ALEXION PHARMACEUTICALS INC
Form 10-Q
April 24, 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 March 31, 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	199,576,769
Class	Outstanding as of April 21, 2015

Alexion Pharmaceuticals, Inc.
Contents

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

	March 31, 2015	December 31, 2014
Assets		
Current Assets:		
Cash and cash equivalents	$916,814	$943,999
Marketable securities	1,008,278	1,017,567
Trade accounts receivable, net	479,883	432,888
Inventories	174,498	176,441
Prepaid expenses and other current assets	273,514	225,134
Total current assets	2,852,987	2,796,029
Property, plant and equipment, net	440,487	392,248
Intangible assets, net	587,035	587,046
Goodwill	254,073	254,073
Other assets	280,343	172,566
Total assets	$4,414,925	$4,201,962
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$52,869	$44,016
Accrued expenses	308,407	395,232
Deferred revenue	106,616	58,837
Current portion of long-term debt	45,500	48,000
Other current liabilities	67,047	60,655
Total current liabilities	580,439	606,740
Long-term debt, less current portion	—	9,500
Contingent consideration	126,862	116,425
Facility lease obligation	114,912	107,099
Other liabilities	75,810	60,180
Total liabilities	898,023	899,944
Commitments and contingencies (Note 17)		
Stockholders' Equity:		
Preferred stock, $.0001 par value; 5,000 shares authorized, no shares issued or outstanding	—	—
Common stock, $.0001 par value; 290,000 shares authorized; 202,876 and 201,944 shares issued at March 31, 2015 and December 31, 2014, respectively	20	20
Additional paid-in capital	2,713,050	2,592,167
Treasury stock, at cost, 3,222 and 2,888 shares at March 31, 2015 and December 31, 2014, respectively	(442,990)	(382,964)
Accumulated other comprehensive income	119,489	56,785
Retained earnings	1,127,333	1,036,010
Total stockholders' equity	3,516,902	3,302,018
Total liabilities and stockholders' equity	$4,414,925	$4,201,962

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

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

	Three months ended March 31,	
	2015	2014
Net product sales	$600,333	$566,616
Cost of sales	69,399	32,939
Operating expenses:		
Research and development	221,080	191,457
Selling, general and administrative	187,116	129,291
Impairment of intangible asset	—	3,464
Acquisition-related costs	11,979	(38)
Restructuring expenses	7,052	—
Total operating expenses	427,227	324,174
Operating income	103,707	209,503
Other income and expense:		
Investment income	2,884	2,213
Interest expense	(651)	(1,063)
Foreign currency gain	1,005	1,258
Income before income taxes	106,945	211,911
Income tax provision	15,622	52,557
Net income	$91,323	$159,354
Earnings per common share		
Basic	$0.46	$0.81
Diluted	$0.45	$0.79
Shares used in computing earnings per common share		
Basic	199,361	197,797
Diluted	202,034	201,804

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 March 31,	
	2015	2014
Net income	$91,323	$159,354
Other comprehensive income (loss), net of tax:		
Foreign currency translation	(5,388)	506
Unrealized gains on marketable securities	1,057	811
Unrealized losses on pension obligation	(252)	—
Unrealized gains (losses) on hedging activities, net of tax of $38,175, and $(1,245), respectively	67,287	(4,895)
Other comprehensive income (loss), net of tax	62,704	(3,578)
Comprehensive income	$154,027	$155,776

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)

	Three months ended March 31,	
	2015	2014
Cash flows from operating activities:		
Net income	$91,323	$159,354
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	10,578	9,268
Impairment of intangible asset	—	3,464
Change in fair value of contingent consideration	11,979	(38)
Share-based compensation expense	42,797	23,840
Premium amortization of available-for-sale securities	3,178	4,175
Deferred taxes	(24,823)	(58,311)
Reduction in taxes payable due to excess tax benefit from stock options	(52,521)	(130,407)
Other	3,027	597
Changes in operating assets and liabilities:		
Accounts receivable	(58,918)	63
Inventories	2,626	(20,900)
Prepaid expenses and other assets	(38,980)	33,633
Accounts payable, accrued expenses and other liabilities	(13,659)	(60,680)
Deferred revenue	46,427	4,887
Net cash provided by (used in) operating activities	23,034	(31,055)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(166,319)	(145,565)
Proceeds from maturity or sale of available-for-sale securities	176,256	99,250
Purchases of trading securities	(2,236)	(1,219)
Purchases of other investments	—	(25,000)
Purchases of property, plant and equipment	(57,075)	(17,733)
Other	951	70
Net cash used in investing activities	(48,423)	(90,197)
Cash flows from financing activities:		
Payments on term loan	(12,000)	(19,500)
Excess tax benefit from stock options	52,521	130,407
Repurchase of common stock	(60,026)	(22,057)
Net proceeds from the exercise of stock options	24,882	30,404
Other	(303)	(42)
Net cash provided by financing activities	5,074	119,212
Effect of exchange rate changes on cash	(6,870)	468
Net change in cash and cash equivalents	(27,185)	(1,572)
Cash and cash equivalents at beginning of period	943,999	529,857
Cash and cash equivalents at end of period	$916,814	$528,285
Supplemental cash flow disclosures from investing and financing activities:		
Construction in process related to facility lease obligation	$7,813	$6,187
Accrued expenses for purchases of property, plant and equipment	$11,436	$—

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

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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 severe and ultra-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 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 ultra-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 months ended March 31, 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, 2016 and allows for adoption using a full retrospective method, or a modified retrospective method. In April 2015, the FASB proposed a one year deferral of the effective date of this standard to annual periods ending after December 15, 2017, along with an option to permit companies to early adopt the standard for annual periods beginning after December 15, 2016. We are currently assessing the method of adoption and the expected impact the new standard has on our financial position and results of operations.

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

3. 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:

	March 31, 2015	December 31, 2014
Raw materials	$14,425	$14,570
Work-in-process	77,932	107,170
Finished goods	82,141	54,701
	$174,498	$176,441

As of March 31, 2015 and December 31, 2014, we capitalized $23,377 and $22,005 of inventory produced for commercial sale for products awaiting regulatory approval, respectively. 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.

4. Intangible Assets and Goodwill

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

	March 31, 2015	December 31, 2014
Licenses, patents and purchased technology, net	$35	$46
Acquired in-process research and development	587,000	587,000
Intangible assets	$587,035	$587,046
Goodwill	$254,073	$254,073

5. Debt

In February 2012, we entered into a credit agreement, as amended (the Credit Agreement) with a syndicate of banks that provides for a $240,000 senior secured term loan facility payable in equal quarterly installments of $12,000 starting June 30, 2012 and a $200,000 senior secured revolving credit facility through February 7, 2017. In addition to borrowings upon prior notice, the revolving credit facility includes borrowing capacity in the form of letters of credit up to $60,000 and borrowings on same-day notice, referred to as swingline loans, of up to $10,000. 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 by an aggregate amount not to exceed $150,000.

As of March 31, 2015, we had $45,500 outstanding on the term loan. As of March 31, 2015, we had open letters of credit of $9,938, and our borrowing availability under the revolving facility was $190,062.

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

6. 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.

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The following table summarizes the calculation of basic and diluted EPS for the three months ended March 31, 2015 and 2014:

	Three months ended March 31,	
	2015	2014
Net income used for basic and diluted calculation	$91,323	$159,354
Shares used in computing earnings per common share—basic	199,361	197,797
Weighted-average effect of dilutive securities:		
Stock awards	2,673	4,007
Shares used in computing earnings per common share—diluted	202,034	201,804
Earnings per common share:		
Basic	$0.46	$0.81
Diluted	$0.45	$0.79

We exclude from EPS the weighted-average number of securities whose effect is anti-dilutive. Excluded from the calculation of EPS for the three months ended March 31, 2015 and 2014 were 2,248 and 1,641 shares of common stock, respectively, because their effect is anti-dilutive.

7. 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 March 31, 2015 and December 31, 2014 were as follows:

	March 31, 2015			
	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Commercial paper	$181,764	$—	$—	$181,764
Corporate bonds	539,271	1,071	(154)	540,188
Municipal bonds	214,707	126	(66)	214,767
Other government-related obligations:				
U.S.	141,810	43	(23)	141,830
Foreign	225,566	330	(31)	225,865
Bank certificates of deposit	59,002	—	—	59,002
	$1,362,120	$1,570	$(274)	$1,363,416

	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 March 31, 2015 and December 31, 2014 was $359,768 and $472,241, respectively. These investments have been in a continuous unrealized loss

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position for less than 12 months. As of March 31, 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:

	March 31, 2015	December 31, 2014
Cash and cash equivalents	$361,685	$167,892
Marketable securities	1,001,731	1,013,290
	$1,363,416	$1,181,182

The fair values of available-for-sale debt securities at March 31, 2015, by contractual maturity, are summarized as follows:

	March 31, 2015
Due in one year or less	$782,688
Due after one year through three years	580,728
	$1,363,416

As of March 31, 2015 and December 31, 2014, the fair value of our trading securities was $6,547 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 months ended March 31, 2015.

8. 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 the hedges of revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. These hedges are designated as cash flow hedges upon contract inception. At March 31, 2015, we have open contracts with notional amounts totaling $1,728,774 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 months ended March 31, 2015 and 2014 were as follows:

	Three months ended March 31,	
	2015	2014
Gain (loss) recognized in AOCI, net of tax	$93,809	$(3,944)
Gain reclassified from AOCI to net product sales (effective portion), net of tax	$25,447	$1,108
Gain (loss) reclassified from AOCI to other income and expense (ineffective portion), net of tax	$1,075	$(157)

Assuming no change in foreign exchange rates from market rates at March 31, 2015, $112,908 of gain 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

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(amounts in thousands, except per share amounts)

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 March 31, 2015, the notional amount of foreign exchange contracts where hedge accounting is not applied was $187,976.
We recognized a gain of $6,423 and $2,289, in other income and expense, for the three months ended March 31, 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 March 31, 2015 and December 31, 2014:

	March 31, 2015			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	$116,092	Other current liabilities	$336
Foreign exchange forward contracts	Other non-current assets	125,374	Other non-current liabilities	66
Total fair value of derivative instruments		$241,466		$402

	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

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The fair value of our foreign exchange forward contracts that are not designated as hedging instruments was zero as of March 31, 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:

	March 31, 2015					
				Gross Amounts Not Offset in the Condensed Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Condensed Consolidated Balance Sheet	Net Amounts of Assets/Liabilities Presented in the Condensed Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$241,466	$—	$ 241,466	$(402)	$—	$241,064
Derivative liabilities	(402)	—	(402)	402	—	—

	December 31, 2014					
				Gross Amounts Not Offset in the Condensed Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Condensed Consolidated Balance Sheet	Net Amounts of Assets/Liabilities Presented in the Condensed Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$136,046	$—	$ 136,046	$(880)	$—	$135,166
Derivative liabilities	(880)	—	(880)	880	—	—

9. 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 March 31, 2015.

10. Stockholders' Equity

In November 2012, our Board of Directors authorized the repurchase of up to $400,000 of our common stock and in December of 2014 they authorized the repurchase of an additional $500,000 of our common stock. The repurchase program does not have an expiration date and we are not obligated to acquire a particular number of shares. The program may be discontinued at any time at the Company's discretion. Under the program, we repurchased 334 and 137 shares of our common stock at a cost of $60,026 and $22,057 during the three months ended March 31, 2015 and 2014, respectively. As of March 31, 2015, there is a total of $459,686 remaining for repurchases under the repurchase program.

Subsequent to March 31, 2015, we repurchased 126 shares of our common stock under our repurchase program at a cost of $22,413.

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

11. Other Comprehensive Income and Accumulated Other Comprehensive Income

The following tables summarize the changes in AOCI, by component, for the three months ended March 31, 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	(488)	1,065	93,809	(5,388)	88,998
Amounts reclassified from other comprehensive income	236	(8)	(26,522)	—	(26,294)
Net other comprehensive income (loss)	(252)	1,057	67,287	(5,388)	62,704
Balances, March 31, 2015	$(16,822)	$823	$154,595	$(19,107)	$ 119,489

	Defined Benefit Pension Plan	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	(72)	812	(3,944)	506	(2,698)
Amounts reclassified from other comprehensive income	72	(1)	(951)	—	(880)
Net other comprehensive income (loss)	—	811	(4,895)	506	(3,578)
Balances, March 31, 2014	$(11,502)	$665	$(8,722)	$(6,876)	$ (26,435)

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(amounts in thousands, except per share amounts)

The table below provides details regarding significant reclassifications from AOCI during the three months ended March 31, 2015 and 2014:

Details about Accumulated Other Comprehensive Income Components	Amount Reclassified From Accumulated Other Comprehensive Income during the three months ended March 31,		Affected Line Item in the Condensed Consolidated Statements of Operations
	2015	2014	
Unrealized Gains (Losses) from Hedging Activity			
Effective portion of foreign exchange contracts	$29,083	$1,266	Net product sales
Ineffective portion of foreign exchange contracts	1,228	(179)	Foreign currency gain
	30,311	1,087	
	(3,789)	(136)	Income tax provision
	$26,522	$951	
Unrealized Gains (Losses) from Marketable Securities			
Realized gains on sale of securities	$13	$2	Investment income
	13	2	
	(5)	(1)	Income tax provision
	$8	$1	
Defined Benefit Pension Plans			
Amortization of prior service costs and actuarial losses	$(311)	$(79)	(a)
	(311)	(79)	
	75	7	Income tax provision
	$(236)	$(72)	

(a) This AOCI component is included in the computation of net periodic pension benefit cost (see Note 14 for additional details).

12. 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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(amounts in thousands, except per share amounts)

The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of March 31, 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 March 31, 2015			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$192,281	$—	$192,281	$—
Cash equivalents	Commercial paper	$151,879	$—	$151,879	$—
Cash equivalents	Corporate bonds	$39,088	$—	$39,088	$—
Cash equivalents	Municipal bonds	$51,750	$—	$51,750	$—
Cash equivalents	Bank certificates of deposit	$57,002	$—	$57,002	$—
Cash equivalents	Other government-related obligations	$61,966	$—	$61,966	$—
Marketable securities	Mutual funds	$6,547	$6,547	$—	$—
Marketable securities	Commercial paper	$29,885	$—	$29,885	$—
Marketable securities	Corporate bonds	$501,100	$—	$501,100	$—
Marketable securities	Municipal bonds	$163,017	$—	$163,017	$—
Marketable securities	Other government-related obligations	$305,729	$—	$305,729	$—
Marketable securities	Bank certificates of deposit	$2,000	$—	$2,000	$—
Other current assets	Foreign exchange forward contracts	$116,092	$—	$116,092	$—
Other assets	Foreign exchange forward contracts	$125,374	$—	$125,374	$—
Other current liabilities	Foreign exchange forward contracts	$336	$—	$336	$—
Other liabilities	Foreign exchange forward contracts	$66	$—	$66	$—
Other current liabilities	Acquisition-related contingent consideration	$48,088	$—	$—	$48,088
Contingent consideration	Acquisition-related contingent consideration	$126,862	$—	$—	$126,862

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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	$—
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 three months ended March 31, 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 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.

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As of March 31, 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 March 31, 2015, the fair value of acquisition-related contingent consideration was $174,950. The following table represents a roll-forward of our acquisition-related contingent consideration:

	March 31, 2015
Balance at beginning of period	$(162,971)
Changes in fair value	(11,979)
Balance at end of period	$(174,950)

13. Income Taxes

The following table provides a comparative summary of our income tax provision and effective tax rate for the three months ended March 31, 2015 and 2014:

	Three months ended March 31,	
	2015	2014
Provision for income taxes	15,622	52,557
Effective tax rate	14.6 %	24.8 %

The tax provision for the three months ended March 31, 2015 and 2014 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. The tax provision for the three months ended March 31, 2014 also includes $2,652 attributable to our agreement with the French government that provided reimbursement for shipments of Soliris made prior to January 1, 2014. The remaining reduction in the effective tax rate for the three months ended March 31, 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.

14. 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.

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The components of net periodic benefit cost are as follows:

	Three months ended March 31,	
	2015	2014
Service cost	$2,421	$1,563
Interest cost	180	200
Expected return on plan assets	(243)	(231)
Employee contributions	(427)	(395)
Amortization	311	79
Total net periodic benefit cost	$2,242	$1,216

15. 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 March 31, 2015, we recorded a construction-in-process asset of $148,470, inclusive of the landlord's costs as well as costs incurred by Alexion, and an offsetting facility lease obligation of $114,912 associated with the new facility.

16. 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.

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.

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17. Commitments and Contingencies

Commitments

Lonza Agreement

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 $413,150. 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.

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.

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 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. To the extent that circumstances related to this matter change, the impact could have a material adverse effect on our financial operations.

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18. Restructuring

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 of 2014. During the three months ended March 31, 2015 we incurred additional restructuring costs of $7,052. The following table presents a reconciliation of the restructuring reserve for the three months ended March 31, 2015:

	Employee Separation Costs	Contract Termination Costs	Other Costs	Total
Balance at 12/31/2014	$15,365	$—	$—	$15,365
Restructuring Charges	4,287	—	91	4,378
Cash Settlements	—	—	—	—
Adjustments to previous estimates	2,674	—	—	2,674
Balance at 3/31/2015	$22,326	$—	$91	$22,417

The restructuring reserve of $22,417 is recorded in accrued expenses on the Company's condensed consolidated balance sheet as of March 31, 2015.

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

Note Regarding Forward-Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements that 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 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 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, 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 severe and ultra-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 evaluating additional potential indications for Soliris in severe and devastating diseases in which we believe that uncontrolled complement activation is the underlying mechanism, and we are progressing in various stages of development with additional biotechnology product candidates as treatments for patients with severe and life-threatening ultra-rare disorders. We were incorporated in 1992 and began commercial sale of Soliris in 2007.

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

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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.

Products and Development Programs

We focus our product development programs on life-transforming therapeutics for severe and life-threatening ultra-rare diseases for which we believe 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

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 of 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 of 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
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
ALXN 1210	Next Generation		Phase I
ALXN 5500	Next Generation		Phase I

*Investigator sponsored clinical program

Soliris (eculizumab)
Neurology
Myasthenia Gravis (MG)
MG is an ultra-rare autoimmune syndrome characterized by complement activation leading to the failure of neuromuscular transmission. Enrollment of patients in a Phase III multinational, placebo-controlled registration trial of eculizumab in patients with refractory generalized MG is ongoing and expected to be completed in 2015. 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-site 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 has 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 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.

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 July 2014, the European Medicines Agency (EMA) validated our Marketing Authorization Application (MAA) for Strensiq (asfotase alfa) for the treatment of HPP. 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.

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. As a result, we are conducting 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.

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(amounts in thousands except per share amounts)

Manufacturing

We currently rely on two manufacturing facilities, Alexion's Rhode Island manufacturing facility (ARIMF) and a facility operated by Lonza Group AG and its affiliates (Lonza), to produce commercial and clinical bulk quantities of Soliris, and we rely on another facility operated by Lonza for clinical and commercial quantities of Strensiq (asfotase alfa). We produce our clinical and preclinical quantities of our other product candidates at ARIMF. We have entered into an agreement with Lonza to manufacture commercial and clinical supplies of Soliris and Strensiq (asfotase alfa) at an additional site. We also depend on a limited number of third party providers for other services with respect to our clinical and commercial requirements, including manufacturing services, product finishing, packaging, filling and labeling.

We have various agreements with Lonza through 2026, with remaining total non-cancellable commitments of approximately $413,150 through 2019. 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 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.

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;