is effective December 31, 2016 through December 31, 2019. The second agreement converts the floating rate on a portion of our term loan to a fixed rate of 0.98%, plus a borrowing spread, from December 31, 2016 through December 2019.

The impact on accumulated other comprehensive income (AOCI) and earnings from derivative instruments that qualified as cash flow hedges, for the three and six months ended June 30, 2016 and 2015 were as follows:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Foreign Exchange Contracts:				
Gain (loss) recognized in AOCI, net of tax	$9,653	$(22,221)	$(39,789)	$71,588
Gain reclassified from AOCI to net product sales (effective portion), net of tax	$10,258	$27,670	$24,917	$53,117
Gain reclassified from AOCI to other income and expense (ineffective portion), net of tax	$—	$256	$—	$1,331
Interest Rate Contracts:				
Loss recognized in AOCI, net of tax	$(3,695)	$—	$(3,695)	$—
Loss reclassified from AOCI to interest expense, net of tax	$—	$—	$—	$—

Assuming no change in foreign exchange rates or LIBOR-based interest rates from market rates at June 30, 2016, $36,074 and $(1,010) of gains (losses) recognized in AOCI will be reclassified to revenue and interest expense, respectively, over the next 12 months.

We enter into foreign exchange forward contracts, with durations of approximately 90 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. 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 June 30, 2016, the notional amount of foreign exchange contracts where hedge accounting is not applied was $433,634.

We recognized a loss of $5,146 and $6,660, in other income and expense, for the three months ended June 30, 2016 and 2015, respectively, and $18,115 and $237, for the six months ended June 30, 2016 and 2015, respectively, associated with the foreign exchange contracts not designated as hedging instruments. These amounts were largely offset by gains or losses in monetary assets and liabilities.

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The following tables summarize the fair value of outstanding derivatives at June 30, 2016 and December 31, 2015:

	June 30, 2016			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	$57,505	Other current liabilities	$21,432
Foreign exchange forward contracts	Other assets	44,196	Other liabilities	36,450
Interest rate contracts	Prepaid expenses and other current assets	—	Other current liabilities	1,010
Interest rate contracts	Other assets	—	Other liabilities	4,813
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	5,833	Other current liabilities	8,740
Total fair value of derivative instruments		$107,534		$72,445

	December 31, 2015			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	$85,058	Other current liabilities	$1,491
Foreign exchange forward contracts	Other assets	66,309	Other liabilities	4,773
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Prepaid expenses and other current assets	6,687	Other current liabilities	4,157
Total fair value of derivative instruments		$158,054		$10,421

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Although we do not offset derivative assets and liabilities within our condensed consolidated balance sheets, our International Swap and Derivatives Association (ISDA) 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:

	June 30, 2016					
				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	$107,534	$ —	$ 107,534	$(42,874)	$ —	$64,660
Derivative liabilities	(72,445)	—	(72,445)	42,874	—	(29,571)

	December 31, 2015					
				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	$158,054	$ —	$ 158,054	$(10,421)	$ —	$147,633
Derivative liabilities	(10,421)	—	(10,421)	10,421	—	—

10. Other Investments

Other investments include our investment of $37,500 in the preferred stock of Moderna LLC. Our investment is recorded at cost within other assets in our condensed consolidated balance sheets. The carrying value of this investment was not impaired as of June 30, 2016.

11. Stockholders' Equity

In November 2012, our Board of Directors authorized a share repurchase program. The repurchase program does not have an expiration date, and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at the Company's discretion. In May 2015, our Board of Directors increased the authorization to acquire shares with an aggregate value of up to $1,000,000 for future purchases under the repurchase program, which superseded all prior repurchase programs. Under the program, for the three months ended June 30, 2016 and 2015 we repurchased 245 and 132 shares of our common stock at a cost of $34,136 and $23,537, respectively, and during the six months ended June 30, 2016 and 2015, we repurchased 2,328 and 466 shares of our common stock at a cost of $330,651 and $83,563, respectively. As of June 30, 2016, there was a total of $425,213 remaining for repurchases under the repurchase program.

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12. Other Comprehensive Income and Accumulated Other Comprehensive Income

The following tables summarize the changes in AOCI, by component, for the six months ended June 30, 2016 and 2015:

	Defined Benefit Pension Plans	Unrealized Gains (Losses) from Marketable Securities	Unrealized Gains (Losses) from Hedging Activities	Foreign Currency Translation Adjustment	Total Accumulated Other Comprehensive Income (Loss)
Balances, December 31, 2015	$(9,589)	$ (785)	$92,670	$ (19,995)	$ 62,301
Other comprehensive income before reclassifications	1,063	3,393	(43,484)	2,121	(36,907)
Amounts reclassified from other comprehensive income	147	70	(24,917)	—	(24,700)
Net other comprehensive income (loss)	1,210	3,463	(68,401)	2,121	(61,607)
Balances, June 30, 2016	$(8,379)	$ 2,678	$24,269	$ (17,874)	$ 694

	Defined Benefit Pension Plans	Unrealized Gains (Losses) from Marketable Securities	Unrealized Gains (Losses) from Hedging Activities	Foreign Currency Translation Adjustment	Total Accumulated Other Comprehensive Income (Loss)
Balances, December 31, 2014	$(16,570)	$ (234)	$87,308	$ (13,719)	$ 56,785
Other comprehensive income before reclassifications	(8,153)	276	71,588	(4,218)	59,493
Amounts reclassified from other comprehensive income	708	(22)	(54,448)	—	(53,762)
Net other comprehensive income (loss)	(7,445)	254	17,140	(4,218)	5,731
Balances, June 30, 2015	$(24,015)	$ 20	$104,448	$ (17,937)	$ 62,516

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The table below provides details regarding significant reclassifications from AOCI during the three and six months ended June 30, 2016 and 2015:

Details about Accumulated Other Comprehensive Income Components	Amount Reclassified From Accumulated Other Comprehensive Income during the three months ended June 30,		Amount Reclassified From Accumulated Other Comprehensive Income during the six months ended June 30,		Affected Line Item in the Condensed Consolidated Statements of Operations
	2016	2015	2016	2015	
Unrealized Gains (Losses) from Hedging Activity					
Foreign exchange contracts (effective portion)	$15,673	$31,622	$38,485	$60,705	Net product sales
Foreign exchange contracts (ineffective portion)	—	293	—	1,521	Foreign currency loss
	15,673	31,915	38,485	62,226	
	(5,415)	(3,989)	(13,568)	(7,778)	Income tax provision
	$10,258	$27,926	$24,917	$54,448	
Unrealized Gains (Losses) from Marketable Securities					
Realized gains (losses) on sale of securities	$151	$22	$(111)	$35	Investment income
	151	22	(111)	35	
	(56)	(8)	41	(13)	Income tax provision
	$95	$14	$(70)	$22	
Defined Benefit Pension Plans					
Amortization of prior service costs and actuarial losses	$(115)	$(626)	$(229)	$(937)	(a)
	(115)	(626)	(229)	(937)	
	54	153	82	229	Income tax provision
	$(61)	$(473)	$(147)	$(708)	

(a) This AOCI component is included in the computation of net periodic pension benefit cost (see Note 15 for additional details).

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.

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The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of June 30, 2016 and December 31, 2015, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

		Fair Value Measurement at June 30, 2016			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$27,319	$—	$27,319	$—
Cash equivalents	Commercial paper	$30,995	$—	$30,995	$—
Cash equivalents	Corporate bonds	$2,003	$—	$2,003	$—
Cash equivalents	Municipal bonds	$41,892	$—	$41,892	$—
Cash equivalents	Bank certificates of deposit	$2,001	$—	$2,001	$—
Marketable securities	Mutual funds	$12,078	$12,078	$—	$—
Marketable securities	Commercial paper	$116,528	$—	$116,528	$—
Marketable securities	Corporate bonds	$208,378	$—	$208,378	$—
Marketable securities	Municipal bonds	$50,080	$—	$50,080	$—
Marketable securities	Other government-related obligations	$181,549	$—	$181,549	$—
Marketable securities	Bank certificates of deposit	$11,000	$—	$11,000	$—
Marketable securities	Equity securities	$2,888	$2,888	$—	$—
Prepaid expenses and other current assets	Foreign exchange forward contracts	$63,338	$—	$63,338	$—
Other assets	Foreign exchange forward contracts	$44,196	$—	$44,196	$—
Other current liabilities	Foreign exchange forward contracts	$30,172	$—	$30,172	$—
Other liabilities	Foreign exchange forward contracts	$36,450	$—	$36,450	$—
Other current liabilities	Interest rate contracts	$1,010	$—	$1,010	$—
Other liabilities	Interest rate contracts	$4,813	$—	$4,813	$—
Other current liabilities	Acquisition-related contingent consideration	$58,049	$—	$—	$58,049
Contingent consideration	Acquisition-related contingent consideration	$109,565	$—	$—	$109,565

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		Fair Value Measurement at December 31, 2015			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$179,898	$—	$179,898	$—
Cash equivalents	Commercial paper	$192,418	$—	$192,418	$—
Cash equivalents	Corporate bonds	$12,250	$—	$12,250	$—
Cash equivalents	Municipal bonds	$60,001	$—	$60,001	$—
Cash equivalents	Other government-related obligations	$31,549	$—	$31,549	$—
Cash equivalents	Bank certificates of deposit	$27,000	$—	$27,000	$—
Marketable securities	Mutual funds	$8,817	$8,817	$—	$—
Marketable securities	Commercial paper	$61,978	$—	$61,978	$—
Marketable securities	Corporate bonds	$120,499	$—	$120,499	$—
Marketable securities	Municipal bonds	$27,110	$—	$27,110	$—
Marketable securities	Other government-related obligations	$156,500	$—	$156,500	$—
Prepaid expenses and other current assets	Foreign exchange forward contracts	$91,745	$—	$91,745	$—
Other assets	Foreign exchange forward contracts	$66,309	$—	$66,309	$—
Other current liabilities	Foreign exchange forward contracts	$5,648	$—	$5,648	$—
Other liabilities	Foreign exchange forward contracts	$4,773	$—	$4,773	$—
Other current liabilities	Acquisition-related contingent consideration	$55,804	$—	$—	$55,804
Contingent consideration	Acquisition-related contingent consideration	$121,424	$—	$—	$121,424

There were no securities transferred between Level 1, 2 and 3 during the six months ended June 30, 2016.

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 institutional money market funds, commercial paper, municipal bonds, 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 the same or 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.

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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.

As of June 30, 2016, 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 acquisitions, 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 on the acquisition date using various estimates that are not observable in the market and represent a Level 3 measurement within the fair value hierarchy. The resulting probability-weighted cash flows were discounted using a cost of debt of 5.5% for developmental milestones and a weighted average cost of capital ranging from 10% to 21% 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.

Estimated future contingent milestone payments related to prior business combinations range from zero if no milestone events are achieved, to a maximum of $826,000 if all development, regulatory and sales-based milestones are reached. As of June 30, 2016, the fair value of acquisition-related contingent consideration was $167,614. The following table represents a roll-forward of our acquisition-related contingent consideration:

	Six months ended June 30, 2016
Balance at December 31, 2015	$(177,228)
Changes in fair value	9,614
Balance at June 30, 2016	$(167,614)

14. Income Taxes

The following table provides a comparative summary of our income tax provision and effective tax rate for the three and six months ended June 30, 2016 and 2015:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Provision for income taxes	$55,022	$7,077	$106,454	$22,699

Effective tax rate	32.4 %	4.0 %	33.9 %	8.0 %

The tax provision for the three and six months ended June 30, 2016 and 2015 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 and six months ended June 30, 2016 as compared to the same period in the prior year is primarily attributable to the deferred tax costs associated with the distribution of earnings from our captive foreign partnership. This non-cash deferred tax cost increased the effective tax rate by approximately 18%. Additionally, the tax provision for the three and six months ended June 30, 2015 included increased tax benefits associated with Orphan Drug Credits as compared to the same periods in 2016.

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Tax years 2013 and 2014 are currently under review by the Examination Division of the Internal Revenue Service (IRS). As of June 30, 2016, we have not been notified of any significant proposed adjustments by the IRS.
We continue to maintain a valuation allowance against certain deferred tax assets where realization is not certain.

15. Defined Benefit Plans

We maintain defined benefit plans for employees in certain countries outside the United States, 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 components of net periodic benefit cost are as follows:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Service cost	$2,075	$4,861	$4,098	$7,282
Interest cost	56	372	116	552
Expected return on plan assets	(166)	(508)	(329)	(751)
Employee contributions	(403)	(900)	(755)	(1,327)
Amortization	115	626	229	937
Total net periodic benefit cost	$1,677	$4,451	$3,359	$6,693

16. 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 sheet.
Construction of the new facility was completed and the building was placed into service in the first quarter 2016. As of June 30, 2016 and December 31, 2015, our facility lease obligation related to this facility was $135,598 and $132,866, respectively.

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 its existing Portsmouth, New Hampshire facility. 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. As of June 30, 2016 and December 31,

2015, we recorded a construction-in-process asset of $65,125 and $19,259 and an offsetting facility lease obligation of $57,715 and $15,229 associated with the manufacturing facility, respectively.

Payments made 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. In 2016, we made $26,000 of payments to Lonza under this agreement, of which $3,380 was applied against the outstanding facility lease obligation and $22,620 was recognized as a prepayment of inventory.

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17. Commitments and Contingencies

Commitments

Manufacturing Agreements

We have various manufacturing development 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 Soliris and Strensiq. We have various agreements with Lonza, with remaining total non-cancellable future commitments of approximately $1,143,638. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at Alexion Rhode Island Manufacturing Facility (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 $33,670 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 available information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, we may reassess the potential liability related to these matters and may revise these estimates, which could result in a material adverse adjustment to our operating results.

We have in the past received, and may in the future receive, notices from third parties claiming that their patents may be infringed by the development, manufacture or sale of Soliris. 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 Soliris that we could be required to pay the owners of patents for technology used in the manufacture and sale of Soliris. 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 U.S. 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, Alexion received a request from the U.S. Department of Justice (DOJ) for the voluntary production of documents and other information pertaining to Alexion's compliance with FCPA. The SEC and DOJ also seek information related to Alexion’s recalls of specific lots of Soliris and related securities disclosures. Alexion is cooperating with these investigations, which are in the early stages. At this time, Alexion is unable to predict the duration, scope or outcome of these investigations. Given the ongoing nature of these investigations, management does not currently believe a loss related to these matters is probable or that the potential magnitude of such loss or range of loss, if any, can be reasonably estimated.

In March 2013, we received a Warning Letter (Warning Letter) from the U.S. Food and Drug Administration (FDA) regarding compliance with current Good Manufacturing Practices (cGMP) at ARIMF. The Warning Letter followed receipt of a Form 483 Inspectional Observations by the FDA in connection with an FDA inspection that concluded in August 2012. The observations relate to commercial and clinical manufacture of Soliris at ARIMF. We responded to the Warning Letter in a letter to the FDA dated in April 2013. As previously announced, the FDA issued Form 483s in

August 2014 and August 2015 related to observations at ARIMF. The inspectional observations from the August 2015 letter have since been closed out by the FDA.

The observations are inspectional and do not represent a final FDA determination of compliance. We continue to manufacture products, including Soliris, in this facility. While the resolution of the issues raised in the Warning Letter is difficult to predict, we do not currently believe a loss related to this matter is probable or that the potential magnitude of such loss or range of loss, if any, can be reasonably estimated.

18. Restructuring

In connection with the acquisition and integration of Synageva in 2015, we recorded a restructuring charge of $10,322 for the three and six months ended June 30, 2015 primarily related to employee costs. Synageva restructuring charges were not material for the three and six months ended June 30, 2016.

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In the fourth quarter 2014, we announced plans to relocate our European headquarters from Lausanne to Zurich, Switzerland. The relocation of our European headquarters supports our operational needs based on growth in the European region. During the three and six months ended June 30, 2016, we incurred additional restructuring costs of $369 and $2,015, respectively, as compared to $5,902 and $12,954, for the three and six months ended June 30, 2015, respectively. We expect to pay all remaining accrued amounts related to this restructuring activity by the first quarter of 2017.

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 six months ended June 30, 2016:

	Three months ended June 30, 2016				Six months ended June 30, 2016			
	Employee Separation Costs	Contract Termination Costs	Other Costs	Total	Employee Separation Costs	Contract Termination Costs	Other Costs	Total
Liability, beginning of period	$1,436	$ 1,627	$ 16	$3,079	$6,390	$ 682	$169	$7,241
Restructuring expenses	—	—	475	475	—	35	892	927
Cash settlements	(537)	(174)	(395)	(1,106)	(4,343)	(682)	(965)	(5,990)
Adjustments to previous estimates	100	(120)	—	(20)	(1,048)	1,298	—	250
Liability, end of period	$999	$ 1,333	$ 96	$2,428	$999	$ 1,333	$96	$2,428

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 have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management's beliefs, and certain assumptions made by our management, and may include, but are not limited to, statements regarding the potential benefits and commercial potential of Soliris®, Strensiq® and Kanuma® for approved indications and any expanded uses, timing and effect of sales of our products in various markets worldwide, pricing for our products, level of insurance coverage and reimbursement for our products, level of future product sales and collections, timing regarding development and regulatory approvals for additional indications or in additional territories, the medical and commercial potential of additional indications for Soliris, failure to satisfactorily address the issues raised by the U.S. Food and Drug Administration (FDA) in the March 2013 Warning Letter and Form 483s issued by the FDA, costs, expenses and capital requirements, cash outflows, cash from operations, status of reimbursement, price approval and funding processes in various countries worldwide, progress in developing commercial infrastructure and interest about our products and our product candidates in the patient, physician and payer communities, the safety and efficacy of our products and our product candidates, estimates of the potential markets and estimated commercialization dates for our product and our product candidates around the world, sales and marketing plans, any changes in the current or anticipated market demand or medical need for our products or our product candidates, status of our ongoing clinical trials for eculizumab, asfotase alfa, sebelipase alfa and our other product candidates, commencement dates for new clinical trials, clinical trial results, evaluation of our clinical trial results by regulatory agencies, the adequacy of our pharmacovigilance and drug safety reporting processes, prospects for regulatory approval of our products and our

product candidates, need for additional research and testing, the uncertainties involved in the drug development process and manufacturing, performance and reliance on third party service providers, our future research and development activities, plans for acquired programs, our ability to develop and commercialize products with our collaborators, assessment of competitors and potential competitors, the outcome of challenges and opposition proceedings to our intellectual property, assertion or potential assertion by third parties that the manufacture, use or sale of our products infringes their intellectual property, estimates of the capacity of manufacturing and other service facilities to support our products and our product candidates, potential costs resulting from product liability or other third party claims, the sufficiency of our existing capital resources and projected cash needs, the possibility that expected tax benefits will not be realized, assessment of impact of recent accounting pronouncements, 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 the government investigations, including our Securities and Exchange Commission (SEC) and U.S. Department of Justice (DOJ) investigations, the short and long term effects of other government healthcare measures, and the effect of shifting

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foreign exchange rates. Words such as “anticipates,” “expects,” “intends,” “plans,” “believes,” “seeks,” “estimates,” variations such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These 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 forward-looking statements. Such risks and uncertainties include, but are not limited to, those 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 Securities and Exchange Commission (SEC).

Business

We are a biopharmaceutical company focused on serving patients with devastating and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products.

In our complement franchise, Soliris (eculizumab) is the first and only therapeutic approved for patients with either PNH or aHUS. In our metabolic franchise, we commercialize Strensiq (asfotase alfa) for the treatment of patients with HPP and Kanuma (sebelipase alfa) for the treatment of patients with LAL-D.

We are also evaluating additional potential indications for eculizumab in other severe and devastating diseases in which uncontrolled complement activation is the underlying mechanism, and we are progressing in various stages of development with additional product candidates as potential treatments for patients with severe and life-threatening rare disorders.

Products and Development Programs

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

Marketed Products

Our marketed products include the following:

Product	Development Area	Indication	Development Stage
Soliris (eculizumab)	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Commercial
		PNH Registry	Phase IV
	Hematology/Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)	Commercial
		aHUS Registry	Phase IV
Strensiq (asfotase alfa)	Metabolic Disorders	Hypophosphatasia (HPP)	Commercial
		HPP Registry	Phase IV
Kanuma (sebelipase alfa)	Metabolic Disorders	Lysosomal Acid Lipase Deficiency (LAL-D)	Commercial
		LAL-D Registry	Phase IV

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, transplant rejection and neurology. Soliris is a humanized monoclonal antibody that effectively blocks terminal complement activity at the doses currently prescribed. The initial indication for which we received approval for Soliris is PNH.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

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

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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 United States, Europe, Japan and several other territories.

Atypical Hemolytic Uremic Syndrome (aHUS)

aHUS is a severe and life-threatening genetic ultra-rare 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 United States, Europe and Japan. In addition, the FDA and EC have granted Soliris orphan drug designation for the treatment of patients with aHUS.

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 European Commission (EC) granted marketing authorization for Strensiq for the treatment of patients with pediatric-onset HPP, and Japan’s Ministry of Health. Labour and Welfare (MHLW) approved Strensiq for the treatment of patients with HPP.

In April 2016, new long-term data was presented showing clinically significant and sustained improvements in bone healing, respiratory support, and physical function in children with perinatal and infantile-onset HPP treated with Strensiq. In addition, adolescents and adult patients reduced or eliminated their need of ambulatory assistive devices and had improvements in physical function.

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. On March 28, 2016, we announced that Japan's MHLW approved Kanuma for the treatment of patients of all ages in Japan with LAL-D.

In March 2016, researchers presented new two-year data from an ongoing, open-label Phase 2/3 trial of Kanuma in infants with LAL-D. Data from this study demonstrated a substantial survival benefit to beyond 2 years of age for patients with rapidly progressive LAL-D during infancy who were treated with Kanuma. Patients also had improvements in a number of key parameters, including weight gain, important markers of liver disease, gastrointestinal symptoms, anemia, and hepatosplenomegaly (enlargement of both the liver and spleen), and 4 out of 5 patients demonstrated normal development.

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Clinical Development Programs
Our programs, including investigator sponsored clinical programs, include the following:

Product	Development Area	Indication	Development Stage
Soliris (eculizumab)	Neurology	Refractory Generalized Myasthenia Gravis (gMG)	Phase III
		Relapsing Neuromyelitis Optica Spectrum Disorder (NMOSD)	Phase III
	Transplant	Delayed Kidney Transplant Graft Function (DGF)	Phase III
		Antibody Mediated Rejection (AMR) Presensitized Renal Transplant - Living Donor	Phase II
		Antibody Mediated Rejection (AMR) Presensitized Renal Transplant - Deceased Donor	Phase II
		Treatment of Antibody Mediated Rejection (AMR) Following Renal Transplantation*	Phase II
cPMP (ALXN1101)	Metabolic Disorders	MoCD Type A	Phase II / III
ALXN1007	Inflammatory Disorders	GI Graft versus Host Disease	Phase II
		Anti-phospholipid Syndrome	Phase II
SBC-103	Metabolic Disorders	Mucopolysaccharidoses IIIB (MPS IIIB)	Phase I / II
ALXN1210	Next Generation Complement Inhibitor	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Phase II
ALXN5500	Next Generation Complement Inhibitor		Phase I

*Investigator sponsored clinical program

Soliris (eculizumab)
Neurology
Refractory Generalized Myasthenia Gravis (gMG)
Refractory gMG is an ultra-rare autoimmune syndrome characterized by complement activation leading to the failure of neuromuscular transmission. We have completed enrollment of patients in a Phase III multinational, placebo-controlled registration trial of eculizumab in patients with refractory gMG. The FDA, EC and MHLW have granted orphan drug designation for eculizumab as a treatment for patients with refractory gMG.
In June 2016, we announced topline results of the Phase III REGAIN trial. The primary efficacy endpoint of change from baseline in Myasthenia Gravis-Activities of Daily Living Profile (MG-ADL) total score, a patient-reported assessment, at week 26, did not reach statistical significance (p=0.0698) as measured by a worst-rank analysis. The totality of data reviewed to date, including the first three secondary endpoints and a series of prospectively defined sensitivity analyses, shows early and sustained substantial improvements over 26 weeks for patients treated with eculizumab compared to placebo. The safety of eculizumab in this study was consistent with the Soliris labels. Additional data from the Phase III study was presented in July 2016. The data showed that 18 of 22 pre-defined endpoints and pre-specified analyses in the study, based on the primary and five secondary endpoints, achieved p-values below 0.05. We are in the process of engaging with regulators to develop plans for next steps for eculizumab in refractory gMG.
Relapsing Neuromyelitis Optica Spectrum Disorder (NMOSD)

Relapsing NMOSD is a severe and ultra-rare autoimmune disease of the central nervous system (CNS) that primarily affects the optic nerves and spinal cord. Enrollment and dosing are ongoing in a global, randomized, double-blind, placebo-controlled to evaluate eculizumab as a treatment for patients with relapsing NMOSD. The FDA, EC, and MHLW have each granted orphan designation for eculizumab as a treatment for patients with relapsing NMOSD.

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Transplant

Delayed Kidney Transplant Graft Function (DGF)

DGF is the term used to describe the failure of a kidney or other organs to function immediately after transplantation due to ischemia-reperfusion and immunological injury. Enrollment is complete in a single, multinational, placebo-controlled DGF registration trial and patient follow-up is ongoing. Eculizumab has been granted orphan drug designation for DGF by the FDA and the EC granted orphan drug designation to eculizumab for prevention of DGF after solid organ transplantation.

Antibody Mediated Rejection (AMR) in Presensitized Kidney Transplant Patients

AMR is the term used to describe a type of transplant rejection that occurs when the recipient has antibodies to the donor organ. Enrollment in a multi-national, multi-center controlled clinical trial of eculizumab in presensitized kidney transplant patients at elevated risk for AMR who received kidneys from deceased organ donors was completed in March 2013 and patient follow-up in the trial is continuing. In September 2013, researchers presented positive preliminary data from the eculizumab deceased-donor AMR kidney transplant study. In May 2015, new data from the Phase II single-arm deceased-donor transplant trial of eculizumab in prevention of acute AMR was presented and was consistent with previous positive reports.

In January 2015, we reported results from a randomized, open-label, multicenter Phase II clinical trial of eculizumab presensitized kidney transplant patients at an elevated risk of AMR who received kidneys from living donors. The primary composite endpoint of the trial did not reach statistical significance. Patient follow-up and data analyses are ongoing and based on discussions with regulators, we are developing plans for next steps for eculizumab in AMR. The EC granted orphan drug designation to eculizumab for the prevention of graft rejection following solid organ transplantation.

cPMP (ALXN1101)

Molybdenum Cofactor Deficiency (MoCD) Disease Type A (MoCD Type A)

MoCD Type A is an ultra-rare metabolic disorder characterized by severe and rapidly progressive neurologic damage and death in newborns. MoCD Type A results from a genetic deficiency in cyclic Pyranopterin Monophosphate (cPMP), a molecule that enables the function of certain enzymes and the absence of which allows neurotoxic sulfite to accumulate in the brain. To date, there is no approved therapy available for MoCD Type A. There has been some early clinical experience with the recombinant cPMP replacement therapy in a small number of children with MoCD Type A, and we have completed enrollment in a natural history study in patients with MoCD Type A. In October 2013, cPMP received Breakthrough Therapy Designation from the FDA for the treatment of patients with MoCD Type A. Evaluation of our synthetic form of cPMP replacement therapy in a Phase I healthy volunteer study is complete. In addition, we completed enrollment in a multi-center, multinational open-label clinical trial of synthetic cPMP in patients with MoCD Type A switched from treatment with recombinant cPMP. Enrollment is ongoing in this Phase II/III pivotal open-label, single-arm trial of ALXN1101 for treatment-naïve neonates with MoCD Type A.

ALXN1007

ALXN1007 is a novel humanized antibody designed to target rare and severe inflammatory disorders and is a product of our proprietary antibody discovery technologies. We have completed enrollment in both a Phase I single-dose, dose escalating safety and pharmacology study in healthy volunteers, as well as in a multi-dose, dose escalating safety and pharmacology study in healthy volunteers. A proof-of-concept study in patients with an ultra-rare disorder, gastrointestinal graft versus host disease (GI-GVHD), is ongoing. Acute GI-GVHD is an immune-mediated disease and a complication of stem cell transplantation occurring in 10-12 percent of allogenic hematopoietic stem cell transplants. Patients with severe acute GI-GVHD have a 30-40 percent mortality rate within the first six months post-transplant. The study is evaluating patients with GI-GVHD following bone marrow or hematopoietic stem cell transplant experience engrafted hematopoietic cells that attack host gastrointestinal tissues in the first 100 days post-transplant causing damage to the GI tract, liver and skin. In December 2015, we announced that interim data from a Phase II study showed an overall 28 day acute GI-GVHD response rate of 80 percent and a 28 day complete

response rate of 70 percent compared to historical response rates of 56 percent and 49 percent, respectively, which supports the continued advancement of ALXN1007 in GI-GVHD. In June 2016, we announced additional interim data from this Phase II study demonstrating an overall 28-day response rate of 77 percent and a complete response rate at days 28 and 56 of 69 percent and 77 percent, respectively in ALXN1007 treated patients.

In addition, enrollment in a Phase II proof-of-concept study in patients with non-criteria manifestations of anti-phospholipid syndrome (APS) was discontinued early due to recruitment difficulties. The study is ongoing for initially enrolled patients. APS is an ultra-rare autoimmune, hypercoagulable state caused by antiphospholipid antibodies.

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SBC-103

Mucopolysaccharidosis IIIB (MPS IIIB)

MPS IIIB is a rare, devastating and life-threatening disease which typically presents in children during the first few years of life. Genetic mutations result in decreased activity of the alpha-N-acetyl-glucosaminidase (NAGLU) enzyme, which leads to a buildup of abnormal amounts of heparan sulfate (HS) in the brain and throughout the body. Over time, this unrelenting systemic accumulation of HS causes progressive and severe cognitive decline, behavioral problems, speech loss, increasing loss of mobility, and premature death. Current treatments are palliative for the behavioral problems, sleep disturbances, seizures, and other complications, and these treatments do not address the root cause of MPS IIIB or stop disease progression.

SBC-103, a recombinant form of natural human NAGLU is designed to replace the missing (or deficient) NAGLU enzyme. SBC-103 was granted orphan drug designation by the FDA in April 2013 and by the European Medicines Agency (EMA) in June 2013. It received Fast Track designation by the FDA in January 2015.The first-in-human trial of patients with MPS IIIB is ongoing. In March 2016, researchers presented 24-week results from this study that showed a 26.2 percent mean reduction in heparan sulfate in cerebrospinal fluid at the highest dose studied (3mg/kg every other week) in a Phase I/II study at six months. In July 2016, researchers presented preliminary results on brain MRI and neurocognitive assessments performed after 24 weeks of dosing suggesting preliminary evidence of potential for dose-dependent disease stabilization in patients treated with .3, 1, or 3mg/kg every other week of doses of SBC-103. Planned dose escalation of SBC-103 is now ongoing in this trial.

ALXN1210

ALXN1210 is a next-generation complement inhibitor in development for PNH and other indications. Phase I data from the first-in-human single-ascending dose study of ALXN1210 was published in the journal Blood in December 2015. Results showed that ALXN1210 was well-tolerated in healthy volunteers and the mean terminal half-life at least three times longer than that of eculizumab. Based upon longer terminal half-life and healthy volunteer studies, ALXN1210 is suitable for longer dosing intervals than Soliris. Enrollment has completed in a multiple-ascending dose study of ALXN1210 to further evaluate the safety and efficacy of ALXN1210. In June 2016, we announced interim data from this Phase I/II study showing that once-monthly dosing of ALXN1210 achieved rapid and sustained reductions in mean levels of lactate dehydrogenase (LDH) in 100 percent of treated patients. Researchers also reported that, at the time of analysis, 80 percent of patients who required at least 1 blood transfusion in the 12 months prior to treatment with ALXN1210 did not require transfusions while on treatment. Alexion also has initiated an open-label, multi-dose Phase II study of ALXN1210 in patients with PNH that is designed to measure change in LDH levels and safety in several dosing cohorts and intervals evaluating monthly and longer dosing intervals.

Additionally, in June 2016, the EC granted orphan drug designation to ALXN1210, for the treatment of patients with PNH.

Manufacturing

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

We have various agreements with Lonza through 2028, with remaining total non-cancellable commitments of approximately $1,143,638. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangements. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at ARIMF and a payment with respect to sales of Soliris manufactured at Lonza facilities. During 2015, we entered into a new supply agreement with Lonza whereby Lonza will construct a new manufacturing line dedicated to Alexion manufacturing at its existing Portsmouth, New Hampshire facility.

In addition, we have non-cancellable commitments of approximately $33,670 through 2019 with other third party manufacturers.

In March 2013, we received a Warning Letter (Warning Letter) from the FDA regarding compliance with current Good Manufacturing Practices (cGMP) at ARIMF. The Warning Letter followed receipt of a Form 483 Inspectional Observations by the FDA in connection with an FDA inspection that concluded in August 2012. The observations relate to commercial and clinical manufacture of Soliris at ARIMF. We responded to the Warning Letter in a letter to the FDA dated in April 2013. As previously announced, the FDA issued Form 483s in August 2014 and 2015 relating to observations at ARIMF. The inspectional observations from the August 2015 letter have since been closed out by the FDA. We continue to manufacture products, including Soliris, at ARIMF. While the resolution of the issues raised in the Warning Letter is difficult to predict, we

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do not currently believe a loss related to this matter is probable or that the potential magnitude of such loss or range of loss, if any, can be reasonably estimated.

In April 2014, we purchased a fill/finish facility in Athlone, Ireland. Following refurbishment of the facility, and after successful completion of the appropriate validation processes and regulatory approvals, the facility will become our first company-owned fill/finish facility for our commercial and clinical products. In November 2015, the construction of office, laboratory and packaging facilities in Dublin, Ireland, acquired in April 2014. 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 by 2020. In July 2016, we announced plans to construct a new biologics manufacturing facility at our Athlone, Ireland site, which is expected to be completed by 2018.

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, 2015. Under accounting principles generally accepted in the United States, we are required to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingent assets and liabilities in our financial statements. Actual results could differ from those estimates.

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

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

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, 2015. We have reviewed our critical accounting policies as disclosed in our Form 10-K, and we have not noted any material changes.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2017 and allows for adoption using a full retrospective method, or a modified retrospective method. Entities may elect to early adopt the standard for annual periods beginning after December 15, 2016. We are currently assessing the method of adoption and the expected impact the new standard has on our financial position and results of operations.

In April 2015, the FASB issued a new standard simplifying the presentation of debt issuance costs. The new standard aligns the treatment of debt issuance costs with debt discounts and premiums and requires debt issuance costs be presented as a direct deduction from the carrying amount of the related debt. We adopted the provisions of this standard in the first quarter 2016 and reclassified $8,635 of deferred financing costs from other current assets to the current portion of long term debt and $26,714 from other non current assets to long-term debt, less current portion in our consolidated balance sheets as of December 31, 2015.

In April 2015, the FASB issued a new standard clarifying the accounting for a customer's fees paid in a cloud computing arrangement. Under this standard, if a cloud computing arrangement includes a software license, the customer would account for the software license consistent with other software licenses. If a cloud computing arrangement does not include a software license, the customer would account for the arrangement as a service contract. We adopted the provisions of this standard in the first quarter 2016. The adoption did not have a material effect on our financial condition or results of operations.

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In February 2016, the FASB issued a new standard requiring that the rights and obligations arising from leases be recognized on the balance sheet by recording a right-of-use asset and corresponding lease liability. The new standard also requires qualitative and quantitative disclosures to understand the amount, timing, and uncertainty of cash flows arising from leases, as well as significant management estimates utilized. The standard is effective for interim and annual periods beginning after December 15, 2018 and requires a modified retrospective adoption. We are currently assessing the impact of this standard on our financial condition and results of operations.

In March 2016, the FASB issued a new standard simplifying aspects of the accounting for employee share-based payments, including the accounting for income taxes, forfeitures, statutory withholding requirements, and classification on the statement of cash flows. The standard is effective for interim and annual periods beginning after December 15, 2016, with early adoption permitted. We are currently assessing the impact of this standard on our financial condition and results of operations.

Results of Operations

Net Product Sales

Net product sales by product are as follows for the three and six months ended June 30, 2016 and 2015:

	Three months ended June 30,		% Variance	Six months ended June 30,		% Variance
	2016	2015		2016	2015	
Net product sales:						
Soliris	$701,009	$635,983	10 %	$1,365,665	$1,236,316	10 %
Strensiq	45,141	—	N/A	78,383	—	N/A
Kanuma	6,396	—	N/A	8,923	—	N/A
	$752,546	$635,983	18 %	$1,452,971	$1,236,316	18 %

The components of this increase in revenues are as follows:

	Three months ended June 30, 2016	Six months ended June 30, 2016
Components of change:		
Price	(2)%	(2)%
Volume	23	24
Foreign exchange	(3)%	(4)%
Total change in net product sales	18 %	18 %

The increase in net product sales for the three and six months ended June 30, 2016, as compared to the same periods in 2015, was primarily due to an increase in unit volumes of 23% and 24%, respectively, due to increased demand globally for Soliris therapy for patients with PNH or aHUS and sales of Strensiq and Kanuma during 2016.

Price had a negative impact on net product sales of 2% for the three and six months ended June 30, 2016 due to increases in estimated rebates.

Foreign exchange had a negative impact of 3% and 4% for the three and six months ended June 30, 2016, respectively, as compared to the same period in 2015. The negative impact of $18,346 and $48,488 (inclusive of hedging activity) for the three and six months ended June 30, 2016, respectively, was primarily due to the weakening of the Euro, Japanese Yen and Russian Ruble against the U.S. dollar. We recorded a gain in revenue from our hedging activity of $15,673 and $38,485 related to our foreign currency cash flow hedging program for the three and six months ended June 30, 2016, respectively. We expect the strong dollar compared to other currencies to continue to have a negative impact on revenue in 2016 compared to 2015.

Cost of Sales

Cost of sales includes manufacturing costs as well as actual and estimated royalty expenses associated with sales of our products.

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The following table summarizes cost of sales the three and six months ended June 30, 2016 and 2015:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Cost of sales	$60,627	$52,007	$119,613	$121,406
Cost of sales as a percentage of net product sales	8 %	8 %	8 %	10 %

We recorded an expense of $24,352 in the first quarter of 2015 associated with a portion of a single manufacturing campaign at a third party manufacturer for Strensiq. The costs were comprised of raw materials, internal overhead and external production costs. This expense did not impact the clinical supply of inventory or the commercial launch of Strensiq.

Exclusive of the items mentioned above, cost of sales as a percentage of net product sales were 8% for the three and six months ended June 30, 2016 and 8% for the three and six months ended June 30, 2015.

Research and Development Expense

Our research and development expense includes personnel, facility and external costs associated with the research and development of our product candidates, as well as product development costs. We group our research and development expenses into two major categories: external direct expenses and all other research and development (R&D) expenses.

External direct expenses are comprised of costs paid to outside parties for clinical development, product development and discovery research, as well as costs associated with strategic licensing agreements we have entered into with third parties. Clinical development costs are comprised of costs to conduct and manage clinical trials related to eculizumab 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. Discovery research costs are incurred in conducting laboratory studies and performing preclinical research for other uses of our products and other product candidates. Licensing agreement costs include upfront and milestone payments made in connection with strategic licensing arrangements we have entered into with third parties. Clinical development costs have been accumulated and allocated to each of our programs, while product development and discovery research costs have not been allocated.

All other R&D expenses consist of costs to compensate personnel, to maintain our facilities, equipment and overhead and similar costs of 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 table provides information regarding research and development expenses:

	Three months ended June 30,			Six months ended June 30,		
	2016	2015	$ Variance	2016	2015	$ Variance
Clinical development	$54,632	$36,286	$18,346	$104,490	$67,233	$37,257
Product development	31,464	25,529	5,935	61,445	45,069	16,376
Licensing agreements	—	1,750	(1,750)	3,050	114,250	(111,200)
Discovery research	13,547	9,022	4,525	26,414	15,066	11,348
Total external direct expenses	99,643	72,587	27,056	195,399	241,618	(46,219)
Payroll and benefits	69,363	47,714	21,649	140,719	92,052	48,667
Facilities and other costs	10,305	11,392	(1,087)	19,483	19,103	380
Total other R&D expenses	79,668	59,106	20,562	160,202	111,155	49,047
Research and development expense	179,311	131,693	47,618	355,601	352,773	2,828

For the three months ended June 30, 2016, the increase of $47,618 in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase of $21,649 in payroll and benefits expense primarily related to the additional headcount acquired as part of the Synageva acquisition on June 22, 2015 and the continued global expansion of staff supporting our increasing number of clinical and development programs.
- Increase of $18,346 in external clinical development expenses related primarily to sebelipase alfa and ALXN1210 (see table below).

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For the six months ended June 30, 2016, the increase of $2,828 in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase of $48,667 in payroll and benefits expense primarily related to the additional headcount acquired as part of the Synageva acquisition on June 22, 2015 and the continued global expansion of staff supporting our increasing number of clinical and development programs.
- Increase of $37,257 in external clinical development expenses related primarily to sebelipase alfa and ALXN1210, as well as an expansion of studies within our eculizumab program (see table below).
- Increase of $16,376 in external product development expenses related primarily to an increase in costs associated with the manufacturing of material for increased clinical research activities and clinical studies.
- Increase of $11,348 in discovery research expenses primarily related to increases in external research expenses associated with our collaboration agreements.

Partially offset by the following:

- Decrease of $111,200 in licensing agreement expenses primarily related to upfront payments made in the first quarter 2015.

The following table summarizes external direct expenses related to our clinical development programs. Please refer to "Clinical Development Programs" above for a description of each of these programs:

	Three months ended			Six months ended		
	June 30,		$	June 30,		$
	2016	2015	Variance	2016	2015	Variance
External direct expenses						
Eculizumab	$21,574	$18,428	$3,146	$43,813	$36,452	$7,361
Asfotase alfa	4,595	6,190	(1,595)	9,522	11,041	(1,519)
cPMP	2,780	2,375	405	4,897	4,072	825
ALXN1007	2,182	5,220	(3,038)	4,780	7,253	(2,473)
Sebelipase alfa	6,424	1,000	5,424	11,330	1,000	10,330
ALXN1210	10,042	814	9,228	14,371	1,411	12,960
SBC-103	3,303	—	3,303	4,526	—	4,526
Other programs	1,151	860	291	4,117	1,466	2,651
Unallocated	2,581	1,399	1,182	7,134	4,538	2,596
	$54,632	$36,286	$18,346	$104,490	$67,233	$37,257

The successful development of our drug candidates is uncertain and subject to a number of risks. We cannot guarantee that results of clinical trials will be favorable or sufficient to support regulatory approvals for our other programs. We could decide to abandon development or be required to spend considerable resources not otherwise contemplated. For additional discussion regarding the risks and uncertainties regarding our development programs, please refer to Item 1A "Risk Factors" in this 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 table below provides information regarding selling, general and administrative expense:

	Three months ended June 30,			Six months ended June 30,		
	2016	2015	$ Variance	2016	2015	$ Variance
Salary, benefits and other labor expense	$141,566	$148,634	$(7,068)	$289,736	$272,737	$16,999
External selling, general and administrative expense	90,236	72,749	17,487	174,627	135,762	38,865
Total selling, general and administrative expense	$231,802	$221,383	$10,419	$464,363	$408,499	$55,864

For the three months ended June 30, 2016, the increase of $10,419 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase in external selling, general and administrative expenses of $17,487. The increase was primarily due to an increase in external marketing costs to support the global launches of Strensiq and Kanuma and increased professional fees. The increase was also attributable to additional facilities costs as a result of continuing growth of operations worldwide.

Partially offset by the following:

- Decrease in salary, benefits and other labor expenses of $7,068. The decrease was primarily a result of a decrease of $29,634 in stock-based compensation expense recorded in June 2015 related to the acceleration of Alexion stock awards for former Synageva employees. This decrease was partially offset by increased staff costs related to commercial development activities to support our infrastructure growth as a global commercial entity and additional global commercial staff costs due to our acquisition of Synageva in the second quarter 2015.

For the six months ended June 30, 2016, the increase of $55,864 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase in salary, benefits and other labor expenses of $16,999. The increase was a result of increased staff costs related to commercial development activities to support our infrastructure growth as a global commercial entity and additional global commercial staff costs due to our acquisition of Synageva in the second quarter 2015. This increase was offset by a decrease of $29,634 in stock-based compensation expense recorded in June 2015 related to the acceleration of Alexion stock awards for former Synageva employees.
- Increase in external selling, general and administrative expenses of $38,865. The increase was primarily due to an increase in external marketing costs to support the global launches of Strensiq and Kanuma and increased professional fees. The increase was also attributable to additional facilities costs as a result of continuing growth of operations worldwide.

Amortization of Purchase Intangible Assets

For the three and six months ended June 30, 2016, we recorded amortization expense of $80,055 and $160,149 respectively, 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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Acquisition-related Costs

Acquisition-related costs for the three and six months ended June 30, 2016 and 2015 associated with our business combinations included the following:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Transaction costs [1]	$—	$26,799	$375	$26,799
Integration costs	974	2,978	1,938	2,978
	$974	$29,777	$2,313	$29,777

(1) Transaction costs include investment advisory, legal, and accounting fees

Change in Fair Value of Contingent Consideration

For the three and six months ended June 30, 2016 , the change in fair value of contingent consideration expense associated with our prior business combinations was $5,186 and $(9,614), respectively, as compared to $4,044 and $16,023 for the three and six months ended June 30, 2015, respectively. The change in the fair value of contingent consideration for the six months ended June 30, 2016 as compared the same period in 2015 was primarily due to changes in the likelihood of payments for contingent consideration.

Restructuring Expenses

For the three and six months ended June 30, 2015, we recorded restructuring expenses of $16,224 and $23,276, respectively, primarily related to employee costs in conjunction with the acquisition and integration of Synageva and the relocation of our European headquarters. Restructuring expenses were not material for the three and six months ended June 30, 2016.

Other Income and Expense

The following table provides information regarding other income and expense:

	Three months ended June 30,			Six months ended June 30,		
	2016	2015	$ Variance	2016	2015	$ Variance
Investment income	$1,872	$2,226	$(354)	$3,423	$5,110	$(1,687)
Interest expense	(23,793)	(3,971)	(19,822)	(47,683)	(4,622)	(43,061)
Foreign currency gain (loss)	(2,820)	(2,045)	(775)	(2,729)	(1,040)	(1,689)
Total other income and expense	$(24,741)	$(3,790)	$(20,951)	$(46,989)	$(552)	$(46,437)

The increase in interest expense for the three and six months ended June 30, 2016 as compared to the prior year was due to us borrowing $3,500,000 under a term loan facility in connection with the acquisition of Synageva on June 22, 2015.

Income Taxes

During the three and six months ended June 30, 2016, we recorded an income tax provision of $55,022 and $106,454 and an effective tax rate of 32.4% and 33.9%, respectively, compared to an income tax provision of $7,077 and $22,699 and an effective tax rate of 4.0% and 8.0% for the three and six months ended June 30, 2015, respectively. The tax provision for the three and six months ended June 30, 2016 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 and six months ended June 30, 2016 as compared to the same period in the prior year is primarily attributable to the deferred tax cost associated with the distribution of earnings from our captive foreign partnership. Additionally, the tax provision for the three and six months ended June 30, 2015 included increased tax benefits associated with Orphan Drug Credits as compared to the same periods in 2016.

We continue to maintain a valuation allowance against certain other deferred tax assets where the realization is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying

amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized.

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Financial Condition, Liquidity and Capital Resources

The following table summarizes the components of our financial condition as of June 30, 2016 and December 31, 2015:

	June 30, 2016	December 31, 2015	$ Variance
Cash and cash equivalents	$597,550	$ 1,010,111	$(412,561)
Marketable securities	$582,501	$ 374,904	$207,597
Long-term debt (includes current portion)	$3,281,250	3,456,250	$(175,000)
Current assets	$2,361,209	$ 2,416,714	$(55,505)
Current liabilities	658,462	709,615	(51,153)
Working capital	$1,702,747	$ 1,707,099	$(4,352)

The net decrease in cash and cash equivalents was primarily attributable to cash utilized to repurchase shares, principal payments on our term loan, purchases of property, plant, and equipment and purchases of available for sale securities. Offsetting these decreases in cash were cash generated through operations and proceeds from the maturity or sale of available for sale securities.

We expect continued growth in our expenditures, particularly those related to research and product development, clinical trials, regulatory approvals, international expansion, commercialization of products and capital investment. However, we anticipate that cash generated from operations and our existing available cash, cash equivalents and marketable securities should provide us adequate resources to fund our operations as currently planned.

We have financed our operations and capital expenditures primarily through positive cash flows from operations. We expect to continue to be able to fund our operations, including principal and interest payments on our credit facility and contingent payments from our acquisitions, principally through our cash flows from operations. We may, from time to time, also seek additional funding through a combination of equity or debt financings or from other sources, if necessary for future acquisitions or other strategic purposes.

Financial Instruments

Until required for use in the business, we may invest our cash reserves in money market funds, bank deposits, and high-quality marketable securities in accordance with our investment policy. The stated objectives of our investment policy is 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 foreign exchange derivative contracts. At June 30, 2016, three individual customers accounted for an aggregate of 46% of the accounts receivable balance, with these individual customers ranging from 13% to 20% of the accounts receivable balance. At December 31, 2015, three individual customers accounted for an aggregate of 51% of the accounts receivable balance, with these individual customers ranging from 14% to 22% of the accounts receivable balance. For the three and six months ended June 30, 2016, two customers accounted for 16% and 11%, respectively, of our product sales. For the three and six months ended June 30, 2015, two customers accounted for 18% and 11%, respectively, of our product sales.

We continue to monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. A substantial portion of our accounts receivable due from these countries are due from or backed by sovereign or local governments, and the amount of non-sovereign accounts receivable is not material. 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.

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 June 30, 2016, we have foreign exchange forward contracts with notional

amounts totaling $2,420,974. These outstanding foreign exchange forward contracts had a net fair value of $40,912, of which an unrealized gain of $107,534 is included in other current assets and non-current assets, offset by an unrealized loss of $66,622 included in other current liabilities and non-current liabilities. As of June 30, 2016, we have interest rate swaps on our outstanding term loan debt which have a fair value of $(5,823) that is recognized in other current and other non-current liabilities. The counterparties to these contracts are large domestic and multinational commercial banks, and we believe the risk of nonperformance is not material.

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At June 30, 2016, our financial assets and liabilities were recorded at fair value. We have classified our financial assets and liabilities as Level 1, 2 or 3 within the fair value hierarchy. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Our Level 1 assets consist of mutual fund investments and equity securities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, but substantially the full term of the financial instrument. Our Level 2 assets consist primarily of institutional money market funds, commercial paper, municipal bonds, U.S. and foreign government-related debt, corporate debt securities, certificates of deposit and foreign exchange forward contracts. Our Level 2 liabilities consist also of foreign exchange forward contracts and interest rate swaps. 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 $826,000 that will become payable if and when certain development and commercial milestones are achieved. Of these milestone amounts, $511,000 and $315,000 of the contingent payments relate to development and commercial milestones, respectively. We do not expect these amounts to have an impact on our liquidity in the near-term, and, during the next 12 months, we expect to make milestone payments of approximately $60,000, 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.

Financing Lease Obligations

In November 2012, we entered into a lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. The term of the lease commenced in 2015 and will expire in 2030, with a renewal option of ten years. Although we do not legally own the premises, we are deemed to be the owner of the building due to the substantial improvements directly funded during the construction period based on applicable accounting guidance for build-to-suit leases. Accordingly, the landlord's costs of constructing the facility during the construction period are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our consolidated balance sheet. Construction of the new facility was completed and the building was placed into service in the first quarter 2016. As of June 30, 2016 and December 31, 2015, our facility lease obligation related to this facility was $135,598 and $132,866, respectively.

During the third quarter 2015, we entered into a new agreement with Lonza whereby Lonza will construct a new manufacturing facility dedicated to Alexion at its existing Portsmouth, New Hampshire facility. 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. As of June 30, 2016 and December 31, 2015, we recorded a construction-in-process asset of $65,125 and $19,259 and an offsetting facility lease obligation of $57,715 and $15,229 associated with the manufacturing facility, respectively.

License Agreements

Our license agreements include contingent payments that will become payable if and when certain development, regulatory and commercial milestones are achieved. 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 $55,000.

Long-term Debt

On June 22, 2015, Alexion entered into a credit agreement (the Credit Agreement) with a syndicate of banks, which provides for a $3,500,000 term loan facility and a $500,000 revolving facility. Borrowings under the term loan facility are payable in quarterly installments equal to 1.25% of the original loan amount, beginning December 31, 2015. Final repayment of the term loan and any draw down of revolving credit loans are due on June 22, 2020. In addition to borrowings in which prior notice is required, the revolving credit facility includes a sublimit of $100,000 in the form

of letters of credit and borrowings on same-day notice, referred to as swingline loans, of up to $25,000. Borrowings can be used for working capital requirements, acquisitions and other general corporate purposes.

In connection with the acquisition of Synageva in June 2015, we borrowed $3,500,000 under the term loan facility and $200,000 under the revolving facility, and we used our available cash for the remaining cash consideration. In June 2015, we repaid the revolving facility in full. As of June 30, 2016, we had $3,281,250 outstanding on the term loan. As of June 30, 2016, we had open letters of credit of $13,829, and our borrowing availability under the revolving facility was $486,171.

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Manufacturing Obligations

We have supply agreements with Lonza through 2028 relating to the manufacture of Soliris and Strensiq, which requires payments to Lonza at the inception of contract and upon the initiation and completion of product manufactured. On an ongoing basis, we evaluate our plans for future levels of manufacturing by Lonza, which depends upon our commercial requirements, the progress of our clinical development programs and the production levels of ARIMF.

We have various agreements with Lonza, with remaining total non-cancellable commitments of approximately $1,143,638 through 2028. Certain commitments may be canceled only in limited circumstances. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at ARIMF and a payment with respect to sales of Soliris manufactured at Lonza facilities. In addition to Lonza, we have non-cancellable commitments of approximately $33,670 through 2019 with other third party manufacturers.

Taxes

We do not record U.S. tax expense on the undistributed earnings of our controlled foreign corporation (CFC) subsidiaries. These earnings relate to ongoing operations and were approximately $1,012,000 at December 31, 2015. We intend to reinvest these earnings permanently outside the U.S. or repatriate the earnings only when it is tax efficient to do so. Accordingly, we believe that U.S. tax on any earnings that might be repatriated would be substantially offset by realizing the benefit of tax attributes, such as U.S. foreign tax credits or by utilizing deficits in the foreign earnings and profits account.

We do not have any present or anticipated future need for cash held by our CFCs, as cash generated in the U.S., as well as borrowings, are expected to be sufficient to meet U.S. liquidity needs for the foreseeable future. At June 30, 2016, approximately $473,000 of our cash and cash equivalents was held by foreign subsidiaries, a significant portion of which is required for liquidity needs of our foreign subsidiaries. These subsidiaries will settle any outstanding trade payables prior to having excess cash available which could be repatriated to our entities in the United States. While we intend to reinvest CFC earnings permanently outside the U.S. or repatriate the earnings only when it is tax efficient to do so, certain unforeseen future events could impact our permanent reinvestment assertion. Such events include acquisitions, corporate restructurings or tax law changes not currently contemplated.

Common Stock Repurchase Program

In November 2012, our Board of Directors authorized a share repurchase program. In May 2015, our Board of Directors increased the authorization to acquire shares with an aggregate value of up to $1,000,000 for future purchases under the repurchase program, which superseded all prior repurchase programs. The repurchase program does not have an expiration date, and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at the Company's discretion. We expect that cash generated from operations and our existing available cash and cash equivalents will be sufficient to fund any share repurchases.

Under the program, for the three months ended June 30, 2016 and 2015 we repurchased 245 and 132 shares of our common stock at a cost of $34,136 and $23,537, respectively, and during the six months ended June 30, 2016 and 2015, we repurchased 2,328 and 466 shares of our common stock at a cost of $330,651 and $83,563, respectively. As of June 30, 2016, there is a total of $425,213 remaining for repurchases under the program.

Cash Flows

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

	Six months ended June 30,		$
	2016	2015	Variance
Net cash provided by operating activities	$411,917	$261,256	$150,661
Net cash used in investing activities	(336,340)	(3,228,389)	2,892,049
Net cash (used in) provided by financing activities	(490,350)	3,351,415	(3,841,765)
Effect of exchange rate changes on cash	2,212	(6,158)	8,370

Net change in cash and cash equivalents	$(412,561)	$378,124	$(790,685)

Operating Activities

Cash flows provided by operations for the six months ended June 30, 2016 were $411,917 compared to $261,256 for the six months ended June 30, 2015. The increase was primarily due to an increase in gross margin on product sales of $219,404

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resulting primarily from an increase in global demand for Soliris and the launch of Strensiq and Kanuma and a decrease in cash outflows related to our licensing arrangements of $111,200. The increase in gross margin was offset by an increase in clinical development costs, interest expense and selling, general and administrative expenses during 2016.

We expect increases in cash flows from operations which will be highly dependent on sales levels, and the related cash collections from sales of our products. We also expect additional cash outflows of approximately $55,000 over the next 12 months related to milestone payments on our license agreements.

Investing Activities

Cash used for investing activities for the six months ended June 30, 2016 were $336,340 compared to $3,228,389 for the six months ended June 30, 2015. The decrease in cash used was primarily due to the payment of $3,939,268 for the six months ended June 30, 2015 related to the Synageva acquisition and net cash flows related to the purchases and maturities of available for sale securities of $(200,836) for the six months ended June 30, 2016, compared to $843,409 for the six months ended June 30, 2015.

Financing Activities

Cash flows (used in) provided by financing activities for the six months ended June 30, 2016 were $(490,350) compared to $3,351,415 for the six months ended June 30, 2015. The decrease was primarily due to the following:

- Borrowing of $3,654,508, net of issuance costs, under our credit facility, in connection with the acquisition of Synageva in June 2015.
- Repurchases of common stock of $330,651 for the six months ended June 30, 2016, compared to $83,563 for the six months ended June 30, 2015.

Contractual Obligations

The disclosure of payments we have committed to make under our contractual obligations are summarized in our Annual Report on Form 10-K for the twelve months ended December 31, 2015, in the section titled “Management's Discussion and Analysis of Financial Condition and Results of Operations” under the caption “Contractual Obligations.”

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.
(amounts in thousands, except percentages)

Interest Rate Risk

As of June 30, 2016, we invested our cash in a variety of financial instruments, principally money market funds, corporate bonds, municipal bonds, commercial paper and government-related obligations. Most of our interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate. Our investment portfolio is comprised of marketable 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 $(5,945) and $5,095, respectively.

In June 2015, we entered into the Credit Agreement with interest at a rate per annum equal to either a base rate or a Eurodollar rate plus, in each case, an applicable margin. The applicable margins on base rate loans range from 0.25% to 1.00% and the applicable margins on Eurodollar loans range from 1.25% to 2.00%, in each case depending upon our consolidated net leverage ratio (as calculated in accordance with the Credit Agreement). Changes in interest rates related to the Credit Agreement could have a material effect on our financial statements.

To achieve a desired mix of floating and fixed interest rates on our term loan, we entered into two interest rate swap agreements in June 2016 that qualified for and are designated as cash flow hedges. The first agreement has a notional amount of $3,281,250 and is effective from effective June 30, 2016 through December 30, 2016. This agreement hedges the contractual floating interest rate of our term loan. As a result of this agreement, the interest rate for our term loan has been fixed at 0.535%, plus the borrowing spread, until December 30, 2016. The second agreement has a notional amount of $656,250 and is effective December 31, 2016 through December 31, 2019. The second agreement converts the floating rate on a portion of our term loan to a fixed rate of 0.98%, plus a borrowing spread, from

December 31, 2016 through December 2019. As of June 30, 2016, our interest rate swaps had a fair value of $(5,823). The impact of a hypothetical increase or decrease in interest rates on the fair value of our interest rate swap contract would be offset by a change in the value of the underlying liability. If interest rates were to increase or decrease by 1%, annual interest expense, beginning in 2017, would increase or decrease by $26,250, based on the unhedged portion of our outstanding term loan.

Foreign Exchange Market Risk

Our operations include activities in many countries outside the United States, including countries in Europe, Latin America and Asia Pacific. As a result, our financial results are impacted by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets where we operate. We have exposure to movements in foreign currency exchange rates, the most significant of which are the Euro and Japanese Yen, against the U.S. dollar. We are a net recipient 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, intercompany receivables and payables denominated in foreign currencies. Approximately 52% of our net product sales were denominated in foreign currencies for the three and six months ended June 30, 2016, 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 Switzerland and Ireland, and accordingly, our expenses are impacted by fluctuations in the value of the Swiss Franc and Euro against the U.S. dollar.

We currently have a derivative program in place to achieve the following: 1) limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet, using contracts with durations of up to 90 days 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 objectives of this program are to reduce the volatility of our operating results due to fluctuation of foreign exchange and to increase the visibility of the foreign exchange impact on forecasted revenues. 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 June 30, 2016 and December 31, 2015, we held foreign exchange forward contracts with notional amounts totaling $2,420,974 and $2,535,490, respectively. As of June 30, 2016 and December 31, 2015, our outstanding foreign exchange forward contracts had a net fair value of $40,912 and $147,633, respectively. The decrease in the net fair value of outstanding foreign exchange forward contracts is primarily due to the decrease in strength of the U.S. dollar as of June 30, 2016 as compared to December 31, 2015 and maturities of foreign exchange forward contracts in 2016.

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

Based on our foreign currency exchange rate exposures at June 30, 2016, 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 $198,568 at June 30, 2016. 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. A substantial portion of our accounts receivable due from these countries are due from or backed by sovereign or local governments, and the amount of non-sovereign accounts receivable is not material. We continue to monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. Although collection of our accounts receivables from certain countries may extend beyond our credit terms, we do not expect any such delays to have a material impact on our financial condition or results of operations.

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Item 4. CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of June 30, 2016. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2016, 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.

There has been no change in our internal control over financial reporting that occurred during the quarter ended June 30, 2016 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, Alexion received a request from the DOJ for the voluntary production of documents and other information pertaining to Alexion's compliance with the FCPA. The 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, which are in the early stages. At this time, Alexion is unable to predict the duration, scope or outcome of these investigations. Given the ongoing nature of these investigations, management does not currently believe a loss related to these matters is probable or that the potential magnitude of such loss or range of loss, if any, can be reasonably estimated.

Item 1A. Risk Factors.

(amounts in thousands, except percentages)

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

Risks Related to Our Products

We depend heavily on the success of our lead product, Soliris. If we are unable to increase sales of Soliris, or 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 health care payers view Soliris as therapeutically effective and safe relative to cost. Since we launched Soliris in the United States in 2007, substantially all of our revenue has been attributed to sales of Soliris. In 2015, we received marketing approval in the United States, the European Union and Japan, of our second marketed product, Strensiq, for the treatment of HPP. We also received marketing approval in 2015 in the United States and the European Union 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 and increase revenues depends on several factors, as discussed in greater detail below, including safety and efficacy of Soliris, coverage or reimbursement by government or third-party payers, pricing, manufacturing and uninterrupted supply, the introduction of and success of competing products, the size of patient populations and the number of patients diagnosed who may be treated with Soliris, adverse legal, administrative, regulatory or legislative developments, and our ability to develop, register and commercialize Soliris for new indications.

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

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

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

pipeline, including Soliris for additional indications, obtain marketing approval for Strensiq and Kanuma in additional territories or acquire or license products and technologies from third parties.

We dedicate significant resources to the worldwide development, manufacture and commercialization of our products. We cannot guarantee that any marketing application for our product candidates will be approved or maintained in any country where we seek marketing authorization. If we do not obtain regulatory approval of new products or additional indications for

existing products, or are significantly delayed or limited in doing so, our revenue growth will be adversely affected, we may experience surplus inventory, our business may be materially harmed and we may need to significantly curtail operations.

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 United States or country specific governmental organizations in foreign countries, and private third-party payers to defray the cost of our products to patients. These entities may refuse to provide coverage and reimbursement, determine to provide a lower level of coverage and reimbursement than anticipated, or reduce previously approved levels of coverage and reimbursement, including in the form of higher mandatory rebates or modified pricing terms.

In certain countries where we sell or are seeking or may seek to commercialize our products, pricing, coverage and level of reimbursement or funding of prescription drugs are subject to governmental control. We may be unable to timely or successfully negotiate coverage, pricing and reimbursement on terms that are favorable to us, or such coverage, pricing, and reimbursement may differ in separate regions in the same country. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed, and the requirements governing drug pricing vary widely from country to country, which may include a combination of distinct potential payers, including private insurance and governmental payers as well as a HTA assessment of medicinal products for pricing and reimbursement methodologies. Therefore, we may not successfully conclude the necessary processes and commercialize our products in every, or even most countries in which we seek to sell our products.

A significant reduction in the amount of reimbursement or pricing for our products in one or more countries may reduce our profitability and adversely affect our financial condition. Certain countries establish pricing and reimbursement amounts by reference to the price of the same or similar products in other countries. Therefore, if coverage or the level of reimbursement is limited in one or more countries, we may be unable to obtain or maintain anticipated pricing or reimbursement in current or new territories. In the United States, the European Union member states, and elsewhere, there have been, and we expect there will continue to be, efforts to control and reduce health care costs. In the U.S. for example, the price of drugs has come under intense scrutiny by the U.S. Congress. Third party payers decide which drugs they will pay for and establish reimbursement and co-payment levels. Government and other third-party payers are increasingly challenging the prices charged for health care 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 headings "Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy and government initiatives that affect coverage and reimbursement of drug products may impact our business in ways that we cannot currently predict and these changes could adversely affect our business and financial condition" and "The credit and financial market conditions may aggravate certain risks affecting our business."

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, or both indications. To the extent we are successful in developing Soliris for indications other than PNH and aHUS, 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 for any other approved indication, or provide a lower level of coverage or reimbursement than anticipated or currently in effect.

Health insurance programs may restrict coverage of some products by using payer formularies under which only selected drugs are covered, variable co-payments that make drugs that are not preferred by the payer more expensive

for patients, and by using utilization management controls, such as requirements for prior authorization or failure first on another type of treatment. Payers may especially impose these obstacles to coverage for higher-priced drugs, and consequently our products may be subject to payer-driven restrictions. Additionally, U.S. payers are increasingly considering new metrics as the basis for reimbursement rates.

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

provide for these and other charitable purposes; however, substantial support could have a material adverse effect on our profitability in the future.

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

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

We cannot be certain that our products will maintain market acceptance in a particular country among physicians, patients, health care payers, and others. Although we have received regulatory approval of our products in certain territories, such approvals do not guarantee future revenue. We cannot predict whether physicians, other health care providers, government agencies or private insurers will determine or continue to accept that our products are safe and therapeutically effective relative to its cost. Physicians' willingness to prescribe, and patients' willingness to accept, our products, depends on many factors, including prevalence and severity of adverse side effects in both clinical trials and commercial use, the timing of the market introduction of competitive drugs, lower demonstrated clinical safety and efficacy compared to other drugs, perceived lack of cost-effectiveness, pricing and lack of availability of reimbursement from third-party payers, convenience and ease of administration, effectiveness of our marketing strategy, publicity concerning the product, our other product candidates and availability of alternative treatments, including bone marrow transplant as an alternative treatment for PNH. The likelihood of physicians to prescribe Soliris for patients with aHUS may also depend on how quickly Soliris can be delivered to the hospital or clinic and our distribution methods may not be sufficient to satisfy this need. In addition, we are aware that medical doctors have determined not to continue Soliris treatment for some patients with aHUS.

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

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

The manufacture of our products and our product candidates is highly regulated, complex and difficult, requiring a multi-step controlled process and even minor problems or deviations could result in defects or failures. We have limited experience manufacturing commercial quantities of Strensiq and Kanuma. Only a small number of companies have the ability and capacity to manufacture our products for our development and commercialization needs. Due to the highly technical requirements of manufacturing our products and the strict quality and control specifications, we and our third party providers may be unable to manufacture or supply our products despite our and their efforts. Failure to produce sufficient quantities of our products and product candidates could result in lost revenue, diminish our profitability, delay the development of our product candidates, or result in supply shortages for our patients, which may lead to lawsuits or could accelerate introduction of competing products to the market.

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

Many additional factors could cause production interruptions at our facilities or at the facilities of our third party providers, including natural disasters, labor disputes, acts of terrorism or war. The occurrence of any such event could adversely affect our ability to satisfy demand for Soliris, which could materially and adversely affect our operating results.

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

We and our third party providers are required to maintain compliance with cGMP and other stringent requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to supply our products and product candidates. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.

We rely on one to two facilities to manufacture each of our products. We are authorized to sell Soliris that is manufactured by Lonza and at ARIMF in the United States, the European Union, Japan and certain other territories. However, manufacturing Soliris for commercial sale in certain other territories may only be performed at a single facility until such time as we have received the required regulatory approval for an additional facility, if ever. We will continue to depend entirely on one facility to manufacture Soliris for commercial sale in such other territories until that time. We also depend entirely on one facility to manufacture Strensiq and on one facility for the purification of Kanuma for commercial sale. Regarding Kanuma, we rely on two animal facilities to produce the starting material, and a single manufacturing facility to manufacture the drug product.

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

Any difficulties or delays in our third party manufacturing, or any failure of our third party providers to comply with our internal and external specifications or any applicable rules, regulations and standards could increase our costs, constrain our ability to satisfy demand for our products from customers, cause us to lose revenue or incur penalties for failure to deliver product, make us postpone or cancel clinical trials, or cause our products to be recalled or withdrawn, such as the voluntary recalls that we initiated in 2013 and 2014 due to the presence of visible particles in a limited number of vials in specific lots. Even if we are able to find alternatives they may ultimately be insufficient for our needs. No guarantee can be made that regulators will approve additional third party providers in a timely manner or at all, or that any third party providers will be able to perform services for sufficient product volumes for any country or territory. Further, due to the nature of the current market for third-party commercial manufacturing, many arrangements require substantial penalty payments by the customer for failure to use the manufacturing capacity for which it contracted. Penalty payments under these agreements typically decrease over the life of the agreement, and may be substantial initially and de minimis or non-existent in the final period. The payment of a substantial penalty could harm our financial condition.

It can take longer than five years to build and validate a new manufacturing facility and it can take longer than three years to qualify and validate a new contract manufacturer. We are currently completing the build-out of a fill-finish facility in Ireland to support global distribution of Soliris and Alexion's other clinical and commercial products. To date, we have relied entirely on third party fill-finish providers and have never operated our own fill-finish facility. 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 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 product withdrawals or recalls. We may also have to write-off inventory and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Such manufacturing issues could increase our cost of goods, cause us to lose revenue, reduce our profitability or damage our reputation.

We operate in a highly regulated industry and if we or our third party providers fail to comply with United States 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 European Union 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. We are working with the FDA to resolve the issues identified in the Warning Letter. Failure to address the FDA's concerns may lead the FDA or other regulatory authorities to 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 do not resolve outstanding concerns expressed by the FDA in the Warning Letter and the Form 483s to the satisfaction of the FDA, EMA or any other regulatory agency, or 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 United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA APHIS), the agency responsible for administering the Animal Welfare Act. Any failure to ensure safety and security of our transgenic chickens and/or animal products could result in regulatory action by the FDA or another regulatory body, including USDA APHIS.

The safety profile of any product continues to be closely monitored by the FDA and other foreign regulatory authorities after approval. Regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, finishing, filling, labeling, advertising, promotion, risk mitigation, adverse event reporting requirements, and export of biologics. For example, the risk management program established in 2007 upon the FDA's approval of Soliris for the treatment of PNH was replaced with a Risk Evaluation and Mitigation Strategy (REMS) program, approved by the FDA in 2010, and further revised in December 2015 concerning prescribing information regarding the level of fever needed to seek medical attention and reporting adverse events. Future changes to the Soliris REMS could be costly and burdensome to implement.

We are required to report any serious and unexpected adverse experiences and certain quality problems with our products to the FDA, the EMA, and other health agencies. We or any health agency may have to notify health care providers of any such developments. 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, 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 United States, 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 United States 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 United States, 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 United States, 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 year-old of age. 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 United States, the FDA can also propose to withdraw approval for a product if it determines that such additional studies are inadequate or if new clinical data or information shows that a product is not safe for use in an approved indication.

Failure to comply with the laws and requirements, including statutes and regulations, administered by the FDA, the EC, the competent authorities of the European Union member states, the MHLW or other agencies, including without limitation, failures or delays in resolving the concerns raised by the FDA in the Warning Letter, could result in:

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

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

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

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

We may be sued by people who use our products, whether as a prescribed therapy, during a clinical trial, during an investigator initiated study, or otherwise. Many patients who use our products are already very ill. Any informed

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

Patients who use our products already often have severe and advanced stages of disease and known as well as unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our products. Some patients treated with our products,

including patients who have participated in our clinical trials, have died or suffered potentially life-threatening diseases either during or after ending their treatments. Patients who delay or miss a dose or discontinue treatment may also experience complications, including death. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals that our products receive or maintain.

For example, use of C5 Inhibitors, such as Soliris, is associated with an increased risk for certain types of infection, including meningococcal infection. Under controlled settings, patients in our eculizumab trials all receive vaccination against meningococcal infection prior to first administration of Soliris and patients who are prescribed Soliris in most countries are required by prescribing guidelines to be vaccinated prior to receiving their first dose. A physician may not have the opportunity to timely vaccinate a patient in the event of an acute emergency episode, such as in a patient presenting with aHUS or during the health crisis that began in May 2011 in Europe, principally in Germany, due to the epidemic of infections from Enterohemorrhagic E. coli. Vaccination does not, however, eliminate all risk of meningococcal infection. Additionally, in some countries there may not be any vaccine approved for general use or approved for use in infants and children. Some patients treated with Soliris who had been vaccinated have nonetheless experienced meningococcal infection, including patients who have suffered serious illness or death. Each such incident is required to be reported to appropriate regulatory agencies in accordance with relevant regulations. Clinical evaluations of outcomes in the post-marketing setting are required to be reported to appropriate regulatory agencies in accordance with relevant regulations. Determination of significant complications associated with the delay or discontinuation of our products could have a material adverse effect on our ability to sell our products.

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

We are marketing and selling our products ourselves in the United States, Europe, Japan and several other territories. Strensiq and Kanuma were approved in 2015, are in the early stages of commercial launch and are the second and third new product launches in Alexion's history. If we are unable to establish and/or expand our capabilities to sell, market and distribute our products, either through our own capabilities or by entering into agreements with others, or to maintain such capabilities in countries where we have already commenced commercial sales, we will not be able to successfully sell our products. In that event, we will not be able to generate significant revenues. We cannot guarantee that we will be able to establish and maintain our own capabilities or enter into and maintain any marketing or distribution agreements with third-party providers on acceptable terms, if at all. Even if we hire the qualified sales and marketing personnel we need to support our objectives, or enter into marketing and distribution agreements with third parties on acceptable terms, we may not do so in an efficient manner or on a timely basis. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell our products. Establishing and maintaining sales, marketing and distribution capabilities are competitive, expensive and time-consuming. Our expenses associated with building up and maintaining the sales force and distribution capabilities around the world may be disproportionate compared to the revenues we may be able to generate on sales. We cannot guarantee that we will be successful in commercializing any of our products.

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

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act (FCA), the anti-kickback provisions of the federal Social Security Act, and other related federal 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 health care item or service reimbursable under Medicare, Medicaid, or other federal health care 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 health care 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. Violations of U.S. federal and state fraud and abuse laws may result in criminal, civil and administrative sanctions, including fines, damages, civil monetary penalties and exclusion from federal healthcare programs (including Medicare and Medicaid).

Although physicians in the United States 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 United States, we market our products for their approved uses. Although we believe our marketing materials and training programs for physicians do not constitute off-label 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 off-label 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 imposes similar strict restrictions on the promotion and marketing of drug products. The off-label promotion of medicinal products is prohibited in the EU and in other territories. The promotion of medicinal products that are not subject to a marketing authorization is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU and in other territories could be penalized by administrative measures, fines and imprisonment.

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

In May 2015, we received a subpoena in connection with an investigation by the Enforcement Division of the SEC requesting information related to our grant-making activities and compliance with the FCPA in various countries. The SEC also seeks information related to Alexion's recalls of specific lots of Soliris and related securities disclosures. In addition, in October 2015, Alexion received a request from the DOJ for the voluntary production of documents and other information pertaining to Alexion's compliance with the FCPA. 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 United States or foreign laws or regulations, including by the SEC or DOJ pursuant to its investigation of our compliance with the FCPA 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. Additionally, 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 the SEC and the DOJ in connection with its investigation of our FCPA practices and other matters, as well as responding to any future U.S. or foreign governmental investigation or whistleblower lawsuit, could result in substantial expenses, and could divert management's attention from other business concerns and could have a material adverse effect on our business and financial condition and growth

prospects.

Completion of preclinical studies or clinical trials does not guarantee advancement to the next phase of development. Completion of preclinical studies or clinical trials does not guarantee that we will initiate additional studies or trials for our product candidates, that if further studies or trials are initiated what the scope and phase of the trial will be or that they will be completed, or that if these further studies or trials are completed, that the design or results will provide a sufficient basis to apply for or receive regulatory approvals or to commercialize products. Results of clinical trials could be inconclusive, requiring additional or repeat trials. Data obtained from preclinical studies and clinical trials are subject to varying interpretations that could delay, limit or prevent regulatory approval. If the design or results achieved in our clinical trials are insufficient to proceed to further trials or to regulatory approval of our product candidates, our company could be materially adversely affected. Failure of a clinical trial to achieve its pre-specified primary endpoint, such as the Phase II Soliris trial for AMR that we announced in January 2015, 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, or we may have to spend considerable resources repeating clinical trials or conducting additional trials, either of which would increase costs and delay any revenue from those product candidates, if any. We may open clinical sites and enroll patients in countries where we have little experience. We rely on a small number of clinical research organizations to carry out our clinical trial related activities, and one CRO is responsible for many of our studies. We rely on such parties to accurately report their results. Our reliance on CROs may impact our ability to control the timing, conduct, expense and quality of our clinical trials.

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

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

Risks Related to Intellectual Property

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

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

We have and may in the future obtain patents or the right to practice patents through ownership or license. Our patent applications may not result in the issue of patents in the United States or other countries. Our patents may not afford adequate protection for our products. Third parties may challenge our patents, and have challenged our patents in the past. If any of our patents are narrowed, invalidated or become unenforceable, competitors may develop and market products similar to ours that

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

Significant legal questions exist concerning the extent and scope of patent protection for biopharmaceutical products and processes in the United States 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. Litigation may be required to enforce, defend or obtain our patent and other intellectual property rights. Any administrative proceeding or litigation could require a significant commitment of our resources and, depending on outcome, could adversely affect the scope, validity or enforceability of certain of our patent or other proprietary rights.

In addition, our business requires using sensitive technology, techniques and proprietary compounds that we protect as trade secrets. However, we may also rely heavily on collaboration with, or discuss the potential for collaboration with, suppliers, outside scientists and other biopharmaceutical companies. Collaboration and discussion of potential collaboration present a strong risk of exposing our trade secrets. If our trade secrets were exposed, it would help our competitors and adversely affect our business prospects.

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

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

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

Any holder of these patents or other patents covering similar technology could sue us for damages and seek to prevent us from manufacturing, selling or developing our products. Legal disputes can be costly and time consuming to defend. If we cannot successfully defend against any future actions or conflicts, if they arise, we may incur substantial legal costs and may be liable for damages, be required to obtain costly licenses or need to stop manufacturing, using or selling our products, which would adversely affect our business. We may seek to obtain a license prior to or during legal actions in order to reduce further costs and the risk of a court determination that our product infringes the third party's patents. A required license may be costly or may not be available on acceptable terms, if at all. A costly license, or inability to obtain a necessary license, could have a material adverse effect on our business.

There can be no assurance that we would prevail in a patent infringement action or that we would be able to obtain a license to any third-party patent on commercially reasonable terms or any terms at all; successfully develop non-infringing alternatives on a timely basis; or license alternative non-infringing technology, if any exists, on commercially reasonable terms. Any impediment to our ability to manufacture, use or sell approved forms of our products or our product candidates could have a material adverse effect on our business and prospects.

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

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

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

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

Risks Related to Our Operations

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

We have maintained profitability on a quarterly basis since the quarter ended June 30, 2008 and on an annual basis beginning with the year ended December 31, 2008. Our quarterly revenues, expenses and net income (loss) may fluctuate, even significantly, due to the risks described in these "Risk Factors" as well as the timing of charges and expenses that we may take. We believe that we formulate our annual operating budgets with reasonable assumptions and targets, however we may not generate sufficient revenues or control expenses to achieve our financial goals, including continued profitability. We may not be able to sustain or increase profitability on a quarterly or annual basis. You should not consider our financial performance, including our revenue growth, in recent periods as indicative of our future performance. We may not accurately forecast demand for our products, especially Strensiq and Kanuma. 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. Product demand is dependent on a number of factors. Our investors may have widely varying expectations that may be materially higher or lower than actual revenues and if our revenues are different from these expectations, our stock price may experience significant volatility. Our revenues are also subject to foreign exchange rate fluctuations due to the global nature of our operations and our results of operations could be adversely affected due to unfavorable foreign exchange rates. Although we use derivative instruments to manage foreign currency risk, our efforts to reduce currency exchange losses may not be successful.

We have significant debt service obligations as a result of the debt we incurred to finance the acquisition of Synageva. Changes in interest rates related to this debt could significantly increase our annual interest expense. As we advance our most robust pipeline in our history and launch our second and third products worldwide, we will have substantial expenses as we continue our research and development efforts, continue to conduct clinical trials and continue to develop manufacturing, sales, marketing and distribution capabilities worldwide, some of which could be delayed, scaled-back or eliminated to achieve our financial objectives.

We have also recorded, or may be required to record, charges that include inventory write-downs for failed quality specifications or recalls, impairments with respect to investments, fixed assets and long-lived assets, outcomes of litigation and other legal or administrative proceedings, regulatory matters and tax matters, and payments in connection with acquisitions and other business development activities, such as milestone payments.

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. We are in advanced clinical studies of Soliris for the treatment of other diseases, and there are currently no approved drugs for any of these other diseases. Strensiq is currently the only product approved to treat HPP and Kanuma is the only product approved to treat LAL-D. In the future, Soliris may compete with new drugs currently in development, and Strensiq and Kanuma may also experience competition. Other companies have initiated clinical studies for the treatment of PNH and NMO, 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 by clinical trial enrollment 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 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. 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, our business may be harmed.

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

In June 2015, we acquired Synageva and used a substantial portion of our cash on hand and incurred significant debt under the terms of a senior secured credit facility to finance the acquisition. In addition, we have substantial contingent liabilities, including milestone and royalty obligations under earlier acquisitions and strategic transactions. Our increased indebtedness, including increased interest expense, together with our significant contingent liabilities, could, among other things:

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

The Credit Agreement requires us to comply with certain financial covenants on a quarterly basis and includes negative covenants, subject to exceptions, restricting or limiting our ability and the ability of our subsidiaries to, among other things, incur additional indebtedness, grant liens, and engage in certain investment, acquisition and disposition transactions. If an event of default occurs, the interest rate would increase and the administrative agent would be entitled to take various actions, including the acceleration of amounts due under the loan.

Our ability to satisfy our obligations under the Credit Agreement and meet our debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations,

many of which are beyond our control.

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

We may need to raise additional capital to supplement our existing funds and cash generated from operations for working capital, capital expenditure and debt service requirements, and other business activities. Funding needs may shift and the amount of capital we may need depends on many factors, including, the cost of any acquisition or any new collaborative, licensing or other commercial relationships that we may establish, the time and cost necessary to build our manufacturing facilities or enhance our manufacturing operations, the cost of obtaining and maintaining the necessary regulatory approvals for

our manufacturing facilities, and the progress, timing and scope of our preclinical studies and clinical trials. The capital and credit markets have experienced extreme volatility and disruption. We may not receive additional funding when we need it or funding may only be available on unfavorable terms. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back or eliminate certain research, development, manufacturing or commercial activities.

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

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

We are seeking to expand our business through strategic initiatives. Our efforts to identify opportunities or complete transactions that satisfy our strategic criteria may not be successful, and we not realize the anticipated benefits of any completed acquisition or other strategic transaction.

Our business strategy includes expanding our products and capabilities. We regularly evaluate potential merger, acquisition, partnering and in-license opportunities that we expect will expand our pipeline or product offerings, and enhance our research platforms. Acquisitions of new businesses or products and in-licensing of new products may involve numerous risks, including:

- substantial cash expenditures;
- potentially dilutive issuance of equity securities;
- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- difficulties in assimilating the operations of the acquired companies;
- failure of any acquired businesses or products or in-licensed products to achieve the scientific, medical, commercial or other results anticipated;
- diverting our management's attention away from other business concerns;
- the potential loss of our key employees or key employees of the acquired companies; and
- risks of entering markets in which we have limited or no direct experience.

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

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

To effectively manage our current and future potential growth, we must continue to effectively enhance and develop our global employee base, and our operational and financial processes. Supporting our growth strategy will require significant capital expenditures and management resources, including investments in research, development, sales and

marketing, manufacturing and other areas of our operations. The development or expansion of our business, any acquired business or any acquired or in-licensed products may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our capital stock, which could dilute current stockholders' ownership interest in our company, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest in our company upon conversion.

We may be required to recognize impairment charges for our goodwill and other intangible assets.

As of June 30, 2016, the net carrying value of our goodwill and other intangible assets totaled $9,585,206. As required by generally accepted accounting principles, we periodically assess these assets to determine if they are impaired. Impairment of intangible assets may be triggered by developments both within and outside our control. Deteriorating economic conditions, technological changes, disruptions to our business, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in use of the assets, intensified competition, divestitures, market capitalization declines and other factors may impair our goodwill and other intangible assets. Any charges relating to such impairments could adversely affect our results of operations in the periods in which an impairment is recognized.

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 United States 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 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. Legal proceedings, government investigations, including the SEC and DOJ investigations, and enforcement actions can be expensive and time consuming. An adverse outcome could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations.

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

As a company with international operations, we are subject to income taxes, as well as non-income based taxes, in both the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities. Although we believe our estimates are reasonable, the ultimate outcome with respect to the taxes we owe may differ from the amounts recorded in our financial statements. If the Internal Revenue Service, 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. We are also integrating the Synageva corporate structure into our own in a manner that is also intended to achieve similar efficiencies. The application of the tax laws and regulations of various countries in which we operate and to our global operations is subject to interpretation. We also must operate our business in a manner consistent with our corporate structure to realize such efficiencies. The tax authorities of the countries in which we operate may challenge our methodologies for valuing developed technology or for transfer pricing. If tax authorities determine that the manner in which we operate results in our business not achieving the intended tax consequences, our effective tax rate could increase and harm our financial position and results of operations.

In addition, the United States government and other governments are considering and may adopt tax reform measures that significantly increase our worldwide tax liabilities. The U.S. Congress, the Organization for Economic Co-operation and Development and other government agencies in countries where we and our affiliates operate have

focused on issues related to the taxation of multinational corporation, including, for example, in the area of “base erosion and profit shifting,” where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. We established operations in Ireland in 2013 and Ireland tax authorities announced changes to the treatment of non-resident Irish entities. The changes are not expected to impact existing non-resident Irish entities, such as ours, until after December 31, 2020. These changes and other prospective changes in the United States and other countries in which we and our affiliates operate could increase our effective tax rate, and harm our financial position and results of operations.

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

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

- difficulties or the inability to obtain necessary foreign regulatory or reimbursement approvals of our products in a timely manner;
- political or economic determinations that adversely impact pricing or reimbursement policies;
- economic problems or political instability;
- fluctuations in currency exchange rates;
- difficulties or inability to obtain financing in markets;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- difficulties enforcing contractual and intellectual property rights;
- compliance with complex import and export control laws;
- trade restrictions and restrictions on direct investments by foreign entities;
- compliance with tax, employment and labor laws;
- costs and difficulties in recruiting and retaining qualified managers and employees to manage and operate the business in local jurisdictions;
- costs and difficulties in managing and monitoring international operations; and
- longer payment cycles.

Additionally, our business and marketing methods are subject to the laws and regulations of the countries in which we operate, which may differ significantly from country to country and may conflict with U.S. laws and regulations. The FCPA and anti-bribery laws and regulations are extensive and far-reaching, and we must maintain accurate records and control over the activities of our distributors and third party service providers in countries where we operate. We have policies and procedures designed to help ensure that we and our representatives, including our employees, comply with such laws, however we cannot guarantee that these policies and procedures will protect us against liability under the FCPA or other anti-bribery laws for actions taken by our representatives. Although we conducted due diligence of Synageva's operations prior to the acquisition, we may discover or identify deficiencies or non-compliance with such laws as we complete the integration of the Synageva business and conduct operations. Failure to comply with the laws and regulations of the countries in which we operate could materially harm our business.

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

We conduct a substantial portion of our business in currencies other than the U.S. dollar. We are exposed to fluctuations in foreign currency exchange rates and fluctuations in foreign currency exchange rates affect our operating results. The exposures result from portions of our revenues, as well as the related receivables, and expenses that are denominated in currencies other than the U.S. dollar, including the Euro, Japanese Yen, British Pound, Swiss Franc, and Russian Ruble. As the U.S. dollar strengthens against these foreign currencies, the relative value of sales made in the respective foreign currencies decreases. When the U.S. dollar weakens against these currencies, the relative value of such sales increases. We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. We enter into foreign exchange forward contracts to hedge exposures resulting from portions of our forecasted revenues, including intercompany revenues, that are denominated in currencies other than the U.S. dollar. The purpose of the hedges of revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. Further, we enter into foreign exchange forward contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results. Gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. While we attempt to hedge certain currency risks, currency fluctuations between the U.S. dollar and the currencies in which we do business have, in the past,

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

Changes in healthcare laws and 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 health care. The Patient Protection and Affordable Care Act (PPACA) was enacted in the United States 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. On January 21, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate Program under PPACA. These regulations become effective on April 1, 2016. We are evaluating the impact of these regulations on our business and operations. 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.

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

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

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. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer price and best price for the quarter. 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 drug discount 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, if we are found to have knowingly submitted false average manufacturer price, ASP, or best price information to the government, we may be liable for civil monetary penalties in the amount of $100 per item of false information. If we are found to have made a misrepresentation in the reporting of our ASP, the Medicare statute provides for civil monetary penalties of up to $10 for each misrepresentation for each day in which

the misrepresentation was applied. Our failure to submit monthly/quarterly average manufacturer price, ASP, and best price data on a timely basis could result in a civil monetary penalty of $10 per day for each day the information is late beyond the due date. Such failure 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 FSS pricing program to be eligible to have its products paid for with federal funds. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws

and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

We are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., we may be subject to state security breach notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure and transmission of personal information. Each of these laws are 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 individually identifiable health information from a covered entity in a manner that is not authorized or permitted by the federal Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA) or for aiding and abetting the violation of HIPAA. Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. European Union 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 imposed 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 European Union member states could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

In May 2016 the EU formally adopted the General Data Protection Regulation, which will apply to all EU member states from May 25, 2018 and will replace the current EU Data Protection Directive on that date. The Regulation introduces new data protection requirements in the EU and substantial fines for breaches of the data protection rules. It will increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules.

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

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

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

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

Risks Related to Our Common Stock

Our stock price is extremely volatile.

The trading price of our common stock has been extremely volatile and may continue to be volatile in the future. Many factors could have an impact on our stock price, including fluctuations in our or our competitors' operating results, clinical trial results or adverse events associated with our products, product development by us or our competitors, changes in laws, including healthcare, tax or intellectual property laws, intellectual property developments, changes in reimbursement or drug pricing, the existence or outcome of litigation or government proceedings, including the SEC/DOJ investigation, failure to resolve, delays in resolving or other developments with respect to the issues raised in the Warning Letter, 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, the President, the Secretary, or a majority of the Board of Directors, or upon the written request of stockholders who together own of record 25% of the outstanding stock of all classes entitled to vote at such meeting. Our bylaws also specify that the authorized number of directors may be changed only by resolution of the board of directors. 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 5,000 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% 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% 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 thousands except per share amounts)

The following table summarizes our common stock repurchase activity during the second quarter of 2016:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of	Maximum Dollar Value of Shares that May Yet

			Publicly Announced Programs	Be Purchased Under the Program
April 1-30, 2016	245	$139.30	245	$425,213
May 1-31, 2016	—	$—	—	$425,213
June 1-30, 2016	—	$—	—	$425,213
Total	245	$139.30	245	

In November 2012, our Board of Directors authorized a share repurchase program. The repurchase program does not have an expiration date and we are no obligated to acquire a particular number of shares. In May 2015, our Board of Directors increased the authorization to acquire shares with an aggregate value of up to $1,000,000 for future purchases under the repurchase program, which superseded all prior repurchase programs.

Item 5. OTHER INFORMATION.
None.

Item 6. EXHIBITS.
(a) Exhibits:

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 June 30, 2016 formatted in eXtensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets at June 30, 2016 and December 31, 2015, (ii) the Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2016 and 2015, (iii) the Condensed Consolidated Statements of Comprehensive Income for the three and six months ended June 30, 2016 and 2015, (iv) the Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and 2015, and (v) Notes to Condensed Consolidated Financial Statements.

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/ David Hallal
David Hallal
Date: July 29, 2016 Chief Executive Officer (principal executive officer)

By: /s/ Vikas Sinha
Vikas Sinha, M.B.A., C.A.
Date: July 29, 2016 Executive Vice President and Chief Financial Officer
(principal financial officer)