ALEXION PHARMACEUTICALS INC
Form 10-Q
July 31, 2015

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, 2015
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.)

352 Knotter Drive, Cheshire Connecticut 06410
(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	226,154,636
Class	Outstanding as of July 29, 2015

Alexion Pharmaceuticals, Inc.
Contents

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

	June 30, 2015	December 31, 2014
Assets		
Current Assets:		
Cash and cash equivalents	$1,322,123	$943,999
Marketable securities	172,229	1,017,567
Trade accounts receivable, net	535,824	432,888
Inventories	234,347	176,441
Prepaid expenses and other current assets	268,715	225,134
Total current assets	2,533,238	2,796,029
Property, plant and equipment, net	555,388	392,248
Intangible assets, net	4,824,520	587,046
Goodwill	5,007,142	254,073
Other assets	247,431	172,566
Total assets	$13,167,719	$4,201,962
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$47,039	$44,016
Accrued expenses	407,345	395,232
Deferred revenue	88,366	58,837
Current portion of long-term debt	131,250	48,000
Deferred tax liabilities	42,018	12,476
Other current liabilities	53,151	48,179
Total current liabilities	769,169	606,740
Long-term debt, less current portion	3,368,750	9,500
Facility lease obligation	129,560	107,099
Contingent consideration	129,546	116,425
Other liabilities	217,823	60,180
Total liabilities	4,614,848	899,944
Commitments and contingencies (Note 18)		
Stockholders' Equity:		
Preferred stock, $0.0001 par value; 5,000 shares authorized, no shares issued or outstanding	—	—
Common stock, $0.0001 par value; 290,000 shares authorized; 229,371 and 201,944 shares issued at June 30, 2015 and December 31, 2014, respectively	23	20
Additional paid-in capital	7,659,311	2,592,167
Treasury stock, at cost, 3,354 and 2,888 shares at June 30, 2015 and December 31, 2014, respectively	(466,527)	(382,964)
Accumulated other comprehensive loss	62,516	56,785
Retained earnings	1,297,548	1,036,010
Total stockholders' equity	8,552,871	3,302,018
Total liabilities and stockholders' equity	$13,167,719	$4,201,962

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

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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,	
	2015	2014	2015	2014
Net product sales	$635,983	$512,495	$1,236,316	$1,079,111
Other revenue	227	—	227	—
Total revenues	636,210	512,495	1,236,543	1,079,111
Cost of sales	52,007	39,626	121,406	72,565
Operating expenses:				
Research and development	131,693	92,554	352,773	284,011
Selling, general and administrative	221,383	159,477	408,499	288,768
Impairment of intangible asset	—	—	—	3,464
Acquisition-related costs	33,821	1,989	45,800	1,951
Restructuring expenses	16,224	—	23,276	—
Total operating expenses	403,121	254,020	830,348	578,194
Operating income	181,082	218,849	284,789	428,352
Other income and expense:				
Investment income	2,226	1,714	5,110	3,927
Interest expense	(3,971)	(715)	(4,622)	(1,778)
Foreign currency (loss) gain	(2,045)	(1,202)	(1,040)	56
Income before income taxes	177,292	218,646	284,237	430,557
Income tax provision	7,077	52,151	22,699	104,708
Net income	$170,215	$166,495	$261,538	$325,849
Earnings per common share				
Basic	$0.84	$0.84	$1.30	$1.65
Diluted	$0.83	$0.83	$1.29	$1.62
Shares used in computing earnings per common share				
Basic	202,234	197,880	200,806	197,838
Diluted	204,546	201,524	203,302	201,715

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,	
	2015	2014	2015	2014
Net income	$170,215	$166,495	$261,538	$325,849
Other comprehensive income (loss), net of tax:				
Foreign currency translation	1,170	46	(4,218)	552
Unrealized (losses) gains on marketable securities	(803)	299	254	1,110
Unrealized losses on pension obligation	(7,193)	(2,685)	(7,445)	(2,685)
Unrealized (losses) gains on hedging activities, net of tax of $(27,623), $(526), $11,010 and $(1,771), respectively	(50,147)	(3,675)	17,140	(8,570)
Other comprehensive (loss) income, net of tax	(56,973)	(6,015)	5,731	(9,593)
Comprehensive income	$113,242	$160,480	$267,269	$316,256

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,	
	2015	2014
Cash flows from operating activities:		
Net income	$261,538	$325,849
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	23,141	19,042
Impairment of intangible asset	—	3,464
Change in fair value of contingent consideration	16,023	1,951
Share-based compensation expense	109,797	52,254
Premium amortization of available-for-sale securities	5,690	8,163
Deferred taxes	(3,565)	(112,425)
Reduction in taxes payable due to excess tax benefit from stock options	(10,763)	(254,547)
Unrealized foreign currency gain	(10,434)	(4,046)
Other	404	309
Changes in operating assets and liabilities, excluding the effect of acquisitions:		
Accounts receivable	(108,984)	(9,179)
Inventories	4,722	(34,972)
Prepaid expenses and other assets	(48,069)	(17,815)
Accounts payable, accrued expenses and other liabilities	(10,761)	78,298
Deferred revenue	32,517	18,749
Net cash provided by operating activities	261,256	75,095
Cash flows from investing activities:		
Purchases of available-for-sale securities	(187,416)	(278,134)
Proceeds from maturity or sale of available-for-sale securities	1,030,825	275,946
Purchases of trading securities	(3,769)	(1,765)
Purchases of other investments	—	(25,000)
Purchases of property, plant and equipment	(130,171)	(61,189)
Payment for acquisition of business, net of cash acquired	(3,939,268)	—
Other	1,410	26
Net cash used in investing activities	(3,228,389)	(90,116)
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	(57,500)	(31,500)
Equity issuance costs for shares issued in connection with acquisition of business	(3,864)	—
Excess tax benefit from stock options	10,763	254,547
Repurchase of common stock	(83,563)	(178,515)
Net proceeds from the exercise of stock options	31,684	52,181
Other	(613)	(81)
Net cash provided by financing activities	3,351,415	96,632
Effect of exchange rate changes on cash	(6,158)	577
Net change in cash and cash equivalents	378,124	82,188
Cash and cash equivalents at beginning of period	943,999	529,857

Cash and cash equivalents at end of period	$1,322,123	$612,045
Supplemental cash flow disclosures from investing and financing activities:		
Common stock issued in acquisition of business	$4,917,849	$—
Construction in process related to facility lease obligation	$19,065	$27,284
Accrued expenses for purchases of property, plant and equipment	$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 rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Our marketed product Soliris® is the first and only therapeutic approved for patients with either of two severe and ultra-rare disorders resulting from chronic uncontrolled activation of the complement component of the immune system: paroxysmal nocturnal hemoglobinuria (PNH), a life-threatening and ultra-rare genetic blood disorder, and atypical hemolytic uremic syndrome (aHUS), a life-threatening and ultra-rare genetic disease.

We are also establishing a global metabolic rare disease franchise with the development of two late-stage therapies, Strensiq® (asfotase alfa) for the treatment of hypophasphatasia (HPP) and Kanuma® (Sebelipase alfa) for the treatment of 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 Soliris 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.

We were incorporated in 1992 and began commercial sale of Soliris in 2007.

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, 2014. 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, 2014 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, 2014 included in our Annual Report on Form 10-K. The results of operations for the three and six months ended June 30, 2015 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, 2014.

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 are also allowed to early adopt the standard for annual

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(amounts in thousands, except per share amounts)

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. The standard is effective for interim and annual periods beginning after December 15, 2015, with early adoption permitted, and requires a retrospective method of adoption. We will adopt the provisions of the guidance for the balance sheet disclosures of debt issuance costs in 2016.

3. Acquisitions

Acquisition of Synageva BioPharma Corp.

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 was intended to further 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, Kanuma™ (sebelipase alfa), is 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 $4,565,485 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 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	$4,917,849
Cash consideration	4,565,485
Total purchase price	$9,483,334

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

Cash	$626,217
Inventory	61,710
Other current assets	13,761
In-process research and development (IPR&D)	4,236,000
Other noncurrent assets	278,584
Assets acquired	5,216,272
Deferred tax liability	(179,212)

Other liabilities assumed	(306,795)
Liabilities assumed	(486,007)
Goodwill	4,753,069
Total purchase price	$9,483,334

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Our accounting for this acquisition is preliminary. The fair value estimates for the assets acquired and liabilities assumed were based upon preliminary calculations, and our estimates and assumptions are subject to change as we obtain additional information for our estimates during the measurement period (up to one year from the acquisition date). The primary areas of these preliminary estimates that are not yet finalized relate to certain tangible assets and liabilities acquired, identifiable intangible assets and tax-related items.

We acquired $61,710 of Kanuma (sebelipase alfa) inventory produced for commercial sale that is awaiting regulatory approval. 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 Synageva's lead product candidate, Kanuma (sebelipase alfa). 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 10.0%, 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 and a global distribution network to facilitate immediate 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 $179,212. This amount was primarily comprised of $586,720 and $22,393, of deferred tax liabilities related to the IPR&D and inventory acquired, respectively, offset by $231,281 and $198,620 of deferred tax assets related to NOLs and tax credits, respectively, 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.

	Three months ended		Six months ended	
	June 30, 2015	June 30, 2014	June 30, 2015	June 30, 2014
Pro forma revenue	$637,491	$514,838	$1,238,751	$1,083,040

Pro forma net income	98,568	116,251	130,289	69,393
Earnings per common share				
Basic	$0.44	$0.52	$0.58	$0.31
Diluted	$0.43	$0.51	$0.57	$0.30

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. These expenses were included in net income for the six months ended June 30, 2014;

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- 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. These expenses were included in net income for the six months ended June 30, 2014.

Acquisition-Related Costs
Acquisition-related costs associated with our business combinations for the three and six months ended June 30, 2015 and 2014 include the following:

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Transaction costs [1]	$26,799	$—	$26,799	$—
Integration costs	2,978	—	2,978	—
Changes in fair value of contingent consideration	4,044	1,989	16,023	1,951
	$33,821	$1,989	$45,800	$1,951

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

The acquisition of Synageva also resulted in $10,322 of restructuring related charges for the three and six months ended June 30, 2015. See Note 19 for additional details.

4. Inventories
Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of inventory using the weighted-average cost method.
The components of inventory are as follows:

	June 30, 2015	December 31, 2014
Raw materials	$21,287	$14,570
Work-in-process	99,575	107,170
Finished goods	113,485	54,701
	$234,347	$176,441

As of June 30, 2015 and December 31, 2014, we capitalized $79,154 and $22,005, respectively, of inventory produced for commercial sale for products awaiting regulatory approval, respectively. Included in this amount as of June 30, 2015, is $61,710 of Kanuma (sebelipase alfa) inventory.
In the first quarter 2015, we recorded an expense of $24,352 associated with a portion of a single manufacturing campaign at a third party manufacturer for Strensiq™ (asfotase alfa). The costs are comprised of raw materials, internal overhead and external production costs.

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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, 2015	December 31, 2014
Licenses, patents and purchased technology, net	$1,520	$46
Acquired IPR&D	4,823,000	587,000
Intangible assets	$4,824,520	$587,046
Goodwill	$5,007,142	$254,073

During the second quarter 2015, we recorded indefinite-lived intangible assets of $4,236,000 of purchased IPR&D from our acquisition of Synageva.

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

Balance at December 31, 2014	$254,073
Goodwill resulting from the Synageva acquisition	4,753,069
Balance at June 30, 2015	$5,007,142

6. Debt

On June 22, 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.

Under the Credit Agreement we may elect that the loans under the Credit Agreement bear 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).

Our obligations under the credit facilities are guaranteed by certain of Alexion's foreign and domestic subsidiaries and secured by liens on certain of Alexion's and its subsidiaries' equity interests, subject to certain exceptions.

The Credit Agreement requires us to comply with certain financial covenants on a quarterly basis. Further, the Credit Agreement 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. The Credit Agreement also contains customary representations and warranties, affirmative covenants and events of default, including payment defaults, breach of representations and warranties, covenant defaults and cross defaults. 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.

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.

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. At June 30, 2015, we had $3,500,000 outstanding on the term loan and zero outstanding on the revolving facility. At June 30, 2015, we had open letters of credit of $5,672, and our borrowing availability under the revolving facility was $494,328.

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

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(unaudited)
(amounts in thousands, except per share amounts)

On June 22, 2015, in connection with, and simultaneously with, the execution of the Credit Agreement described above, the 2012 Credit Agreement (Prior Credit Agreement) dated February 7, 2012 was terminated, and outstanding borrowings of $33,500 were repaid.

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, unvested restricted stock units or other contracts to issue common stock were exercised or converted into common stock, using the treasury stock method.

The following table summarizes the calculation of basic and diluted EPS for the three and six months ended June 30, 2015 and 2014:

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Net income used for basic and diluted calculation	$170,215	$166,495	$261,538	$325,849
Shares used in computing earnings per common share—basic	202,234	197,880	200,806	197,838
Weighted-average effect of dilutive securities:				
Stock awards	2,312	3,644	2,496	3,877
Shares used in computing earnings per common share—diluted	204,546	201,524	203,302	201,715
Earnings per common share:				
Basic	$0.84	$0.84	$1.30	$1.65
Diluted	$0.83	$0.83	$1.29	$1.62

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, 2015 were 2,435 and 2,387 shares of common stock, respectively, because their effect is anti-dilutive. Similarly, we excluded 1,698 and 1,151 shares from the calculation of EPS for the three and six months ended June 30, 2014, 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, 2015 and December 31, 2014 were as follows:

	June 30, 2015			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Commercial paper	$44,921	$—	$—	$44,921
Corporate bonds	88,828	59	(21)	88,866
Municipal bonds	57,519	6	(2)	57,523
Other government-related obligations:				
U.S.	8,399	—	—	8,399
Foreign	49,464	17	(15)	49,466
Bank certificates of deposit	33,550	—	—	33,550
	$282,681	$82	$(38)	$282,725

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	December 31, 2014			
	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Commercial paper	$142,495	$—	$—	$142,495
Corporate bonds	494,032	415	(581)	493,866
Municipal bonds	174,759	132	(46)	174,845
Other government-related obligations:				
U.S.	99,668	14	(71)	99,611
Foreign	193,439	100	(174)	193,365
Bank certificates of deposit	77,000	—	—	77,000
	$1,181,393	$661	$(872)	$1,181,182

The aggregate fair value of available-for-sale securities in an unrealized loss position as of June 30, 2015 and December 31, 2014 was $68,024 and $472,241, respectively. Investments that have been in a continuous unrealized loss position for more than 12 months are not material. As of June 30, 2015, 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, 2015	December 31, 2014
Cash and cash equivalents	$118,193	$167,892
Marketable securities	164,532	1,013,290
	$282,725	$1,181,182

The fair values of available-for-sale debt securities at June 30, 2015, by contractual maturity, are summarized as follows:

	June 30, 2015
Due in one year or less	$250,374
Due after one year through three years	32,351
	$282,725

As of June 30, 2015 and December 31, 2014, the fair value of our trading securities was $7,697 and $4,277, 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, 2015 and 2014.

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 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, 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. 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

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upon contract inception. At June 30, 2015, we had open contracts with notional amounts totaling $1,843,491 that qualified for hedge accounting.

The impact on accumulated other comprehensive income (AOCI) and earnings from foreign exchange contracts that qualified as cash flow hedges, for the three and six months ended June 30, 2015 and 2014 were as follows:

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
(Loss) gain recognized in AOCI, net of tax	$(22,221)	$(4,119)	$71,588	$(8,063)
Gain (loss) reclassified from AOCI to net product sales (effective portion), net of tax	$27,670	$(608)	$53,117	$500
Gain reclassified from AOCI to other income and expense (ineffective portion), net of tax	$256	$164	$1,331	$7

Assuming no change in foreign exchange rates from market rates at June 30, 2015, $84,046 of gains recognized in AOCI will be reclassified to revenue over the next 12 months.

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. 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, 2015, the notional amount of foreign exchange contracts where hedge accounting is not applied was $184,392.

We recognized a (loss) gain of $(6,660) and $(1,640), in other income and expense, for the three months ended June 30, 2015 and 2014, respectively, and $(237) and $649, for the six months ended June 30, 2015 and 2014, 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.

The following tables summarize the fair value of outstanding derivatives at June 30, 2015 and December 31, 2014:

	June 30, 2015			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	$89,327	Other current liabilities	$2,934
Foreign exchange forward contracts	Other non-current assets	82,343	Other non-current liabilities	5,486
Total fair value of derivative instruments		$171,670		$8,420

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	December 31, 2014			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	$77,348	Other current liabilities	$794
Foreign exchange forward contracts	Other non-current assets	58,698	Other non-current liabilities	86
Total fair value of derivative instruments		$136,046		$880

The fair value of our foreign exchange forward contracts that are not designated as hedging instruments was zero as of June 30, 2015 and December 31, 2014.

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 subject to such provisions:

	June 30, 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	Amounts of Assets/Liabilities Presented in the Condensed Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$171,670	$—	$ 171,670	$(8,420)	$—	$163,250
Derivative liabilities	(8,420)	—	(8,420)	8,420	—	—

	December 31, 2014					
				Gross Amounts Not Offset in the Condensed Consolidated Balance Sheet		
Description						Net Amount

	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Condensed Consolidated Balance Sheet	Amounts of Assets/Liabilities Presented in the Condensed Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	
Derivative assets	$136,046	$—	$ 136,046	$(880)	$—	$135,166
Derivative liabilities	(880)	—	(880)	880	—	—

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, 2015.

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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. During the three months ended June 30, 2015 and 2014, we repurchased 132 and 1,012 shares of our common stock at a cost of $23,537 and $156,458, respectively, and during the six months ended June 30, 2015 and 2014, we repurchased 466 and 1,149 shares of our common stock at a cost of $83,563 and $178,515, respectively. In May 2015, our Board of Directors increased the authorization of shares up to $1,000,000 for future purchases under the repurchase program, which superseded all prior repurchase programs. As previously disclosed, the Company did not repurchase any shares during the pendency of the Synageva acquisition. As of June 30, 2015, there is a total of $1,000,000 remaining for repurchases under the repurchase program.

In June 2015, in connection with our acquisition of Synageva, we issued 26,125 shares of common stock to Synageva shareholders and employees. The value of the stock was $4,917,849, and we incurred $3,864 of issuance costs.

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, 2015 and 2014:

	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

	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, 2013	$(11,502)	$(146)	$(3,827)	$(7,382)	$(22,857)
Other comprehensive income before reclassifications	(3,086)	1,111	(8,063)	552	(9,486)
Amounts reclassified from other comprehensive income	401	(1)	(507)	—	(107)

Net other comprehensive income (loss)	(2,685)	1,110	(8,570)	552	(9,593)
Balances, June 30, 2014	$(14,187)	$964	$(12,397)	$(6,830)	$(32,450)

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The table below provides details regarding significant reclassifications from AOCI during the three and six months ended June 30, 2015 and 2014:

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
	2015	2014	2015	2014	
Unrealized Gains (Losses) from Hedging Activity					
Effective portion of foreign exchange contracts	$31,622	$(695)	$60,705	$571	Net product sales
Ineffective portion of foreign exchange contracts	293	187	1,521	8	Foreign currency (loss) gain
	31,915	(508)	62,226	579	
	(3,989)	64	(7,778)	(72)	Income tax provision
	$27,926	$(444)	$54,448	$507	
Unrealized Gains (Losses) from Marketable Securities					
Realized gains on sale of securities	$22	$—	$35	$2	Investment income
	22	—	35	2	
	(8)	—	(13)	(1)	Income tax provision
	$14	$—	$22	$1	
Defined Benefit Pension Plans					
Amortization of prior service costs and actuarial losses	$(626)	$(359)	$(937)	$(438)	(a)
	(626)	(359)	(937)	(438)	
	153	31	229	37	Income tax provision
	$(473)	$(328)	$(708)	$(401)	

(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, 2015 and December 31, 2014, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

		Fair Value Measurement at June 30, 2015			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$605,523	$—	$605,523	$—
Cash equivalents	Commercial paper	$44,921	$—	$44,921	$—
Cash equivalents	Municipal bonds	$31,323	$—	$31,323	$—
Cash equivalents	Bank certificates of deposit	$33,550	$—	$33,550	$—
Cash equivalents	Other government-related obligations	$8,399	$—	$8,399	$—
Marketable securities	Mutual funds	$7,697	$7,697	$—	$—
Marketable securities	Corporate bonds	$88,866	$—	$88,866	$—
Marketable securities	Municipal bonds	$26,200	$—	$26,200	$—
Marketable securities	Other government-related obligations	$49,466	$—	$49,466	$—
Prepaid expenses and other current assets	Foreign exchange forward contracts	$89,327	$—	$89,327	$—
Other assets	Foreign exchange forward contracts	$82,343	$—	$82,343	$—
Other current liabilities	Foreign exchange forward contracts	$2,934	$—	$2,934	$—
Other liabilities	Foreign exchange forward contracts	$5,486	$—	$5,486	$—
Other current liabilities	Acquisition-related contingent consideration	$49,448	$—	$—	$49,448
Contingent consideration	Acquisition-related contingent consideration	$129,546	$—	$—	$129,546

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		Fair Value Measurement at December 31, 2014			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$176,331	$—	$176,331	$—
Cash equivalents	Commercial paper	$117,529	$—	$117,529	$—
Cash equivalents	Corporate bonds	$9,315	$—	$9,315	$—
Cash equivalents	Municipal bonds	$12,050	$—	$12,050	$—
Cash equivalents	Other government-related obligations	$23,998	$—	$23,998	$—
Cash equivalents	Bank certificates of deposit	$5,000	$—	$5,000	$—
Marketable securities	Mutual funds	$4,277	$4,277	$—	$—
Marketable securities	Commercial paper	$24,966	$—	$24,966	$—
Marketable securities	Corporate bonds	$484,551	$—	$484,551	$—
Marketable securities	Municipal bonds	$162,795	$—	$162,795	$—
Marketable securities	Other government-related obligations	$268,978	$—	$268,978	$—
Marketable securities	Bank certificates of deposit	$72,000	$—	$72,000	$—
Prepaid expenses and other current assets	Foreign exchange forward contracts	$77,348	$—	$77,348	$—
Other assets	Foreign exchange forward contracts	$58,698	$—	$58,698	$—
Other current liabilities	Foreign exchange forward contracts	$794	$—	$794	$—
Other liabilities	Foreign exchange forward contracts	$86	$—	$86	$—
Other current liabilities	Acquisition-related contingent consideration	$46,546	$—	$—	$46,546
Contingent consideration	Acquisition-related contingent consideration	$116,425	$—	$—	$116,425

There were no securities transferred between Level 1, 2 and 3 during the six months ended June 30, 2015.

Valuation Techniques
We classify mutual fund investments, 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

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understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances.

Our derivative assets and liabilities include foreign exchange 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, 2015, 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 and reimbursement 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 4.8% for developmental milestones and a weighted average cost of capital ranging from 12% 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 as development work progresses towards the achievement of the milestones.

Estimated future contingent milestone payments related to prior business combinations range from zero if no milestone events are achieved, to a maximum of $876,000 if all development, regulatory and sales-based milestones are reached. As of June 30, 2015, the fair value of acquisition-related contingent consideration was $178,994. The following table represents a roll-forward of our acquisition-related contingent consideration:

	Six months ended June 30, 2015
Balance at beginning of period	$(162,971)
Changes in fair value	(16,023)
Balance at end of period	$(178,994)

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, 2015 and 2014:

	Three months ended June 30,	Six months ended June 30,

	2015		2014		2015		2014	
Provision for income taxes	$7,077		$52,151		$22,699		$104,708	
Effective tax rate	4.0	%	23.9	%	8.0	%	24.3	%

The tax provision for the three and six months ended June 30, 2015 and 2014 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. Additionally, reflected in the tax provision for the for the three and six months ended June 30, 2015 are the benefits realized in connection with our acquisition of Synageva. These benefits primarily include current year operating losses. The tax provision for the three and six months ended June 30, 2014 also includes $2,128 attributable to our agreement with the French government that provided reimbursement for shipments of Soliris made prior to

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January 1, 2014. The remaining reduction in the effective tax rate for the three and six months ended June 30, 2015 as compared to the same period in the prior year is primarily attributable to an increase in our Federal Orphan Drug Credit and an increase in the amount of income taxed in jurisdictions with rates lower than the rate in the U.S. We continue to maintain a valuation allowance against certain other 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 were as follows:

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Service cost	$4,861	$2,622	$7,282	$4,185
Interest cost	372	200	552	400
Expected return on plan assets	(508)	(232)	(751)	(463)
Employee contributions	(900)	(482)	(1,327)	(877)
Amortization	626	359	937	438
Total net periodic benefit cost	$4,451	$2,467	$6,693	$3,683

16. Leases

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 new lease will commence upon the landlord's substantial completion of the building and will expire 12 years later, with a minimum renewal option of 7 years and a maximum renewal option of 20 years, provided that we expand our lease to include all rentable space in the building. Although we will not legally own the premises, we are deemed to be the owner of the building during the construction period based on applicable accounting guidance for build-to-suit leases due to our involvement during the construction period. Accordingly, the landlord's costs of constructing the facility are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our condensed consolidated balance sheet.

Construction of the new facility began in June 2013 and is expected to be completed in late 2015. As of June 30, 2015, we recorded a construction-in-process asset of $196,480, inclusive of the landlord's costs as well as costs incurred by Alexion, and an offsetting facility lease obligation of $126,164 associated with the new facility.

17. License Agreements

In March 2015, we entered into an agreement with a third party that allowed us to exercise an option with another third party for exclusive, worldwide, perpetual license rights to a specialized technology and other intellectual property, and we simultaneously exercised the option. Due to the early stage of these assets, we recorded expense for the payments of $47,000 during the first quarter 2015.

In March 2015, we entered into a collaboration agreement with a third party that allows us to identify and optimize drug candidates. Alexion will have the exclusive worldwide rights to develop and commercialize products arising from the collaboration. Due to the early stage of the assets we are licensing in connection with the collaboration, we recorded expense for the upfront payment of $15,000 during the first quarter 2015. In addition, we could be required to pay up to an additional $252,500 if certain development, regulatory, and commercial milestones are met over time, as well as royalties on commercial sales.

In January 2015, we entered into a license agreement with a third party to obtain an exclusive research, development and commercial license for specific therapeutic molecules. Due to the early stage of these assets, we recorded expense for the upfront payment of $50,000 during the first quarter 2015. In addition, we could be required to pay up to an additional $830,000 if certain development, regulatory, and commercial milestones are met over time, as well as royalties on commercial sales.

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In January 2014, we entered into an agreement with Moderna Therapeutics, Inc. (Moderna) that allows us to purchase ten product options to develop and commercialize treatments for rare diseases with Moderna's messenger RNA (mRNA) therapeutics platform. Alexion will lead the discovery, development and commercialization of the treatments produced through this broad, long-term strategic agreement, while Moderna will retain responsibility for the design and manufacture of the messenger RNA against selected targets. Due to the early stage of these assets, we recorded expense for an upfront payment of $100,000. We will also be responsible for funding research activities under the program. In addition, for each drug target, up to a maximum of ten targets, we could be required to make an option exercise payment of $15,000 and to pay up to an additional $120,000 with respect to a rare disease product and $400,000 with respect to a non-rare disease product in development and sales milestones if the specific milestones are met over time as well as royalties on commercial sales.

18. Commitments and Contingencies

Commitments

Manufacturing obligations

We rely on Lonza Group AG and its affiliates (Lonza), a third party manufacturer, to produce a portion of commercial and clinical quantities of Soliris and for clinical and commercial quantities of Strensiq (asfotase alfa). We have various agreements with Lonza, with remaining total non-cancellable future commitments of approximately $1,226,360. 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 July 2015, we announced a new supply agreement with Lonza whereby Lonza will construct a new manufacturing line dedicated to Alexion at their existing Portsmouth, New Hampshire facility.

In addition, we have non-cancellable commitments of approximately $40,950 with other third party manufacturers.

Contingent Liabilities

On an ongoing basis, we are involved in various claims, and legal proceedings, none of which we deem material to our operations. 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 adjustments 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.

As previously disclosed, 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 in various countries. The SEC also

seeks information related to Alexion's recalls of specific lots of Soliris and related securities disclosures. Alexion is cooperating with the SEC's investigation, which is in its early stages. At this time, Alexion is unable to predict the duration, scope or outcome of the SEC investigation. Given the early stage of this investigation, management does 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 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 an FDA inspection which concluded in August 2012. At the conclusion of that inspection, the FDA issued a Form 483 Inspectional Observations, to which we responded in August 2012 and provided additional information to the FDA in September and December 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. At the conclusion of another inspection of ARIMF in August 2014, the FDA issued a Form 483 with three inspectional observations, none of which was designated as a repeat observation to the Warning Letter. The observations are inspectional and do not represent a final FDA determination of compliance. We continue

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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 reasonable estimated.

19. Restructuring

In conjunction with the acquisition and integration of Synageva, we recorded restructuring expense of $10,322 related to employee costs in the second quarter 2015. We currently estimate incurring approximately $5,000 to $10,000 of additional restructuring related charges in 2015. We expect to pay all accrued amounts related to this restructuring activity within twelve months.

In the fourth quarter 2014, we announced plans to relocate our European headquarters from Lausanne to Zurich, Switzerland. The relocation of the European headquarters will support our operational needs based on growth in the European region. The activities primarily occurring at our Lausanne site will be relocated to our Zurich, Cheshire, Connecticut, and Dublin, Ireland locations. As a result of this action, we recorded restructuring expenses of $15,365 related to employee costs in the fourth quarter 2014. During the three and six months ended June 30, 2015 we incurred additional restructuring costs of $5,902 and $12,954, respectively.

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, 2015:

	Three months ended June 30, 2015				Six months ended June 30, 2015			
	Employee Separation Costs	Contract Termination Costs	Other Costs	Total	Employee Separation Costs	Contract Termination Costs	Other Costs	Total
Liability, beginning of period	$22,326	$ —	$91	$22,417	$15,365	$ —	$—	$15,365
Restructuring expenses	14,324	—	1,027	15,351	18,611	—	1,118	19,729
Cash settlements	(1,816)	—	(841)	(2,657)	(1,816)	—	(841)	(2,657)
Adjustments to previous estimates	873	—	—	873	3,547	—	—	3,547
Liability, end of period	$35,707	$ —	$277	$35,984	$35,707	$ —	$277	$35,984

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® (eculizumab) for its approved indications and any expanded uses, timing and effect of sales of Soliris in various markets worldwide, pricing for Soliris, level of insurance coverage and reimbursement for Soliris, level of future Soliris sales and collections, timing regarding development and regulatory approvals for additional indications or in additional territories for Soliris, 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 483 issued by the FDA in August 2014, 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 Soliris and our drug candidates in the patient, physician and payer communities, the safety and efficacy of Soliris and our product candidates, estimates of the potential markets and estimated commercialization dates for Soliris and our drug candidates around the world, sales and marketing plans, any changes in the current or anticipated market demand or medical need for Soliris or our drug 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 Strensiq (asfotase alfa) and our other 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

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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 Soliris infringes their intellectual property, estimates of the capacity of manufacturing and other service facilities to support Soliris 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 Soliris, 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 government investigations, the short and long term effects of other government healthcare measures, and the effect of shifting foreign exchange rates. Words such as “anticipates,” “expects,” “intends,” “plans,” “believes,” “seeks,” “estimates,” variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. 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.

Business

We are a biopharmaceutical company focused on serving patients with devastating and rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Our marketed product Soliris is the first and only therapeutic approved for patients with either of two severe and ultra-rare disorders resulting from chronic uncontrolled activation of the complement component of the immune system: paroxysmal nocturnal hemoglobinuria (PNH), a life-threatening and ultra-rare genetic blood disorder, and atypical hemolytic uremic syndrome (aHUS), a life-threatening and ultra-rare genetic disease.

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. 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).

Soliris was approved for the treatment of PNH by the FDA and the European Commission (EC) in 2007 and by Japan’s Ministry of Health, Labour and Welfare (MHLW) in 2010, and has been approved in several other territories. Additionally, Soliris has been granted orphan drug designation for the treatment of PNH in the United States, Europe, Japan and several other territories.

In September and November 2011, Soliris was approved by the FDA and EC, respectively, for the treatment of pediatric and adult patients with aHUS in the United States and Europe. In September 2013, the MHLW approved Soliris for the treatment of pediatric and adult patients with aHUS in Japan. 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. In addition, the FDA and EC have granted Soliris orphan drug designation for the treatment of patients with aHUS.

We are also establishing a global metabolic rare disease franchise with the development of two late-stage therapies, Strensiq® (asfotase alfa) for the treatment of hypophasphatasia (HPP) and Kanuma® (Sebelipase alfa) for the treatment of 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 Soliris 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.

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We were incorporated in 1992 and began commercial sale of Soliris in 2007. In June 2015, we acquired all of the outstanding shares of common stock of Synageva BioPharma Corp. (Synageva), a publicly-held clinical-stage biotechnology company. We financed the acquisition with existing cash, proceeds from a new credit facility and exchange of shares of common stock.

Products and Development Programs

We focus our product development programs on life-transforming therapeutics for severe and life-threatening 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

In addition to our marketed products above, we received regulatory approval for Strensiq (asfotase alfa) for the treatment of patients with HPP in Japan in July 2015.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

Soliris is the first and only therapy approved for the treatment of patients with PNH, a debilitating and life-threatening ultra-rare blood disorder in which an acquired genetic deficiency causes uncontrolled complement activation which leads to life-threatening complications. We continue to work with researchers to expand the base of knowledge in PNH and the utility of Soliris to treat patients with PNH. In 2013, the EC extended the Soliris label to include pediatric patients with PNH. The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommends that the renewal be granted with unlimited validity. We are sponsoring a multinational registry to gather information regarding the natural history of patients with PNH and the longer term outcomes during Soliris treatment. In April 2014, the EC approved an update to the EU label that supports Soliris treatment for patients with PNH regardless of history of transfusion and additional updates to inform physicians to make treatment decisions based on elevated hemolysis and the presence of common symptoms associated with PNH.

Atypical Hemolytic Uremic Syndrome (aHUS)

aHUS is a chronic and life-threatening ultra-rare genetic disease in which uncontrolled complement activation causes blood clots in small blood vessels throughout the body or TMA leading to kidney failure, stroke, heart attack and death. Soliris is the first and only therapy approved for the treatment of pediatric and adult patients with aHUS. In May 2014, the FDA approved conversion of Soliris accelerated approval in aHUS to regular approval for the treatment of adult and pediatric patients with aHUS to inhibit complement-mediated TMA. In April 2014, the EC approved an update to the EU label for Soliris treatment for patients with aHUS that included new efficacy data which specifies that longer-term treatment with Soliris is associated with a greater proportion of patients achieving clinically significant benefits, including complete TMA response and hematologic normalization, as well as the importance of sustained Soliris therapy.

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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	Myasthenia Gravis (MG)	Phase III
		Neuromyelitis Optica (NMO)	Phase III
	Transplant	Delayed Kidney Transplant Graft Function	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
Strensiq (asfotase alfa)	Metabolic Disorders	Hypophosphatasia (HPP)	Phase II
Kanuma (sebelipase alfa)	Metabolic Disorders	Lysosomal Acid Lipase Deficiency (LAL-D)	Phase III
cPMP (ALXN 1101)	Metabolic Disorders	MoCD Type A	Phase II
ALXN 1007	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
ALXN 1210	Next Generation Complement Inhibitor		Phase I
ALXN 5500	Next Generation Complement Inhibitor		Phase I

* Investigator Initiated Trial

Soliris (eculizumab)
Neurology
Myasthenia Gravis (MG)
MG 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 generalized MG. The FDA, EC and MHLW have granted orphan drug designation for eculizumab as a treatment for patients with MG.
Neuromyelitis Optica (NMO)
NMO 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 NMO. The FDA, EC, and MHLW have each granted orphan designation for eculizumab as a treatment for patients with NMO.
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 ongoing in a single, multinational, placebo-controlled DGF registration trial. 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.

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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. The study was re-opened in October 2013 to enroll additional patients at the request of participating investigators. Enrollment and dosing in this expanded trial have been completed 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 at the European Society of Organ Transplant in Vienna, Austria. In May 2015, new data from the Phase II single-arm deceased-donor transplant trial of eculizumab in prevention of acute AMR was presented at the American Transplant Congress and were 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 to commence a clinical trial with eculizumab as a treatment for patients with AMR.

The EC granted orphan drug designation to eculizumab for the prevention of graft rejection following solid organ transplantation.

Shiga-toxin producing Escherichia coli-hemolytic uremic syndrome (STEC-HUS)

Following an evaluation of our development portfolio and our STEC-HUS program, we notified European regulators that we elected to discontinue development of eculizumab for treatment of patients with STEC-HUS. We are aware that independent investigators are examining the role of eculizumab for the treatment of patients with STEC-HUS.

Strensiq (asfotase alfa)

Hypophosphatasia (HPP)

HPP is an ultra-rare, genetic, and life-threatening metabolic disease characterized by impaired phosphate and calcium regulation, leading to progressive damage to multiple vital organs including destruction and deformity of bones, profound muscle weakness, seizures, impaired renal function, and respiratory failure.

Strensiq (asfotase alfa), a targeted enzyme replacement therapy in Phase II clinical trials for patients with HPP, 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 2013, Strensiq (asfotase alfa) received Breakthrough Therapy Designation from the FDA. In September 2014, the MHLW granted orphan drug designation to Strensiq (asfotase alfa) for the treatment of patients with HPP.

In 2014, we filed for regulatory approval with the FDA, EMA and MHLW. In March 2015, the FDA accepted, for Priority Review, our Biologics License Application (BLA) for Strensiq (asfotase alfa) for treatment of patients with infantile- and juvenile-onset HPP. In June 2015, the CHMP adopted a positive opinion recommending marketing authorization of Strensiq (asfotase alfa) for long-term enzyme treatment of patients with pediatric onset HPP. Based on the CHMP's positive recommendation, final decision from the EC is expected in the third quarter of 2015. In July 2015, Japan’s MHLW approved Strensiq (asfotase alfa) for the treatment of patients with HPP.

Kanuma (sebelipase alfa)

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

LAL-D is a serious, life-threatening 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. This 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. LAL-D affects patients of all ages with sudden and unpredictable clinical complications manifesting from infancy through adulthood. The decreased LAL enzyme activity can be diagnosed with a simple blood test.

Kanuma (sebelipase alfa), a recombinant form of the human LAL enzyme, is an enzyme-replacement therapy under development for patients with LAL-D. The U.S. Food and Drug Administration (FDA) has accepted for review the BLA for Kanuma (sebelipase alfa) and granted the request for Priority Review, and the EMA has validated the MAA for Kanuma (sebelipase alfa) and granted the request for accelerated assessment. In addition, a New Drug Application (NDA) for Kanuma (sebelipase alfa) has been submitted to Japan's MHLW.

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In June 2015, the CHMP adopted a positive opinion recommending marketing authorization of Kanuma (sebelipase alfa) for long-term enzyme replacement therapy in patients of all ages with LAL-D. Based on the CHMP's positive recommendation, final decision from the EC is expected in the third quarter 2015.

cPMP (ALXN 1101)
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 are conducting 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.

ALXN 1007
ALXN 1007 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. 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 addition, enrollment is ongoing in a Phase II proof-of-concept study in patients with non-criteria manifestations of anti-phospholipid syndrome (APS). APS is an ultra-rare autoimmune, hypercoagulable state caused by antiphospholipid antibodies.

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 U.S. Food and Drug Administration (FDA) in April 2013 and by the EMA in June 2013. It received Fast Track designation by the FDA in January 2015. In June 2015, the first-in-human trial of patients with MPS IIIB reached its targeted enrollment of nine patients, and the trial is ongoing.
Manufacturing
We currently rely on internal manufacturing facilities and third party contract manufacturers to supply clinical and commercial quantities of our commercial products and product candidates. Our internal manufacturing facilities include Alexion's 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 finishing, packaging, filling and labeling.

We have various agreements with Lonza through 2028, with remaining total non-cancellable commitments of approximately $1,226,360 through 2028. 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. In July 2015, we announced a new supply agreement with Lonza whereby Lonza will construct a new manufacturing line dedicated to Alexion manufacturing at their existing Portsmouth, New Hampshire facility.

In addition, we have non-cancellable commitments of approximately $40,950 through 2019 with other third party manufacturers.

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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 an FDA inspection which concluded in August 2012. At the conclusion of that inspection, the FDA issued a Form 483 Inspectional Observations, to which we responded in August 2012 and provided additional information to the FDA in September and December 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. At the conclusion of another inspection of ARIMF in August 2014, the FDA issued a Form 483 with three inspectional observations, none of which were designated as a repeat observation to the Warning Letter. 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 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. To the extent that circumstances related to this matter change, the impact could have a material adverse effect on our financial operations.

The EMA inspected ARIMF in January 2013, and issued a cGMP certificate in May 2013.

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 Soliris and other clinical and commercial products. We have also initiated the construction of office, laboratory and packaging facilities on property in Dublin, Ireland, which we purchased 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.

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, 2014. 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, 2014. 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 are also allowed 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

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direct deduction from the carrying amount of the related debt. The standard is effective for interim and annual periods beginning after December 15, 2015, with early adoption permitted, and requires a retrospective method of adoption. We will adopt the provisions of the guidance for the balance sheet disclosures of debt issuance costs in 2016.

Results of Operations

Net Product Sales

The following table summarizes net product sales for the three and six months ended June 30, 2015 and 2014:

	Three months ended June 30,			Six months ended June 30,		
	2015	2014	$ Variance	2015	2014	$ Variance
Net product sales	$635,983	$512,495	$123,488	$1,236,316	$1,079,111	$157,205

In March 2014, we entered into an agreement with the French government which positively impacts prospective reimbursement of Soliris and also provides for reimbursement for shipments made in years prior to January 1, 2014. As a result of the agreement, in the first quarter of 2014, we recognized $87,830 of net product sales from Soliris in France relating to years prior to January 1, 2014.

Exclusive of the $87,830 recognized related to prior years, net product revenues increased by $123,488 and $245,035 for the three and six months ended June 30, 2015 compared to the three and six months ended June 30, 2014. The components of this increase in revenues, are as follows:

	Three months ended June 30, 2015	Six months ended June 30, 2015
Components of change:		
Price	1.0 %	1.0 %
Volume	31.0 %	31.0 %
Foreign exchange	(8.0)%	(7.0)%
Total change in net product sales	24.0 %	25.0 %

The increase in net product sales for the three and six months ended June 30, 2015, as compared to the same period in 2014, was primarily due to an increase in unit volumes of 31.0% due to increased physician demand globally for Soliris therapy for patients with PNH or aHUS during the respective periods.

Price had a positive impact on net product sales of 1.0% for the three and six months ended June 30, 2015.

Foreign exchange had a negative impact of 8.0% and 7.0% for the three and six months ended June 30, 2015, as compared to the same period in 2014. The negative impact on foreign exchange of $38,999 and $70,398, or 8.0% and 7.0%, was due to changes in foreign currency exchange rates (inclusive of hedging activity) versus the U.S. dollar for the three and six months ended June 30, 2015. The negative impact was primarily due to the weakening of the Euro, Japanese Yen and Russian Ruble. Offsetting the impact of the stronger dollar, we recorded a gain in revenue of $31,623 and $60,705 related to our foreign currency cash flow hedging program for the three and six months ended June 30, 2015. We expect the strong dollar compared to other currencies, especially the Euro, Japanese Yen and Russian Ruble, to continue to have a negative impact on revenue in 2015 compared to 2014.

Cost of Sales

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

The following table summarizes cost of sales the three and six months ended June 30, 2015 and 2014:

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Cost of sales	$52,007	$39,626	$121,406	$72,565
Cost of sales as a percentage of net product sales	8.2 %	7.7 %	9.8 %	6.7 %

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 (asfotase alfa). The costs are comprised of raw materials, internal

overhead and external production costs. We do not expect this expense will impact the clinical supply of inventory or the expected

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commercial launch of Strensiq (asfotase alfa) later in 2015, and we do not expect further material financial impact related to this campaign.

In the first quarter 2014, we entered into a settlement agreement with a third party related to the calculation of royalties payable to such third party under a pre-existing license agreement. Based on this settlement agreement, we recorded a reversal of accrued royalties of $5,124 as a reduction of cost of sales. Also, in the first quarter of 2014, we recorded the incremental impact in cost of sales of $2,055 for additional royalties related to the $87,830 of net product sales from prior year shipments.

Exclusive of the items mentioned above, cost of sales as a percentage of net product sales were 8.2% and 7.9% for the three and six months ended June 30, 2015 and 7.7% and 7.6% for the three and six months ended June 30, 2014.

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 eculizumab 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 facility, 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,		
	2015	2014	$ Variance	2015	2014	$ Variance
Clinical development	$33,859	$26,382	$7,477	$62,866	$50,299	$12,567
Product development	27,843	12,142	15,701	49,169	25,181	23,988
Licensing agreements	1,750	—	1,750	114,250	101,925	12,325
Discovery research	9,022	2,349	6,673	15,066	4,930	10,136
Total external direct expenses	72,474	40,873	31,601	241,351	182,335	59,016
Payroll and benefits	47,827	44,480	3,347	92,319	88,499	3,820
Operating and occupancy	5,786	3,765	2,021	8,876	6,641	2,235
Depreciation and amortization	5,606	3,436	2,170	10,227	6,536	3,691
Total other R&D expenses	59,219	51,681	7,538	111,422	101,676	9,746
Research and development expense	$131,693	$92,554	$39,139	$352,773	$284,011	$68,762

For the three months ended June 30, 2015, the increase of $39,139 in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase of $7,477 in external clinical development expenses related primarily to an expansion of studies within our eculizumab and other clinical programs (see table below).
-

Increase of $15,701 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 $6,673 in discovery research expenses primarily related to increases in external research expenses associated with our Moderna agreement and other external research fees.

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

For the six months ended June 30, 2015, the increase of $68,762 in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase of $12,567 in external clinical development expenses related primarily to an expansion of studies within our eculizumab and other clinical programs (see table below).
- Increase of $23,988 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 $12,325 in licensing agreements primarily due to the upfront payments of $112,000 in the first quarter of 2015 as compared to $100,000 in the first quarter of 2014.
- Increase of $10,136 in discovery research expenses primarily related to increases in external research expenses associated with our Moderna agreement and other external research fees.

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 June 30,		$	Six months ended June 30,		$
	2015	2014	Variance	2015	2014	Variance
External direct expenses						
Eculizumab	$18,670	$17,235	$1,435	$36,579	$32,731	$3,848
Asfotase alfa	5,411	5,105	306	9,682	9,347	335
cPMP	2,346	1,855	491	3,900	3,408	492
Other programs	6,746	1,212	5,534	9,702	2,813	6,889
Unallocated	686	975	(289)	3,003	2,000	1,003
	$33,859	$26,382	$7,477	$62,866	$50,299	$12,567

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 Soliris; human resources; finance, legal, information technology and support personnel expenses; and other corporate costs such as telecommunications, insurance, audit, government affairs and our global corporate compliance program.

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

	Three months ended June 30,		$	Six months ended June 30,		$
	2015	2014	Variance	2015	2014	Variance
Salary, benefits and other labor expense	$148,634	$95,338	$53,296	$272,737		