ALEXION PHARMACEUTICALS INC
Form 10-Q
July 25, 2014

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, 2014
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	197,814,997
Class	Outstanding as of July 23, 2014

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

	June 30, 2014	December 31, 2013
Assets		
Current Assets:		
Cash and cash equivalents	$612,045	$529,857
Marketable securities	982,317	984,994
Trade accounts receivable, net	440,699	421,752
Inventories	144,859	102,602
Deferred tax assets	50,281	41,432
Prepaid expenses and other current assets	111,105	106,220
Total current assets	2,341,306	2,186,857
Property, plant and equipment, net	273,326	201,109
Intangible assets, net	599,786	609,719
Goodwill	254,073	254,073
Deferred tax assets	7,417	3,394
Other assets	77,902	62,544
Total assets	$3,553,810	$3,317,696
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$36,066	$21,596
Accrued expenses	204,743	402,344
Deferred revenue	72,271	53,801
Current portion of long-term debt	48,000	48,000
Other current liabilities	56,621	56,688
Total current liabilities	417,701	582,429
Long-term debt, less current portion	33,500	65,000
Contingent consideration	108,232	106,744
Facility lease obligation	59,515	32,230
Deferred tax liabilities	96	101,241
Other liabilities	53,184	47,973
Total liabilities	672,228	935,617
Commitments and contingencies (Note 16)		
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; 200,035 and 197,941 shares issued at June 30, 2014 and December 31, 2013, respectively	20	20
Additional paid-in capital	2,467,945	2,106,183
Treasury stock, at cost, 2,134 and 985 shares at June 30, 2014 and December 31, 2013, respectively	(258,880)	(80,365)
Accumulated other comprehensive loss	(32,450)	(22,857)
Retained earnings	704,947	379,098
Total stockholders' equity	2,881,582	2,382,079
Total liabilities and stockholders' equity	$3,553,810	$3,317,696

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

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

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Net product sales	$512,495	$370,091	$1,079,111	$709,032
Cost of sales	39,626	39,377	72,565	74,646
Operating expenses:				
Research and development	92,554	68,563	284,011	143,099
Selling, general and administrative	159,477	123,189	288,768	232,015
Impairment of intangible asset	—	—	3,464	—
Acquisition-related costs	1,989	1,167	1,951	4,401
Amortization of purchased intangible assets	—	104	—	208
Total operating expenses	254,020	193,023	578,194	379,723
Operating income	218,849	137,691	428,352	254,663
Other income and expense:				
Investment income	1,714	718	3,927	1,155
Interest expense	(715)	(1,056)	(1,778)	(2,227)
Foreign currency gain (loss)	(1,202)	(90)	56	413
Income before income taxes	218,646	137,263	430,557	254,004
Income tax provision	52,151	41,378	104,708	75,902
Net income	$166,495	$95,885	$325,849	$178,102
Earnings per common share				
Basic	$0.84	$0.49	$1.65	$0.92
Diluted	$0.83	$0.48	$1.62	$0.90
Shares used in computing earnings per common share				
Basic	197,880	195,247	197,838	193,944
Diluted	201,524	199,299	201,715	198,096

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,	
	2014	2013	2014	2013
Net income	$166,495	$95,885	$325,849	$178,102
Other comprehensive income (loss), net of tax:				
Foreign currency translation	46	(77)	552	(1,529)
Unrealized gains (losses) on marketable securities	299	(226)	1,110	(226)
Unrealized losses on pension obligation	(2,685)	(2,684)	(2,685)	(2,684)
Unrealized (losses) gains on hedging activities, net of tax of $(526), $(587), $(1,771) and $1,923, respectively	(3,675)	(8,448)	(8,570)	17,330
Other comprehensive loss, net of tax	(6,015)	(11,435)	(9,593)	12,891
Comprehensive income	$160,480	$84,450	$316,256	$190,993

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,	
	2014	2013
Cash flows from operating activities:		
Net income	$325,849	$178,102
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	19,042	13,014
Impairment of intangible asset	3,464	—
Change in fair value of contingent consideration	1,951	3,378
Share-based compensation expense	52,254	34,812
Premium amortization of available-for-sale securities	8,163	25
Deferred taxes	(112,425)	25,985
Unrealized foreign currency gain	(4,046)	(457)
Unrealized loss (gain) on forward contracts	161	(561)
Excess tax benefit from stock options	(254,547)	(57,317)
Other	148	23
Changes in operating assets and liabilities:		
Accounts receivable	(9,179)	(55,178)
Inventories	(34,972)	(14,391)
Prepaid expenses and other assets	(17,815)	10,160
Accounts payable, accrued expenses and other liabilities	78,298	4,246
Deferred revenue	18,749	2,352
Net cash provided by operating activities	75,095	144,193
Cash flows from investing activities:		
Purchases of available-for-sale securities	(278,134)	(185,322)
Proceeds from maturity or sale of available-for-sale securities	275,946	2,002
Purchases of trading securities	(1,765)	—
Purchases of other investments	(25,000)	—
Purchases of property, plant and equipment	(61,189)	(14,012)
Other	26	(207)
Net cash used in investing activities	(90,116)	(197,539)
Cash flows from financing activities:		
Payments on term loan	(31,500)	(12,000)
Excess tax benefit from stock options	254,547	57,317
Repurchase of common stock	(178,515)	(66,136)
Net proceeds from the exercise of stock options	52,181	23,577
Other	(81)	(99)
Net cash provided by financing activities	96,632	2,659
Effect of exchange rate changes on cash	577	(2,350)
Net change in cash and cash equivalents	82,188	(53,037)
Cash and cash equivalents at beginning of period	529,857	989,501
Cash and cash equivalents at end of period	$612,045	$936,464
Supplemental cash flow disclosures from investing and financing activities:		
Construction in process related to facility lease obligation	$27,284	$6,854

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 ultra-rare 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.

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 our Annual Report on Form 10-K for the year ended December 31, 2013. 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, 2013 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, 2013 included in our Annual Report on Form 10-K. The results of operations for the three and six months ended June 30, 2014 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 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, 2013.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board 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. We are currently assessing the method of adoption and the expected impact the new standard has on our financial position and results of operations.

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

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:

	June 30, 2014	December 31, 2013
Raw materials	$16,693	$12,170
Work-in-process	56,783	62,192
Finished goods	71,383	28,240
	$144,859	$102,602

As of June 30, 2014, we had capitalized $9,627 of inventory produced for commercial sale for products awaiting regulatory approval. At December 31, 2013, we did not have any inventory capitalized associated with such products.

4. Intangible Assets and Goodwill

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

	June 30, 2014	December 31, 2013
Licenses, patents and purchased technology, net	$4,736	$ 11,205
Acquired in-process research and development	595,050	598,514
Intangible assets	$599,786	$ 609,719
Goodwill	$254,073	$ 254,073

During first quarter of 2014, we reviewed for impairment the value of an early stage, Phase I indefinite-lived intangible asset related to the Taligen acquisition. We initiated such review based on a reassessment of scientific findings associated with this acquired asset. As a result, during the six months ended June 30, 2014, we recognized an impairment of $3,464 to adjust this asset to fair value, which was determined to be de minimis.

5. Debt

On February 7, 2012, we entered into a 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 June 30, 2014, we had $81,500 outstanding on the term loan. As of June 30, 2014, we had open letters of credit of $12,445, and our borrowing availability under the revolving facility was $187,555.

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.

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

The following table summarizes the calculation of basic and diluted EPS for the three and six months ended June 30, 2014 and 2013:

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Net income used for basic and diluted calculation	$166,495	$95,885	$325,849	$178,102
Shares used in computing earnings per common share—basic	197,880	195,247	197,838	193,944
Weighted-average effect of dilutive securities:				
Stock awards	3,644	4,052	3,877	4,152
Dilutive potential common shares	3,644	4,052	3,877	4,152
Shares used in computing earnings per common share—diluted	201,524	199,299	201,715	198,096
Earnings per common share:				
Basic	$0.84	$0.49	$1.65	$0.92
Diluted	$0.83	$0.48	$1.62	$0.90

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, 2014 were 1,698 and 1,151 shares of common stock, respectively, because their effect is anti-dilutive. Similarly, we excluded 2,265 and 3,037 shares from the calculation of EPS for the three and six months ended June 30, 2013, respectively, because their effect was 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 June 30, 2014 and December 31, 2013 were as follows:

	June 30, 2014			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Commercial paper	$66,448	$—	$—	$66,448
Corporate bonds	484,588	916	(120)	485,384
Municipal bonds	207,643	251	—	207,894
Other government-related obligations:				
U.S.	51,969	37	(21)	51,985
Foreign	149,573	208	(41)	149,740
Bank certificates of deposit	18,004	5	—	18,009
	$978,225	$1,417	$(182)	$979,460

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	December 31, 2013			
	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Commercial paper	$112,679	$—	$—	$112,679
Corporate bonds	476,459	487	(588)	476,358
Municipal bonds	202,396	47	(40)	202,403
Other government-related obligations:				
U.S.	46,466	30	(7)	46,489
Foreign	156,974	54	(204)	156,824
Bank certificates of deposit	33,004	—	—	33,004
	$1,027,978	$618	$(839)	$1,027,757

The aggregate fair value of available-for-sale securities in an unrealized loss position as of June 30, 2014 and December 31, 2013 was $210,079 and $461,634, respectively. Investments that have been in a continuous unrealized loss position for more than 12 months are not material. As of June 30, 2014, 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, 2014	December 31, 2013
Cash and cash equivalents	$—	$43,780
Marketable securities	979,460	983,977
	$979,460	$1,027,757

The fair values of available-for-sale debt securities at June 30, 2014, by contractual maturity, are summarized as follows:

	June 30, 2014
Due in one year or less	$417,471
Due after one year through three years	561,989
Due after three years through five years	—
	$979,460

As of June 30, 2014 and December 31, 2013, the fair value of our trading securities was $2,857 and $1,017, respectively.

We utilize the specific identification method in computing realized gains and losses. Realized gains and losses on our trading securities and available-for-sale investments were not material for the three and six months ended June 30, 2014 and 2013.

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, Japanese Yen, and British Pound. 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.

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

We enter into foreign exchange forward contracts, with durations of up to 36 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 June 30, 2014, we had open contracts with notional amounts totaling $1,410,389 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, 2014 and 2013 were as follows:

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Gain (loss) recognized in AOCI, net of tax	$(4,119)	$(1,388)	$(8,063)	$29,537
Gain (loss) reclassified from AOCI to net product sales (effective portion), net of tax	$(608)	$6,864	$500	$11,579
Gain reclassified from AOCI to other income and expense (ineffective portion), net of tax	$164	$196	$7	$628

Assuming no change in foreign exchange rates from market rates at June 30, 2014, $7,000 of losses 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, 2014, the notional amount of foreign exchange contracts where hedge accounting is not applied was $239,318.

We recognized a gain (loss) of $(1,640) and $1,837, in other income and expense, for the three months ended June 30, 2014 and 2013, respectively, and $649 and $8,787, for the six months ended June 30, 2014 and 2013, 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, 2014 and December 31, 2013:

	June 30, 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	$13,018	Other current liabilities	$19,729
Foreign exchange forward contracts	Other non-current assets	4,115	Other non-current liabilities	11,285
Total fair value of derivative instruments		$17,133		$31,014

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

	December 31, 2013			
	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	$21,815	Other current liabilities	$20,228
Foreign exchange forward contracts	Other non-current assets	9,839	Other non-current liabilities	14,864
Total fair value of derivative instruments		$31,654		$35,092

The fair value of our foreign exchange forward contracts that are not designated as hedging instruments was zero as of June 30, 2014 and December 31, 2013.

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 table summarizes the potential effect on our condensed consolidated balance sheets of offsetting our foreign exchange forward contracts subject to such provisions:

	June 30, 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	Amounts of Assets/Liabilities Presented in the Condensed Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$17,133	$—	$ 17,133	$(15,934)	$—	$1,199
Derivative liabilities	(31,014)	—	(31,014)	15,934	—	(15,080)

	December 31, 2013					
				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	$31,654	$—	$ 31,654	$(27,256)	$—	$4,398
Derivative liabilities	(35,092)	—	(35,092)	27,256	—	(7,836)

9. Stockholders' Equity

In November 2012, our Board of Directors authorized the repurchase of up to $400,000 of our common stock. This 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 1,012 and 353 shares of our common stock at a cost of $156,458 and $31,029 during the three months ended June 30, 2014 and 2013,

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

respectively, and 1,149 and 758 shares of our common stock at a cost of $178,515 and $66,136 during the six months ended June 30, 2014 and 2013, respectively. As of June 30, 2014, there is a total of $143,796 remaining for repurchases under the program.

Subsequent to June 30, 2014, we repurchased 180 shares of our common stock under our repurchase program at a cost of $28,968.

10. 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, 2014 and 2013:

	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)

	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, 2012	$(5,712)	$—	$15,156	$(2,809)	$6,635
Other comprehensive income before reclassifications	(2,873)	(225)	29,537	(1,529)	24,910
Amounts reclassified from other comprehensive income	189	(1)	(12,207)	—	(12,019)
Net other comprehensive income (loss)	(2,684)	(226)	17,330	(1,529)	12,891
Balances, June 30, 2013	$(8,396)	$(226)	$32,486	$(4,338)	$19,526

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The table below provides details regarding significant reclassifications from AOCI during the three and six months ended June 30, 2014 and 2013:

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
	2014	2013	2014	2013	
Unrealized Gains (Losses) from Hedging Activity					
Effective portion of foreign exchange contracts	$(695)	$7,502	$571	$12,655	Net product sales
Ineffective portion of foreign exchange contracts	187	214	8	686	Foreign currency gain (loss)
	(508)	7,716	579	13,341	
	64	(656)	(72)	(1,134)	Income tax provision
	$(444)	$7,060	$507	$12,207	
Unrealized Gains (Losses) from Marketable Securities					
Realized gains (losses) on sale of securities	$—	$2	$2	$2	Investment income
	—	2	2	2	
	—	(1)	(1)	(1)	Income tax provision
	$—	$1	$1	$1	
Defined Benefit Pension Plans					
Amortization of prior service costs and actuarial losses	$(359)	$(131)	$(438)	$(207)	(a)
	(359)	(131)	(438)	(207)	
	31	11	37	18	Income tax provision
	$(328)	$(120)	$(401)	$(189)	

(a) This AOCI component is included in the computation of net periodic pension benefit cost (see Note 13 for additional details).

11. 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, 2014 and December 31, 2013, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

		Fair Value Measurement at June 30, 2014			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$256,300	$—	$256,300	$—
Marketable securities	Mutual funds	$2,857	$2,857	$—	$—
Marketable securities	Commercial paper	$66,448	$—	$66,448	$—
Marketable securities	Corporate bonds	$485,384	$—	$485,384	$—
Marketable securities	Municipal bonds	$207,894	$—	$207,894	$—
Marketable securities	Other government-related obligations	$201,725	$—	$201,725	$—
Marketable securities	Bank certificates of deposit	$18,009	$—	$18,009	$—
Other current assets	Foreign exchange forward contracts	$13,018	$—	$13,018	$—
Other assets	Foreign exchange forward contracts	$4,115	$—	$4,115	$—
Other current liabilities	Foreign exchange forward contracts	$19,729	$—	$19,729	$—
Other liabilities	Foreign exchange forward contracts	$11,285	$—	$11,285	$—
Other current liabilities	Acquisition-related contingent consideration	$36,395	$—	$—	$36,395
Contingent consideration	Acquisition-related contingent consideration	$108,232	$—	$—	$108,232

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		Fair Value Measurement at December 31, 2013			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$234,212	$—	$234,212	$—
Cash equivalents	Commercial paper	$6,298	$—	$6,298	$—
Cash equivalents	Corporate bonds	$15,255	$—	$15,255	$—
Cash equivalents	Municipal bonds	$2,225	$—	$2,225	$—
Cash equivalents	Bank certificates of deposit	$20,003	$—	$20,003	$—
Marketable securities	Mutual funds	$1,017	$1,017	$—	$—
Marketable securities	Commercial paper	$106,381	$—	$106,381	$—
Marketable securities	Corporate bonds	$461,103	$—	$461,103	$—
Marketable securities	Municipal bonds	$200,178	$—	$200,178	$—
Marketable securities	Other government-related obligations	$203,313	$—	$203,313	$—
Marketable securities	Bank certificates of deposit	$13,001	$—	$13,001	$—
Other current assets	Foreign exchange forward contracts	$21,815	$—	$21,815	$—
Other assets	Foreign exchange forward contracts	$9,839	$—	$9,839	$—
Other current liabilities	Foreign exchange forward contracts	$20,228	$—	$20,228	$—
Other liabilities	Foreign exchange forward contracts	$14,864	$—	$14,864	$—
Other current liabilities	Acquisition-related contingent consideration	$35,932	$—	$—	$35,932
Contingent consideration	Acquisition-related contingent consideration	$106,744	$—	$—	$106,744

There were no securities transferred between Level 1, 2 and 3 during the six months ended June 30, 2014.

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.

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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, 2014, 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 approval 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 ranging from 5.3% to 6.2% for developmental milestones and a weighted average cost of capital ranging from 14% 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, 2014, the fair value of acquisition-related contingent consideration was $144,627. The following table represents a roll-forward of our acquisition-related contingent consideration:

	Six months ended June 30, 2014
Balance at beginning of period	$(142,676)
Changes in fair value	(1,951)
Balance at end of period	$(144,627)

12. 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, 2014 and 2013:

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013

Provision for income taxes	$52,151		$41,378		$104,708		$75,902	
Effective tax rate	23.9	%	30.1	%	24.3	%	29.9	%

The tax provision for the three and six months ended June 30, 2014 is attributable to the U.S. federal, state and foreign income taxes on our operations. Additionally, included in the six months ended June 30, 2014 is $2,128 of tax attributable to our agreement with the French government that provided reimbursement for shipments of Soliris made prior to January 1, 2014. The tax provision for the three and six months ended June 30, 2013 is attributable to the U.S. federal, state and foreign income taxes on our operations. Additionally, included in the six months ended June 30, 2013 is a benefit of $3,033 attributable to the 2012 U.S. Federal tax credit for research and experimentation. The reduction in the effective tax rate for the

three and six months ended June 30, 2014 as compared to the same periods in the prior year is primarily attributable to the centralization of our global supply chain and technical operations in Ireland.

The U.S. Federal tax credit for research and experimentation expenses expired December 31, 2011. In connection with this expiration, our 2012 tax expense did not include any benefit from the U.S. Federal tax credit for research and experimentation. In January 2013, the American Taxpayer Relief Act of 2012, which retroactively extended the tax credit for research and experimentation back to January 1, 2012 through the end of 2013, was signed into law. The effects of a change in tax law is recognized in the period that includes the date of enactment and, therefore, our tax benefit attributable to the 2012 U.S. Federal tax credit for research and experimentation was recorded in the first quarter of 2013.

The U.S. Federal tax credit for research and experimentation expenses expired again on December 31, 2013. In connection with this expiration, our 2014 tax provision does not include any benefit from the U.S. Federal tax credit for research and experimentation.

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

13. Employee Benefit Plans

Deferred Compensation Plan

Effective June 15, 2013, we began sponsoring a nonqualified deferred compensation plan which allows certain highly-compensated employees to make voluntary deferrals of up to 80% of their base salary and incentive bonuses. The plan is designed to work in conjunction with the 401(k) plan and provides for a total combined employer match of up to 6% of an employee's eligible earnings, up to the IRS annual 401(k) contribution limitations. Employee deferrals and employer matching contributions under the plan began in the third quarter of 2013. Matching contributions were not material for the three and six months ended June 30, 2014. As of June 30, 2014 and December 31, 2013, we recorded a liability of $2,857 and $1,097 associated with our nonqualified deferred compensation plan. We invest employee deferrals and employer matching contributions in mutual fund investments. These investments, which are recorded at the same value as the liability, are classified as trading securities and are included in marketable securities in our condensed consolidated balance sheet.

Defined Contribution Plan

We have one qualified 401(k) plan covering all eligible employees. Under the plan, employees may contribute up to the statutory allowable amount for any calendar year. We make matching contributions equal to $1.00 for each dollar contributed up to the first 6% of an individual's base salary and incentive cash bonus. For the three months ended June 30, 2014 and 2013, we recorded matching contributions of approximately $2,279, and $1,497, respectively. For the six months ended June 30, 2014 and 2013, we recorded matching contributions of approximately $4,936 and $3,264, respectively.

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 were as follows:

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Service cost	$2,622	$1,326	$4,185	$2,711
Interest cost	200	123	400	249
Expected return on plan assets	(232)	(156)	(463)	(314)
Employee contributions	(482)	(358)	(877)	(713)
Amortization	359	131	438	207
Total net periodic benefit cost	$2,467	$1,066	$3,683	$2,140

14. Leases

In November 2012, we entered into a lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. 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 2015. As of June 30, 2014, we recorded a construction-in-process asset of $62,157, inclusive of the landlord's costs as well as costs incurred by Alexion, and an offsetting facility lease obligation of $59,515 associated with the new facility.

15. License Agreements

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.

In addition to the option agreement, we purchased $25,000 of non-voting preferred equity of Moderna LLC, Moderna's non-public parent company. We recorded this investment at cost within other assets in our condensed consolidated balance sheets. We regularly monitor the investment to evaluate whether there has been an other-than-temporary decline in its fair value, based on the implied value of recent company financings, public market prices of comparable companies, and general market conditions. The carrying value of this investment was not impaired as of June 30, 2014.

16. Commitments and Contingencies

Commitments

Lonza Agreement

We have supply agreements with Lonza Group AG and its affiliates (Lonza), a third party manufacturer, relating to the manufacture of Soliris and asfotase alfa. We have various agreements with Lonza, with remaining total commitments of approximately $146,000 through 2018. Such commitments may be canceled only in limited circumstances. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at Alexion Rhode Island Manufacturing Facility (ARIMF).

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Contingent Liabilities

We are currently involved in various claims, lawsuits and legal proceedings. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, we accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on our best estimates based on available information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, we may reassess the potential liability related to these matters and may revise these estimates, which could result in a material adverse adjustment to our operating results.

In March 2013, we received a Warning Letter from the U.S. Food and Drug Administration (FDA) regarding compliance with current Good Manufacturing Practices 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 in April 2013. We continue to manufacture products, including Soliris, in this facility. In the first quarter of 2014, we submitted our request for inspection to the FDA, and we are currently awaiting this re-inspection of ARIMF. While the resolution of this 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.

In 2013 and 2014, we initiated voluntary recalls and replacements of certain lots of Soliris due to the presence of visible particles detected in a limited number of vials in these lots. These recalls did not interrupt the supply of Soliris to patients. Following investigation, we believe that we have identified the filling process step that resulted in the presence of the visible particles and we have implemented the changes necessary to modify the process step. During the fourth quarter of 2013, we recorded expense of $14,277 in cost of sales resulting from the expected disposal of inventory in 2014, and we do not expect a material impact from these recalls in 2014.

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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 in the March 2013 Warning Letter, 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, 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 (the SEC).

Business

Overview

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 ultra-rare 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.

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

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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.

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 Product/Indications

Our marketed product/indications 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 Long-term Follow-up	Phase IV
		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. . Additionally, 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.

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 (TMA) leading to kidney failure, stroke, heart attack and death. Soliris is the first and only therapy approved for the treatment of adult and pediatric patients with aHUS. Pursuant to a post marketing requirement imposed by the FDA, we have now completed both a prospective open-label trial in adults with aHUS, as well as, a prospective trial of pediatric patients with aHUS. In May 2014, based on data from these trials, 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.

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

Product	Development Area	Indication	Development Stage
Soliris (eculizumab)	Transplant	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
		Delayed Kidney Transplant Graft Function*	Phase II
	Nephrology	STEC-HUS (Shiga-toxin producing E. Coli Hemolytic Uremic Syndrome)*	Phase II
	Neurology	Neuromyelitis Optica (NMO)	Phase III
		Myasthenia Gravis (MG)	Phase III
Asfotase alfa	Metabolic Disorders	Hypophosphatasia (HPP)	Phase II
cPMP (ALXN 1101)	Metabolic Disorders	MoCD Type A	Phase II
ALXN 1007	Inflammatory Disorders	Anti-phospholipid Syndrome	Phase II

* Investigator Initiated Trial

Soliris (eculizumab)

Transplant
Acute 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 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.
Enrollment in a multi-national, multi-site randomized controlled clinical trial of eculizumab in presensitized kidney transplant patients at elevated risk for AMR who received kidneys from living donors has been completed and patient follow-up in the trial is ongoing. Enrollment in a U.S., multi-site, open-label, randomized, controlled, investigator-initiated trial of eculizumab to treat kidney transplant patients who are diagnosed with biopsy proven acute AMR has been initiated.
In April 2014, the EC granted orphan drug designation to eculizumab for the prevention of graft rejection following solid organ transplantation.
Delayed Kidney Transplant Graft Function
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 has been completed in an investigator-initiated Phase II study of eculizumab in patients at elevated risk for delayed graft function (DGF) following kidney transplant.

Eculizumab has been granted orphan drug designation for DGF by the FDA and, in the first quarter of 2014, the EC granted orphan drug designation to eculizumab for prevention of DGF after solid organ transplantation. Following positive discussions with regulators in the U.S. and EU, we plan to initiate a single multinational DGF registration trial in the third quarter of 2014.

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Nephrology
Shiga-toxin producing E. coli Hemolytic Uremic Syndrome (STEC-HUS)
STEC-HUS is an ultra-rare disorder, comprising only a small sub-set of the already rare population of patients with enterohemorrhagic Escherichia coli (EHEC). We are aware that independent investigators are examining the role of eculizumab for the treatment of patients with STEC-HUS.
Neurology
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. In an investigator-initiated Phase II clinical trial of eculizumab in severe and relapsing NMO, eculizumab reduced the median number of NMO attacks at 12 months with a high degree of statistical significance. In the first half of 2014, a single pivotal trial in patients with relapsing NMO commenced patient enrollment. The FDA and the EC have each granted orphan designation for eculizumab as a treatment for patients with NMO.
Myasthenia Gravis (MG)
MG is an ultra-rare autoimmune syndrome characterized by complement activation leading to the failure of neuromuscular transmission. Data from a Phase II trial evaluating the safety and efficacy of eculizumab in patients with refractory generalized MG indicated improvement in clinical measures. In the second quarter of 2014, we commenced a Phase III pivotal trial to evaluate eculizumab as a treatment for patients with refractory generalized MG. In addition, the FDA has granted orphan designation for eculizumab as a treatment for patients with MG.

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.
Asfotase alfa, a targeted enzyme replacement therapy in Phase II clinical trials for patients with HPP, is designed to directly address the morbidities and mortality of HPP by targeting alkaline phosphatase directly to the deficient tissue. In this way, asfotase alfa is designed to normalize the genetically defective metabolic process and prevent or reverse its severe, crippling and life-threatening complications in patients with HPP. Initial studies with asfotase alfa in HPP patients indicate that the treatment significantly decreases the levels of targeted metabolic substrates. In 2013, asfotase alfa received Breakthrough Therapy Designation from the FDA.
We continue to enroll and dose patients in a separate multinational Phase II open-label study of infants and children with HPP. Interim results of this trial were presented at the European Society of Pediatric Endocrinology meeting held in September 2013. Results of 15 enrolled and treated patients representing a range of HPP characteristics were summarized, showing that the primary efficacy endpoint was achieved with a high degree of clinical and statistical significance and several key secondary endpoints were also achieved.
We have completed enrollment in a natural history study in infantile-onset patients with HPP and have completed our initial analysis for the study. The natural history study in juveniles with HPP is ongoing and is expected to be completed in the fall. We have commenced a rolling submission of our U.S. Biologics License Application (BLA) for asfotase alfa, which allows completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. We submitted certain portions of the BLA to the FDA during the second quarter and expect to complete the submission of the remaining sections in the fall of 2014. In July 2014, we announced that the European Medicines Agency (EMA) informed us that it had validated, and granted accelerated assessment to, our Marketing Authorization Application (MAA) for asfotase alfa for the treatment of HPP. We believe the analysis of our clinical data is supportive of our regulatory filings in the U.S. and EU and anticipated regulatory filing in Japan.

cPMP (ALXN 1101)
Molybdenum Cofactor Deficiency (MoCD) Disease Type A (MoCD Type A)

MoCD Type A is a 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 production of certain enzymes, 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 cPMP replacement therapy in a small number of children with MoCD Type A, and we have initiated a natural history study in patients

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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 cPMP replacement therapy in a Phase I healthy volunteer study is complete. As a result, we have initiated a multi-center, multinational, open-label clinical trial of synthetic cPMP in patients with MoCD Type A being treated with recombinant Escherichia coli-derived 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. As a result of meetings with the FDA, we commenced screening in a Phase II proof-of-concept study in patients with anti-phospholipid syndrome, a severe life-threatening and ultra-rare disorder, in the second quarter of 2014. A second proof-of-concept study in another severe life-threatening and ultra-rate disorder is expected to start in the second half of 2014.

Manufacturing

We currently rely on three manufacturing facilities, Alexion's Rhode Island manufacturing facility (ARIMF) and two facilities operated by Lonza Group AG and its affiliates (Lonza), to produce commercial and clinical bulk quantities of Soliris, and we rely on a facility operated by Lonza for clinical quantities of asfotase alfa. We produce our clinical and preclinical quantities of our other product candidates at ARIMF. 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.

In March 2013, we received a 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 in April 2013. We continue to manufacture products, including Soliris, in this facility. In the first quarter of 2014, we submitted our request for inspection to the FDA, and we are currently awaiting this re-inspection of ARIMF. While the resolution of the issues raised in this 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 a good manufacturing practices certificate was issued in May 2013. In 2013 and 2014, we initiated voluntary recalls and replacements of certain lots of Soliris due to the presence of visible particles detected in a limited number of vials in these lots. These recalls did not interrupt the supply of Soliris to patients. Following investigation, we believe that we have identified the filling process step that resulted in the presence of the visible particles and we have implemented the changes necessary to modify the process step. During the fourth quarter of 2013, we recorded expense of $14,277 in cost of sales resulting from the expected disposal of inventory in 2014, and we do not expect a material impact from these recalls in 2014.

In April 2014, we purchased a filling 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 filling and packaging facility for Soliris and other clinical and commercial products. Our plans for future expansion in Ireland also include the purchase of property in Dublin, Ireland, in April 2014, for the construction of office and laboratory facilities.

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 our financial statements included in our Form 10-K for the year ended December 31, 2013. 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;

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- Inventories;
- Research and development expenses;
- 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, 2013. 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 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. We are currently assessing the method of adoption and the expected impact the new standard has on our financial position and results of operations.

Results of Operations

Net Product Sales

The following table summarizes net product sales for the three and six months ended June 30, 2014 and 2013:

	Three months ended June 30,			Six months ended June 30,		
	2014	2013	$ Variance	2014	2013	$ Variance
Net product sales	$512,495	$370,091	$142,404	$1,079,111	$709,032	$370,079

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, the increase of 38% and 40% in revenue for the three and six months ended June 30, 2014, as compared to the same periods in 2013, was primarily due to an increased volume of unit shipments and increased price, partially offset by a negative impact of foreign exchange. The increase in revenue of 38.5% and 40% for the three and six months ended June 30, 2014, respectively, was due to an increase in unit volumes of 34.4% and 35.6% and a positive price impact of 5.4% and 5.9%, offset by a negative impact on foreign exchange of 1.3% and 1.7%. The increase in volume was largely due to physicians globally requesting Soliris therapy for additional patients. The positive price impact of 5.4% and 5.9% for the three and six months ended June 30, 2014, respectively, was primarily due to the agreement with the French government and a reduction in estimated rebates in Germany, offset by an increase in rebates in certain countries in Europe.

The negative impact on foreign exchange of $4,885 and $11,747, or 1.3% and 1.7%, for the three and six months ended June 30, 2014 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, 2013. The negative impact was primarily due to changes in the Japanese Yen and the Russian Ruble. We recorded a (loss) gain in revenue of $(695) and $7,502 for the three months ended June 30, 2014 and 2013, respectively, and $571 and $12,655 for the six months ended June 30, 2014 and 2013,

respectively, related to our foreign currency cash flow hedging program.

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Cost of Sales

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

In the first quarter of 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, the Company recorded a reversal of accrued royalties of $5,124 as a reduction of cost of sales.

In the first quarter of 2014, we also recorded an 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 royalty items noted above, cost of sales were $39,626 and $39,377 for the three months ended June 30, 2014 and 2013, respectively, and $75,634 and $74,646 for the six months ended June 30, 2014 and 2013, respectively. Exclusive of the royalty items noted above, cost of sales as a percentage of product revenue (exclusive of the $87,830 recognized related to prior years), was 7.7% and 10.6% for the three months ended June 30, 2014 and 2013, respectively, and 7.6% and 10.5% for the six months ended June 30, 2014 and 2013, respectively. The decrease in cost of sales as a percentage of sales resulted from a decrease in royalties on sales of Soliris.

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,		
	2014	2013	$ Variance	2014	2013	$ Variance
Clinical development	$26,382	$16,501	$9,881	$50,299	$27,996	$22,303
Product development	12,142	12,921	(779)	25,181	36,516	(11,335)
Licensing agreements	—	—	—	101,925	3,000	98,925
Discovery research	2,349	2,648	(299)	4,930	3,978	952
Total external direct expenses	40,873	32,070	8,803	182,335	71,490	110,845
Payroll and benefits	44,480	32,066	12,414	88,499	62,784	25,715
Operating and occupancy	3,765	1,973	1,792	6,641	4,209	2,432
Depreciation and amortization	3,436	2,454	982	6,536	4,616	1,920
Total other R&D expenses	51,681	36,493	15,188	101,676	71,609	30,067
Research and development expense	$92,554	$68,563	$23,991	$284,011	$143,099	$140,912

For the three months ended June 30, 2014, the increase of $23,991 in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase of $9,881 in external clinical development expenses related primarily to an expansion of studies within our eculizumab programs (see table below).

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- Increase of $12,414 in R&D payroll and benefit expense related primarily to the continued global expansion of staff supporting our increasing number of clinical and development programs.

For the six months ended June 30, 2014, the increase of $140,912 in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase of $22,303 in external clinical development expenses related primarily to an expansion of studies within our eculizumab programs and additional clinical costs associated with our asfotase alfa program (see table below).
- Decrease of $11,335 in external product development expenses related primarily to a decrease in costs associated with the production of asfotase alfa for clinical trials.
- Increase of $98,925 in licensing agreements primarily related to the upfront payment of $100,000 on the license agreement entered into with Moderna Therapeutics, Inc. in the first quarter of 2014.
- Increase of $25,715 in R&D payroll and benefit expense related primarily to the continued global expansion of staff supporting our increasing number of clinical and development programs.

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,		$
	2014	2013	Variance	2014	2013	Variance
External direct expenses						
Eculizumab	$17,235	$9,578	$7,657	$32,731	$16,321	$16,410
Asfotase alfa	5,105	4,019	1,086	9,347	6,284	3,063
cPMP	1,855	1,468	387	3,408	2,788	620
Other programs	1,212	975	237	2,813	1,783	1,030
Unallocated	975	461	514	2,000	820	1,180
	$26,382	$16,501	$9,881	$50,299	$27,996	$22,303

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 legal expenses.

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

	Three months ended June 30,		$	Six months ended June 30,		$
	2014	2013	Variance	2014	2013	Variance
Salary, benefits and other labor expense	$95,338	$73,233	$22,105	$177,756	$141,162	$36,594
External selling, general and administrative expense	64,139	49,956	14,183	111,012	90,853	20,159
Total selling, general and administrative expense	$159,477	$123,189	$36,288	$288,768	$232,015	$56,753

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For the three months ended June 30, 2014, the increase of $36,288 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase in salary, benefits and other labor expenses of $22,105. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of $13,200 related to our global commercial staff to support global expansion. This increase was also due to increases in payroll and benefits of $8,900 within our general and administrative functions to support our infrastructure growth as a global commercial entity.
- Increase in external selling, general and administrative expenses of $14,183. The increase was primarily due to an increase in marketing costs to support the continued growth in global sales of Soliris, as well as an increase in other administrative functions to support our infrastructure growth.

For the six months ended June 30, 2014, the increase of $56,753 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase in salary, benefits and other labor expenses of $36,594. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of $22,100 related to our global commercial staff to support global expansion. This increase was also due to increases in payroll and benefits of $14,500 within our general and administrative functions to support our infrastructure growth as a global commercial entity.
- Increase in external selling, general and administrative expenses of $20,159. This increase was primarily due to an increase in marketing costs to support the continued growth in global sales of Soliris, as well as an increase in other administrative functions to support our infrastructure growth.

Impairment of Intangible Asset

During the first quarter of 2014, we reviewed for impairment the value of an early stage, Phase I indefinite-lived intangible asset related to the Taligen acquisition. We initiated such review based on a reassessment of scientific findings associated with this acquired asset. As a result, in the first quarter of 2014, we recognized an impairment of $3,464 to adjust this asset to fair value, which was determined to be de minimis. We did not recognize any impairment loss for intangible assets during the three and six months ended June 30, 2013.

Acquisition-related Costs

For the three and six months ended June 30, 2014 and 2013, acquisition-related costs associated with our business combinations included the following:

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Separately-identifiable employee costs	$—	$—	$—	$248
Professional fees	—	—	—	775
Changes in fair value of contingent consideration	1,989	1,167	1,951	3,378
	$1,989	$1,167	$1,951	$4,401

The following table provides information for acquisition-related costs for each business combination:

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Enobia Pharma Corp.	$2,087	$719	$4,537	$3,710
Taligen Therapeutics, Inc.	23	56	(2,435)	171
Orphatec Pharmaceuticals GmbH	(121)	392	(151)	520
	$1,989	$1,167	$1,951	$4,401

Included in the acquisition-related costs for Taligen for the six months ended June 30, 2014 is a benefit of $2,458 related to the decrease in the fair value of contingent consideration related to this acquisition during the first quarter of 2014. The decrease in fair value was a result of a decreased likelihood of payments for contingent consideration due to

a reassessment of scientific findings associated with an early stage Phase I asset.

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Other Income and Expense

The following table provides information regarding other income and expense:

	Three months ended June 30,		$	Six months ended June 30,		$
	2014	2013	Variance	2014	2013	Variance
Investment income	$1,714	$718	$996	$3,927	$1,155	$2,772
Interest expense	(715)	(1,056)	341	(1,778)	(2,227)	449
Foreign currency gain (loss)	(1,202)	(90)	(1,112)	56	413	(357)
Total other income and expense	$(203)	$(428)	$225	$2,205	$(659)	$2,864

We recognize investment income primarily from our portfolio of cash equivalents and marketable securities. Investment income was $1,714 and $718, for the three months ended, and $3,927 and $1,155 for the six months ended June 30, 2014 and 2013, respectively.

We incur interest on our term notes and revolving credit facility. Interest expense was $715 and $1,056, for the three months ended, and $1,778 and $2,227 for the six months ended June 30, 2014 and 2013, respectively.

Foreign currency transaction gains and losses relate to changes in the fair value of monetary assets and liabilities denominated in foreign currencies. The foreign currency transaction gains (losses) totaled $(1,202) and $(90), for the three months ended, and $56 and $413, for the six months ended June 30, 2014 and 2013, respectively. The amounts recorded in these periods were a result of the costs of hedging our exposures, as well as the fluctuation in exchange rates on the portion of our monetary assets and liabilities that were not fully hedged as part of our hedging programs.

Income Taxes

During the three and six months ended June 30, 2014, we recorded an income tax provision of $52,151 and $104,708 and an effective tax rate of 23.9% and 24.3%, compared to an income tax provision of $41,378 and $75,902 and an effective tax rate of 30.1% and 29.9% for the three and six months ended June 30, 2013. The reduction in the effective tax rate is primarily attributable to the centralization of our global supply chain and technical operations in Ireland.

The tax provision for the three and six months ended June 30, 2014 is attributable to the U.S. federal, state and foreign income taxes on our operations. Additionally, included in the six months ended June 30, 2014 is $2,128 of tax attributable to our agreement with the French government that provided reimbursement for shipments of Soliris made prior to January 1, 2014. The tax provision for the three and six months ended June 30, 2013 is attributable to the U.S. federal, state and foreign income taxes on our operations. Additionally, included in the six months ended June 30, 2013 is a benefit of $3,033 attributable to the 2012 U.S. Federal tax credit for research and experimentation.

The U.S. Federal tax credit for research and experimentation expenses expired December 31, 2011. In connection with this expiration, our 2012 tax expense did not include any benefit from the U.S. Federal tax credit for research and experimentation. In January 2013, the American Taxpayer Relief Act of 2012, which retroactively extended the tax credit for research and experimentation back to January 1, 2012 through the end of 2013, was signed into law. The effects of a change in tax law is recognized in the period that includes the date of enactment and, therefore, our tax benefit attributable to the 2012 U.S. Federal tax credit for research and experimentation was recorded in the first quarter of 2013.

The U.S. Federal tax credit for research and experimentation expenses expired again on December 31, 2013. In connection with this expiration, our 2014 tax provision does not include any benefit from the U.S. Federal tax credit for research and experimentation.

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

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Financial Condition, Liquidity and Capital Resources

The following table summarizes the components of our financial condition as of June 30, 2014 and December 31, 2013:

	June 30, 2014	December 31, 2013	$ Variance
Cash and cash equivalents	$612,045	$529,857	$82,188
Marketable securities	$982,317	$984,994	$(2,677)
Long-term debt (includes current portion)	$81,500	$113,000	$(31,500)
Current assets	$2,341,306	$2,186,857	$154,449
Current liabilities	417,701	582,429	(164,728)
Working capital	$1,923,605	$1,604,428	$319,177

The increase in cash and cash equivalents was primarily attributable to cash generated from operations, proceeds from the maturity or sale of available-for-sale securities, and net proceeds from the exercise of stock options. Offsetting these increases in cash were purchases of marketable securities, payments on our outstanding term loan, purchases of property, plant and equipment, and the repurchase of common stock. We also paid an upfront fee of $100,000 during the first quarter of 2014 related to an option agreement we entered into with Moderna Therapeutics, Inc. and an additional $25,000 for the purchase of Moderna LLC preferred equity.

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

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

Financial Instruments

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

Financial instruments that potentially expose us to concentrations of credit risk are cash equivalents, marketable securities, accounts receivable and our foreign exchange derivative contracts. At June 30, 2014, two individual customers accounted for 21% and 10% of the accounts receivable balance. At December 31, 2013, two individual customers accounted for 20% and 10% of the accounts receivable balance. For the three and six months ended June 30, 2014, one customer accounted for 19% and 18% of our product sales, respectively. For the three and six months ended June 30, 2013, one customer accounted for 20% of our product sales.

We continue to monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. Substantially all of our accounts receivable due from these countries are due from or backed by sovereign or local governments, and the amount of non-sovereign accounts receivable is not material. The adverse credit and economic conditions in Italy and Spain, among other members of the European Union, have improved in recent periods and, although collection of our accounts receivables due from these countries may extend beyond our standard credit terms, we do not expect any such delays to have a material impact on our financial condition or results of operations.

We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative

trading purposes. As of June 30, 2014, we have foreign exchange forward contracts with notional amounts totaling $1,649,707. These outstanding foreign exchange forward contracts had a net fair value of $(13,881), of which an unrealized gain of $17,133 is included in other assets, offset by an unrealized loss of $31,014 included in other liabilities. The counterparties to these foreign exchange forward contracts are large multinational commercial banks, and we believe the risk of nonperformance is not material.

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At June 30, 2014, our financial assets and liabilities were recorded at fair value. We have classified our financial assets and liabilities as Level 1, 2 or 3 within the fair value hierarchy. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Our Level 1 assets consist of mutual fund investments. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, but substantially the full term of the financial instrument. Our Level 2 assets consist primarily of money market funds, marketable securities and foreign exchange forward contracts. Our Level 2 liabilities consist also of foreign exchange forward contracts. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. Our Level 3 liabilities consist of contingent consideration related to acquisitions.

Business Combinations and Contingent Consideration Obligations

The purchase agreements for our business combinations include contingent payments totaling up to $876,000 that will become payable if and when certain development and commercial milestones are achieved. Of these milestone amounts, $561,000 and $315,000 of the contingent payments relate to development and commercial milestones, respectively. We do not expect these amounts to have a significant impact on our liquidity in the near-term, and, during the next 12 months, we expect to make milestone payments totaling approximately $40,000. As additional future payments become probable, we will evaluate methods of funding payments, which could be made from available cash and marketable securities, cash generated from operations or proceeds from other financing.

Leases

In November 2012, we entered into a lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. 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 consolidated balance sheet. As of June 30, 2014, we recorded a construction-in-process asset of $62,157, inclusive of the landlord's costs as well as costs incurred by Alexion, and an offsetting facility lease obligation of $59,515 associated with the new facility.

License Agreements

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. In addition to the option agreement, we purchased $25,000 of non-voting preferred equity of Moderna LLC, Moderna's non-public parent company.

Long-term Debt

In February 2012, we entered into a Credit Agreement (Credit Agreement) with a syndicate of lenders and other parties named in the Credit Agreement 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, which includes up to a $60,000 sublimit for letters of credit and a $10,000 sublimit for swingline loans. We may use the facilities for working capital requirements, acquisitions and other general corporate purposes. Any of Alexion's wholly-owned foreign subsidiaries may borrow funds under the facilities upon satisfaction of certain conditions described in the Credit Agreement. As of June 30, 2014, we had $81,500 outstanding on the term loan. As of June 30, 2014, we had open letters of credit of $12,445, and our borrowing availability under the revolving facility was $187,555. We expect that cash generated from operations will be sufficient to meet debt service obligations.

Lonza Agreement

We have supply agreements with Lonza relating to the manufacture of eculizumab and asfotase alfa, which requires payments to Lonza at the inception of contract and upon the initiation and completion of product manufactured. On an ongoing basis, we evaluate our plans for future levels of manufacturing by Lonza, which depends upon our commercial requirements, the progress of our clinical development programs and the production levels of ARIMF. We have various agreements with Lonza, with remaining total commitments of approximately $146,000 through 2018. Such commitments may be canceled only in limited circumstances. If we terminate certain supply agreements with Lonza

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(amounts in thousands, except per share amounts)

without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at ARIMF.

Taxes

We do not record U.S. tax expense on the undistributed earnings of our controlled foreign corporation (CFC) subsidiaries as these earnings are intended to be permanently reinvested offshore. During the fourth quarter of 2013, in connection with the centralization of our global supply chain and technical operations in Ireland, our U.S. parent company became a direct partner in a foreign partnership subsidiary. To the extent that our U.S. parent company receives its allocation of partnership taxable income, the amounts will be taxable in the U.S. and therefore the permanent reinvestment assertion will no longer apply. The recognition of deferred tax liabilities associated with the aforementioned partnership resulted in tax expense of approximately $95,800 during the fourth quarter of 2013. We also distributed the majority of earnings and profits of our non-U.S. subsidiaries via a dividend in the amount of $152,000 during the fourth quarter of 2013. This resulted in repatriation of a significant portion of our unremitted earnings at December 31, 2013.

We do not have any present or anticipated future need for cash held by our CFCs, as cash generated in the U.S., as well as borrowings, are expected to be sufficient to meet U.S. liquidity needs for the foreseeable future. At June 30, 2014, approximately $281,000 of our cash and cash equivalents was held by foreign subsidiaries, a significant portion of which is required for liquidity needs of our foreign subsidiaries. Due to the liability position of our foreign subsidiaries, these subsidiaries will repay any outstanding intercompany debt, prior to having excess cash available which could be used to repatriate to our entities in the United States. While our expectation is that all future undistributed earnings of our CFCs will be permanently reinvested, there could be certain unforeseen future events that could impact our permanent reinvestment assertion. Such events include acquisitions, corporate restructurings or tax law changes not currently contemplated.

Common Stock Repurchase Program

In November 2012, we announced that our Board of Directors authorized the repurchase of up to $400,000 of our common stock. This repurchase program does not have an expiration date. We expect that cash generated from operations and our existing available cash and cash equivalents are sufficient to fund any share repurchases.

Under the program, we repurchased 1,149 and 758 shares of our common stock at a cost of $178,515 and $66,136 during the six months ended June 30, 2014 and 2013, respectively. As of June 30, 2014, there is a total of $143,796 remaining for repurchases under the program.

Subsequent to June 30, 2014, we repurchased 180 shares of our common stock under our repurchase program at a cost of $28,968.

Cash Flows

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

	Six months ended June 30,		
	2014	2013	$ Variance
Net cash provided by operating activities	$75,095	$144,193	$(69,098)
Net cash used in investing activities	(90,116)	(197,539)	107,423
Net cash provided by financing activities	96,632	2,659	93,973
Effect of exchange rate changes on cash	577	(2,350)	2,927
Net change in cash and cash equivalents	$82,188	$(53,037)	$135,225

The increase in cash and cash equivalents was primarily attributable to cash generated from operations, proceeds from the maturity or sale of available-for-sale securities, and net proceeds from the exercise of stock options. Offsetting these increases in cash were purchases of marketable securities, payments on our outstanding term loan, purchases of property, plant and equipment, and the repurchase of common stock. We also paid an upfront fee of $100,000 during the first quarter of 2014 related to an option agreement we entered into with Moderna Therapeutics, Inc. and an additional $25,000 for the purchase of Moderna LLC preferred equity.

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

Operating Activities

The components of cash flows from operating activities, as reported in our Condensed Consolidated Statements of Cash Flows, are as follows:

- Our net income was $325,849 and $178,102 for the six months ended June 30, 2014 and 2013, respectively. During the first quarter of 2014, we recorded expense of $100,000 for an upfront payment related to an option agreement we entered into with Moderna Therapeutics, Inc.
- Non-cash items included depreciation and amortization, impairment of intangible assets, change in fair value of contingent consideration, share-based compensation expense, premium amortization of available-for-sale securities, deferred taxes, unrealized foreign currency gains, and unrealized gains and losses on forward contracts, and were $(31,288) and $76,219 for the six months ended June 30, 2014 and 2013, respectively.
- We reclassified $254,547 and $57,317 of windfall tax benefits from cash flows from operations to cash flows from financing activities, which caused a decrease in cash from operations during the six months ended June 30, 2014 and 2013. The amount of the windfall tax benefit was significantly higher during the six months ended June 30, 2014 due to an increased stock price and increased level of stock option exercises.
- Net cash inflow (outflow) due to changes in operating assets and liabilities was $35,081 and $(52,811) for the six months ended June 30, 2014 and 2013, respectively. The $35,081 change in operating assets and liabilities primarily relates to:
  - Increase in inventory of $34,972 related to increased production of inventory to support commercial growth and the capitalization of $9,627 of inventory produced for commercial sale for products awaiting regulatory approval.
  - Increase of $17,815 in prepaid expenses and other assets primarily related to an increase in prepaid manufacturing expenses and prepaid taxes.
  - Increase of $78,298 in accounts payable, accrued expenses and other liabilities primarily related to an increase in trade accounts payable and a change in accrued income taxes, offset by a decrease in accruals for rebates of approximately $87,800 resulting from the agreement with the French government for reimbursement of prior year shipments and a decrease in accruals for royalties of approximately $20,100 resulting from the settlement agreement we entered into with a third party related to the calculation of royalties under a pre-existing license agreement.
  - Increase in deferred revenue of $18,749 due to increased shipments in advance of recognizing revenue.

Investing Activities

The components of cash flows from investing activities consisted of the following:

- Purchases of available-for-sale marketable securities of $278,134 and $185,322 for the six months ended June 30, 2014 and 2013, respectively, offset by proceeds from the maturity or sale of available-for-sale marketable securities of $275,946 and $2,002, respectively, during the same periods.
- Purchase of $25,000 of preferred equity of Moderna LLC during the six months ended June 30, 2014.
- Additions to property, plant and equipment of $61,189 and $14,012 for the six months ended June 30, 2014 and 2013, respectively.

Financing Activities

Net cash flows from financing activities reflected proceeds from the exercise of stock options of $52,181 and $23,577 for the six months ended June 30, 2014 and 2013, respectively. Net cash flows for the six months ended June 30, 2014 and 2013 also include $254,547 and $57,317, respectively, of excess tax benefits from stock options attributable to the utilization of the excess tax benefit portion of federal and state net operating losses and tax credits.

In connection with the acquisition of Enobia in February 2012, we borrowed $240,000 under the term loan facility. During the six months ended June 30, 2014 and 2013, we made payments of $31,500 and $12,000, respectively, against the term loan facility and the facility had $81,500 remaining outstanding as of June 30, 2014.

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During the six months ended June 30, 2014 and 2013, we repurchased $178,515 and $66,136 worth of shares of our common stock under a repurchase program that was approved by our Board of Directors in November 2012. As of June 30, 2014, there is a total of $143,796 remaining for repurchases under the program.

Contractual Obligations

The disclosure of payments we have committed to make under our contractual obligations are summarized in our Annual Report on Form 10-K for the twelve months ended December 31, 2013, in the section titled “Management's Discussion and Analysis of Financial Condition and Results of Operations” under the caption “Contractual Obligations.” There have not been any material changes to such contractual obligations since December 31, 2013.

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

Interest Rate Risk

As of June 30, 2014, we invested our cash in a variety of financial instruments, principally money market funds, corporate bonds, municipal bonds, commercial paper and government-related obligations. Most of our interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate. Our investment portfolio is comprised of marketable securities of highly rated financial institutions and investment-grade debt instruments, and we have guidelines to limit the term-to-maturity of our investments. Based on the type of securities we invest in, we do not believe a change in interest rates would have a material impact on our financial statements. If interest rates were to increase or decrease by 1%, the fair value of our investment portfolio would increase (decrease) by approximately $(11,697) and $6,918, respectively.

In February 2012, we entered into the Credit Agreement with a floating rate of interest based on LIBOR, Prime Rate, Federal Funds Rate or Eurodollar Rate, at our election, plus an applicable credit spread. We do not expect changes in interest rates related to the Credit Agreement to have a material effect on our financial statements. As of June 30, 2014, we had approximately $81,500 of variable rate debt outstanding. If interest rates were to increase or decrease by 1% for the year, annual interest expense would increase or decrease by approximately $815.

Foreign Exchange Market Risk

As a result of our foreign operations, we face exposure to movements in foreign currency exchange rates, primarily the Euro, Japanese Yen, and British Pound against the U.S. dollar. The current exposures arise primarily from cash, accounts receivable, intercompany receivables and payables, and product sales denominated in foreign currencies. Both positive and negative impacts to our international product sales from movements in foreign currency exchange rates are partially mitigated by the natural, opposite impact that foreign currency exchange rates have on our international operating expenses. We have operations based in Switzerland, and accordingly, our expenses are also impacted by fluctuations in the value of the Swiss Franc against the U.S. dollar.

We currently have a derivative program in place to achieve the following: 1) limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet, using contracts with durations of up to 30 days and 2) hedge a portion of our forecasted product sales, including intercompany sales, using contracts with durations of up to 36 months. The objectives of this program are 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. This program utilizes foreign exchange forward contracts intended to reduce, not eliminate, the impact of fluctuations in foreign currency rates.

As of June 30, 2014 and December 31, 2013, we held foreign exchange forward contracts with notional amounts totaling $1,649,707 and $1,222,464, respectively. As of June 30, 2014 and December 31, 2013, our outstanding foreign exchange forward contracts had a net fair value of $(13,881) and $(3,438), respectively. The increase in outstanding foreign exchange forward contracts resulted primarily from increases in forecasted intercompany revenues.

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

Based on our foreign currency exchange rate exposures at June 30, 2014, a hypothetical 10% adverse fluctuation in exchange rates would decrease the fair value of our foreign exchange forward contracts that are designated as cash flow hedges by approximately $152,000 at June 30, 2014. The resulting loss on these forward contracts would be offset by the gain on the underlying transactions and therefore would have minimal impact on future anticipated earnings and cash flows. Similarly, adverse fluctuations in exchange rates that would decrease the fair value of our foreign exchange forward contracts that are not designated as hedge instruments would be offset by a positive impact of the underlying monetary assets and liabilities.

Credit Risk

As a result of our foreign operations, we are exposed to changes in the general economic conditions in the countries in which we conduct business. Substantially all of our accounts receivable due from these countries are due from or backed by sovereign or local governments, and the amount of non-sovereign accounts receivable is not material. We continue to monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. The adverse credit and economic conditions in Italy and Spain, among other members of the European Union, have improved in recent periods and, although collection of our accounts receivables due from these countries may extend beyond our standard credit terms, we do not expect any such delays to have a material impact on our financial condition or results of operations.

Item 4. CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of June 30, 2014. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2014, our disclosure controls and procedures were effective to provide reasonable assurance that information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure, and ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

There has been no change in our internal control over financial reporting that occurred during the quarter ended June 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS.
None.

Item 1A. Risk Factors.
(amounts in thousands, except percentages)
You should carefully consider the following risk factors before you decide to invest in Alexion and our business because these risk factors may have a significant impact on our business, operating results, financial condition, and cash flows. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of the following risks actually occurs, our business, financial condition and results of operations could be materially and adversely affected.
Risks Related to Our Lead Product Soliris
We depend heavily on the success of our lead product, Soliris. If we are unable to increase sales of Soliris, or obtain approval or commercialize Soliris in new territories for the treatment of PNH, aHUS or for additional indications, or if we are significantly delayed or limited in doing so, our business may be materially harmed.
Our ability to generate revenues will continue to depend on commercial success of Soliris in the United States, Europe, Japan and in a number of key markets in the rest of the world and whether physicians, patients and health care payers view Soliris as therapeutically effective and safe relative to cost. Since we launched Soliris in the United States in April 2007, essentially all of our revenue has been attributed to sales of Soliris, and we expect that Soliris product sales will continue to contribute to a significant percentage or almost all of our total revenue over the next several years.
In September and November 2011 we obtained marketing approval in the United States and the European Union, respectively, for Soliris for the treatment of a second indication, aHUS. In September 2013, the MHLW approved Soliris for the treatment of patients with aHUS in Japan.
We dedicate significant resources to the worldwide commercialization of Soliris. We have established sales and marketing capabilities in the United States and in many countries throughout the world. We cannot guarantee that any marketing application for Soliris for the treatment of PNH, aHUS or any other indication, will be approved or maintained in any country where we seek marketing authorization to sell Soliris. In certain countries, we continue discussions with authorities to finalize operational, reimbursement, price approval and funding processes so that we may, upon conclusion of such discussions, commence commercial sales of Soliris for the treatment of PNH in those countries. We have had and will continue to have similar discussions with authorities to facilitate the commercialization of Soliris for the treatment of aHUS in certain countries in the European Union. Our ability to complete such processes successfully is subject to the risks and uncertainties described in this Quarterly Report on Form 10-Q. We cannot guarantee that we will be able to obtain reimbursement for Soliris or successfully commercialize Soliris in any additional countries, or that we will be able to maintain coverage or reimbursement at anticipated levels in any country in which we have already received marketing approval. As a result, sales in certain countries may be delayed or never occur, or may be subsequently reduced.
The commercial success of Soliris and our ability to generate and increase revenues will depend on several factors, including the following:

- receipt of marketing approvals for Soliris for the treatment of PNH in new territories and the maintenance of marketing approvals for the treatment of PNH in the United States, the European Union, Japan and other territories;
- receipt and maintenance of marketing approvals for Soliris for the treatment of aHUS in other territories and the maintenance of the marketing approval in the United States, Japan and the European Union;
- our ability to obtain sufficient coverage or reimbursement by government or third-party payers and our ability to maintain coverage or reimbursement at anticipated levels;
- establishment and maintenance of commercial manufacturing capabilities ourselves or through third-party manufacturers;

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- the number of patients with PNH and aHUS, and the number of those patients who are diagnosed with PNH and aHUS and identified to us;
- the number of patients with PNH and aHUS that may be treated with Soliris;
- successful continuation of commercial sales in the United States, Japan and in European countries where we are already selling Soliris for the treatment of PNH, and successful launch in countries where we have not yet obtained, or only recently obtained, marketing approval or commenced sales;
- successfully launching commercial sales of Soliris for the treatment of aHUS in the United States, Japan and Europe, and in countries where we have not yet obtained marketing approval;
- acceptance of Soliris and maintenance of safety and efficacy in the medical community; and
- our ability to develop, register and commercialize Soliris for indications other than PNH, including aHUS.

If we are not successful in increasing sales of Soliris in the United States, Europe and Japan and commercializing in the rest of the world, or are significantly delayed or limited in doing so, we may experience surplus inventory, our business may be materially harmed and we may need to significantly curtail operations.

Because the target patient populations of Soliris for the treatment of PNH and aHUS are small and have not been definitively determined, we must be able to successfully identify patients in order to maintain profitability and growth.

PNH and aHUS are each ultra-rare diseases with small patient populations that have not been definitively determined. There can be no guarantee that any of our programs will be effective at identifying patients and the number of patients in the United States, Japan and Europe and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with Soliris, or new patients may become increasingly difficult to identify, all of which would adversely affect our results of operations and our business.

If we are unable to obtain, or maintain at anticipated levels, reimbursement for Soliris from government health administration authorities, private health insurers and other organizations, our pricing may be affected or our product sales, results of operations or financial condition could be harmed.

We may not be able to sell Soliris on a profitable basis or our profitability may be reduced if we are required to sell our product at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. Soliris is significantly more expensive than traditional drug treatments and almost all patients require some form of third party coverage to afford its cost. Our future revenues and profitability will be adversely affected if we cannot depend on governmental payers, such as Medicare and Medicaid in the United States or country specific governmental organizations, and private third-party payers to defray the cost of Soliris to patients. These entities may refuse to provide coverage and reimbursement with respect to Soliris, determine to provide a lower level of coverage and reimbursement than anticipated, or reduce previously approved levels of coverage and reimbursement, including in the form of higher mandatory rebates or modified pricing terms. In any such case, our pricing or reimbursement for Soliris may be affected and our product sales, results of operations or financial condition could be harmed.

In certain countries where we sell or are seeking or may seek to commercialize Soliris, including certain countries where we both sell Soliris for the treatment of PNH and sell or seek to commercialize Soliris for the treatment of aHUS, if approved by the appropriate regulatory authority, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control. We may be unable to timely or successfully negotiate coverage, pricing, and reimbursement on terms that are favorable to us, or such coverage, pricing, and reimbursement may differ in separate regions in the same country. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country, and we cannot guarantee that we will have the capabilities or resources to successfully conclude the necessary processes and commercialize Soliris in every or even most countries in which we seek to sell Soliris. Reimbursement sources are different in each country and in each country may include a combination of distinct potential payers, including private insurance and governmental payers. For example, the European Union member states' authorities may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and adopt additional measures to control the prices of medicinal products for human use. This includes the use of reference pricing and Health Technology Assessment (HTA). HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of the use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products

as well as their potential implications for the healthcare system. These elements of medicinal products are compared with other treatment options available on the market. The national authorities of some European Union member states may from time to time approve a specific price for the medicinal product. Others may

adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the national market. Some countries have and others may seek to impose limits on the aggregate reimbursement for Soliris or for the use of Soliris for certain indications. In such cases, our commercial operations in such countries and our results of operations and our business are and may be adversely affected. Our results of operations may suffer if we are unable to successfully and timely conclude reimbursement, price approval or funding processes and market Soliris in such foreign countries or if coverage and reimbursement for Soliris is limited or reduced. If we are not able to obtain coverage, pricing or reimbursement on terms acceptable to us or at all, or if such terms should change in any foreign countries, we may not be able to or we may determine not to sell Soliris for one or more indications in such countries, or we could decide to sell Soliris at a lower than anticipated price in such countries, and our revenues may be adversely affected as a result.

The potential increase in the number of patients receiving Soliris may cause third-party payers to modify or limit coverage or reimbursement for Soliris for the treatment of PNH, aHUS, or both indications.

Changes in pricing or the amount of reimbursement in countries where we currently commercialize Soliris may also reduce our profitability and worsen our financial condition. In the United States, the European Union member states, and elsewhere, there have been, and we expect there will continue to be, efforts to control and reduce health care costs. Government and other third-party payers in the United States and the European Union member states are challenging the prices charged for health care products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs. A significant reduction in the amount of reimbursement or pricing for Soliris in one or more countries may have a material adverse effect on our business. See additional discussion below under the headings “Government initiatives that affect coverage and reimbursement of drug products could adversely affect our business” and “The credit and financial market conditions may aggravate certain risks affecting our business.” In addition, certain countries establish pricing and reimbursement amounts by reference to the price of the same or similar products in other countries. If coverage or the level of reimbursement is limited in one or more countries, we may be unable to obtain or maintain anticipated pricing or reimbursement in current or new territories. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Third-party payers may be especially likely to impose these obstacles to coverage for higher-priced drugs such as Soliris.

Even in countries where patients have access to insurance, their insurance co-payment amounts or annual or lifetime caps on reimbursements may represent a barrier to obtaining or continuing Soliris. We have financially supported non-profit organizations which assist patients in accessing treatment for PNH and aHUS, including Soliris. Such organizations assist patients whose insurance coverage leaves them with prohibitive co-payment amounts or other expensive financial obligations. Such organizations' ability to provide assistance to patients is dependent on funding from external sources, and we cannot guarantee that such funding will be provided at adequate levels, if at all. We have also provided Soliris without charge to patients who have no insurance coverage for drugs for related charitable purposes. We are not able to predict the financial impact of the support we may provide for these and other charitable purposes; however, substantial support could have a material adverse effect on our profitability in the future.

We are also focusing development efforts on the use of eculizumab for the treatment of additional diseases. The success of these programs depends on many factors, including those described under the heading "Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candidates." As eculizumab is approved by regulatory agencies for indications other than PNH, the potential increase in the number of patients receiving Soliris may cause third-party payers to refuse coverage or reimbursement for Soliris for the treatment of PNH or for any other approved indication, or provide a lower level of coverage or reimbursement than anticipated or currently in effect.

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

We cannot be certain that Soliris will gain or maintain market acceptance in a particular country among physicians, patients, health care payers, and others. Although we have received regulatory approval for Soliris in certain territories, including the United States, Japan and the European Union, such approvals do not guarantee future revenue. We cannot predict whether physicians, other health care providers, government agencies or private insurers will determine or continue to accept that Soliris is safe and therapeutically effective relative to its cost. Medical

doctors' willingness to prescribe, and patients' willingness to accept, Soliris depends on many factors, including prevalence and severity of adverse side effects in both clinical trials and commercial use, effectiveness of our marketing strategy and the pricing of Soliris, publicity concerning Soliris, our other product candidates or competing products, our ability to obtain and maintain third-party coverage or reimbursement, and availability of alternative treatments, including bone marrow transplant as an alternative treatment for PNH. The likelihood of medical doctors to prescribe Soliris for patients with aHUS may also depend on how quickly Soliris can be delivered to the hospital or clinic and our distribution methods may not be sufficient to satisfy this need. In addition, we are aware that medical doctors have determined not to continue Soliris treatment for some patients with aHUS. If Soliris fails to achieve or maintain

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

If we or our contract manufacturers fail to comply with continuing United States and foreign regulations, we could lose our approvals to market Soliris or our manufacturers could lose their approvals to manufacture Soliris, and our business would be seriously harmed.

We cannot guarantee that we will be able to maintain our regulatory approvals for Soliris. If we do not maintain our regulatory approvals for Soliris, the value of our company and our results of operations will be materially harmed. We and our current and future partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by the FDA, other federal and state agencies, and governmental authorities in other territories. For example, in March 2013, we received a Warning Letter (Warning Letter) from the FDA relating to compliance with cGMP at ARIMF. While we believe that we will successfully resolve outstanding concerns expressed by the FDA in the Warning Letter, we cannot guarantee that we will do so to the satisfaction of the FDA, EMA or other regulatory agencies and approval of the facility by any such agencies could be withdrawn as a result.

Regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, finishing, filling, labeling, advertising, promotion, risk mitigation, adverse event reporting requirements, and export of biologics. For example, the risk management program established in 2007 upon the FDA's approval of Soliris for the treatment of PNH was replaced with a Risk Evaluation and Mitigation Strategy (REMS) program, approved by the FDA in 2010. The REMS program requires mandatory physician certification in the United States. Each physician must certify that the physician is aware of the potential risks associated with the administration of Soliris and that the physician will inform each patient of these risks using educational material approved by the FDA.

As a condition of approval for marketing Soliris, governmental authorities may require us to conduct additional studies. For example, in connection with the approval of Soliris in the United States, European Union and Japan, for the treatment of PNH, we agreed to establish a PNH Registry, monitor immunogenicity, monitor compliance with vaccination requirements, and determine the effects of anticoagulant withdrawal among PNH patients receiving eculizumab, and, specifically in Japan, we agreed to conduct a trial in a limited number of Japanese PNH patients to evaluate the safety of a meningococcal vaccine. Further, in connection with the approval of Soliris in the United States for the treatment of aHUS, we agreed to establish an aHUS Registry and complete additional human clinical studies in adult and pediatric patients. In the United States, for example, the FDA can propose to withdraw approval for a product if it determines that such additional studies are inadequate or if new clinical data or information shows that a product is not safe for use in an approved indication. We are required to report any serious and unexpected adverse experiences and certain quality problems with Soliris to the FDA, the EMA, the competent authorities of the European Union member states, MHLW, and certain other health agencies. We or any health agency may have to notify health care providers of any such developments.

The discovery of any previously unknown problems with Soliris, a manufacturer or a facility may result in restrictions on Soliris, a manufacturer or a facility, including withdrawal of Soliris from the market, batch failures, or interruption of production or a product recall such as the recalls we announced and voluntarily initiated in 2013 and 2014. Certain changes to an approved product, including the way it is manufactured or promoted, often require prior regulatory approval before the product as modified may be marketed. Our manufacturing and other facilities and those of any third parties manufacturing Soliris will be subject to inspection prior to grant of marketing approval by each regulatory authority where we seek marketing approval and subject to continued review and periodic inspections by the regulatory authorities, such as the inspections that resulted in issuance of the Warning Letter. We and any third party we would use to manufacture Soliris for sale, including Lonza, must also be licensed by applicable regulatory authorities.

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

- a product recall;
- a product withdrawal;

- significant administrative and judicial sanctions, including, warning letters or untitled letters;
- significant fines and other civil penalties;
- suspension or withdrawal of a previously granted approval for Soliris;
- interruption of production;
- operating restrictions, such as a shutdown of production facilities or production lines;
- suspension of ongoing clinical trials;

- delays in approving or refusal to approve Soliris or a facility that manufactures Soliris;
- seizing or detaining product;
- injunctions; and/or
- criminal prosecution.

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

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

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

We may be sued by people who use Soliris, whether as a prescribed therapy, during a clinical trial, during an investigator initiated study, or otherwise. Many patients who use Soliris are already very ill. Any informed consents or waivers obtained from people who enroll in our trials or use Soliris may not protect us from liability or litigation. Our product liability insurance may not cover all potential types of liabilities or may not cover certain liabilities completely. Moreover, we may not be able to maintain our insurance on acceptable terms. In addition, negative publicity relating to the use of Soliris or a product candidate, or to a product liability claim, may make it more difficult, or impossible, for us to market and sell Soliris. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Patients who use Soliris already often have severe and advanced stages of disease and known as well as unknown significant pre-existing and potentially life-threatening health risks, including, for example, bone marrow failure, kidney failure and thrombosis. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to Soliris. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market Soliris, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to Soliris, the investigation into the circumstance may be time consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals Soliris receives or

maintains.

Some patients treated with Soliris for PNH and other diseases, including patients who have participated in our clinical trials, have died or suffered potentially life-threatening diseases either during or after ending their Soliris treatments. In particular, use of C5 Inhibitors, such as Soliris, is associated with an increased risk for certain types of infection, including meningococcal infection. Serious cases of meningococcal infection can result in severe illness, including but not limited to brain damage, loss of limbs or parts of limbs, kidney failure, or death. Under controlled settings, patients in our eculizumab trials all receive vaccination against meningococcal infection prior to first administration of Soliris and patients who are prescribed Soliris in most countries are required by prescribing guidelines to be vaccinated prior to receiving their first dose. A

physician may not have the opportunity to timely vaccinate a patient in the event of an acute emergency episode, such as in a patient presenting with aHUS or during the health crisis that began in May 2011 in Europe, principally in Germany, due to the epidemic of infections from Enterohemorrhagic E. coli. Vaccination does not, however, eliminate all risk of meningococcal infection. Additionally, in some countries there may not be any vaccine approved for general use or approved for use in infants and children. Some patients treated with Soliris who had been vaccinated have nonetheless experienced meningococcal infection, including patients who have suffered serious illness or death. Each such incident is required to be reported to appropriate regulatory agencies in accordance with relevant regulations.

We are also aware of a potential risk for PNH patients who delay a dose of Soliris or discontinue their treatment of Soliris. Treatment with Soliris blocks complement and allows complement-sensitive PNH red blood cells to increase in number. If treatment with Soliris is thereafter delayed or discontinued, a greater number of red blood cells therefore would become susceptible to destruction when the patient's complement system is no longer blocked. The rapid destruction of a larger number of a patient's red blood cells may lead to numerous complications, including death. Several PNH patients in our studies of Soliris have received delayed doses or discontinued their treatment. In none of those circumstances were significant complications shown to be due to rapid destruction of a larger number of PNH red blood cells; however, we have not studied the delay or termination of treatment in enough patients to determine that such complications in the future are unlikely to occur. Additionally, such delays or discontinuations may be associated with significant complications without evidence of such rapid cell destruction.

We are aware of a risk for aHUS patients who delay or miss a dose of Soliris or discontinue their treatment of Soliris. Treatment with Soliris blocks complement and inhibits complement-mediated TMA. After missing a dose or discontinuing Soliris, blood clots may form in small blood vessels throughout the body, causing a reduction in platelet count. The reduction in platelet count may lead to numerous complications, including changes in mental status, seizures, angina, thrombosis, renal failure or even death. In our aHUS clinical studies, such TMA complications were observed in some patients who missed a dose.

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

Although we obtained regulatory approval to market and sell Soliris for PNH and aHUS in the United States, the European Union and Japan, and in other territories, we cannot guarantee that we will obtain the regulatory approval or reimbursement approval for Soliris for the treatment of PNH, aHUS or other diseases in each territory where we seek approvals.

Governments in countries where we seek to commercialize Soliris regulate the distribution of drugs and the facilities where such drugs are manufactured, and obtaining their approvals can be lengthy, expensive and highly uncertain. The approval process varies from country to country, and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. In certain jurisdictions, we are required to finalize operational, reimbursement, price approval and funding processes prior to marketing our products, even in countries where marketing approval has been obtained. We have received regulatory approval for Soliris for treatment of patients with PNH in the United States, the European Union, Japan and other territories. In September and November 2011 we received regulatory approval for Soliris for the treatment of patients with aHUS in the United States and the European Union, respectively. In September 2013, the MHLW approved Soliris for the treatment of patients with aHUS in Japan. We may not receive regulatory or reimbursement approval for Soliris for the treatment of PNH, aHUS or any other disease in any other territories on a timely basis, if ever.

Regulatory agencies may require additional information or data with respect to our submissions for Soliris, including the marketing authorization applications submitted to the EMA for the treatment of patients with aHUS. We may have to conduct additional lengthy clinical testing and other costly and time-consuming procedures to satisfy foreign regulatory agencies. Even with approval of Soliris in certain countries, the regulatory agencies in other countries may not agree with our interpretations of our clinical trial data for Soliris and may decide that our results are not adequate to support approval for marketing of Soliris. In those circumstances, we would not be able to obtain regulatory approval in such country on a timely basis, if ever. Even if approval is granted in such country, the approval may require limitations on the indicated uses for which the drug may be marketed. The foreign regulatory approval process

includes all of the risks associated with FDA approval as well as country-specific regulations. We must obtain approval of a product by the comparable regulatory authorities and ethics committees of foreign countries before we can commence clinical trials or marketing of the product in those countries. We were required to conduct clinical studies with Soliris in patients with PNH in Japan prior to obtaining marketing approval in that country and Japanese authorities could require additional studies in Japan for Soliris for the treatment of patients with aHUS. We are also conducting prospective clinical trials in adult and pediatric patients to confirm the benefit of Soliris for the treatment of aHUS. Commercialization of Soliris for the treatment of PNH, aHUS or any other indication could be delayed, limited or may not

occur in territories where we seek marketing approval if the applicable regulatory agency requires additional information or data.

Our commercialization of Soliris may be stopped, delayed or made less profitable if we or any other third party provider fails to provide sufficient quantities of Soliris. Commercial quantities of Soliris can only be manufactured at three facilities, including our own facility in Rhode Island. Vial filling can only be performed at three third party facilities.

Commercial quantities of Soliris are manufactured by Alexion at ARIMF and by Lonza. Manufacturing processes must comply with applicable regulations and manufacturing practices, as well as our own quality standards. In particular, the manufacture of Soliris is heavily regulated by governmental authorities around the world, including the FDA, EMA, the competent authorities of the European Union member states, and MHLW. If we do not resolve outstanding concerns expressed by the FDA in the Warning Letter to the satisfaction of the FDA, EMA or any other regulatory agency, or we or our third-party providers, including our product fillers, packagers and labelers, fail to comply fully with applicable regulations then we may be required to initiate a recall or withdrawal of our products. We may also lose any redundancy in our manufacturing capabilities if we are no longer able to perform operations at ARIMF or any other facility. Regulatory agencies could take action that leads to product shortages. Such action may include:

- issuing warning or untitled letters, such as the Warning Letter;
- requiring corrective action or restrictions on operations, including costly and time-consuming new manufacturing requirements;
- ordering shutdown of production facilities or production lines;
- seizing or detaining product;
- suspending or withdrawing the approval of Soliris;
- imposing significant civil penalties and criminal fines;
- suspending ongoing clinical studies for Soliris;
- require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; and/or
- refusing to approve pending BLAs or BLA supplements for Soliris.

The manufacture of Soliris is difficult. Manufacture of a biologic requires a multi-step controlled process and even minor problems or deviations could result in defects or failures. We cannot be certain that we, Lonza or our other third party providers will be able to perform uninterrupted supply chain services. The failure to manufacture appropriate supplies of Soliris, on a timely basis, or at all, may prevent or interrupt the commercialization of Soliris. If we, Lonza or our other third party providers were unable to manufacture Soliris for any period, or if we, Lonza or our other third party providers do not obtain approval for the manufacturing of Soliris in the respective facility by the applicable regulatory agencies, we may incur substantial loss of sales. If we are forced to find an alternative supplier or other third party providers for Soliris, in addition to loss of sales, we may also incur significant costs and experience significant delay in establishing a new arrangement.

We are authorized to sell product that is manufactured by Lonza and at ARIMF in the United States, the European Union, Japan and certain other territories. However, manufacturing Soliris for commercial sale in certain other territories may only be performed at a single facility until such time as we have received the required regulatory approval for an additional facility, if ever. We will continue to depend entirely on one facility to manufacture Soliris for commercial sale in such other territories until that time.

In September and November 2011 we received marketing approval for Soliris for the treatment of patients with aHUS in the United States and European Union, respectively. In September 2013, the MHLW approved Soliris for the treatment of patients with aHUS in Japan. If Soliris is approved in other territories for the treatment of patients with aHUS, or for additional indications, we expect that the demand for Soliris will increase. We may underestimate demand, or experience product interruptions at ARIMF, Lonza or a facility of a third party provider, including as a result of risks and uncertainties described in this report. If we, Lonza or our other third party providers do not manufacture sufficient quantities of Soliris to satisfy demand, our business will be materially harmed.

We depend on a very limited number of third party providers for other services with respect to our clinical and commercial requirements, including product finishing, packaging, filling and labeling. We have changed or added third party fillers in the past in order to support uninterrupted supply, and may do so in the future. We currently rely on two third party fillers to support our commercial requirements in the United States, three to support requirements in the European Union, and two to support requirements in Japan. No guarantee can be made that any third party filler will be able to perform such

services for sufficient product volumes for any country or territory. We do not have control over any third party provider's compliance with our internal or external specifications or the rules and regulations of the FDA, EMA, competent authorities of the European Union member states, MHLW or any other applicable regulations or standards. In the past, we have had to write off and incur other charges and expenses for production that failed to meet requirements, including $14,277 with respect to the recall initiated in November 2013. Any difficulties or delays in our third party manufacturing of Soliris, or any failure of our third party providers to comply with our internal and external specifications or any applicable rules, regulations and standards could increase our costs, constrain our ability to satisfy demand for Soliris from customers, cause us to lose revenue or incur penalties for failure to deliver product, make us postpone or cancel clinical trials, or cause our products to be recalled or withdrawn, such as the voluntary recalls that we initiated and announced in 2013 and 2014 due to the presence of visible particles in a limited number of vials in specific lots.

In April 2014, we acquired a filling facility in Ireland to support global distribution of Soliris and Alexion's other clinical and commercial products. To date, we have relied entirely on third party fillers and have never operated our own filling facility. We cannot guarantee that we will be able to successfully complete the appropriate validation processes or obtain the necessary regulatory approvals, or that we will be able to perform filling services at this facility to support our product requirements.

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

We are dependent upon a small number of customers for a significant portion of our revenue, and the loss of, or significant reduction or cancellation in sales to, any one of these customers could adversely affect our operations and financial condition.

For the six months ended June 30, 2014, our largest customer accounted for 18% of our global Soliris net product sales, and our three largest customers accounted for approximately 33% of our global net product sales. As of June 30, 2014, our single largest customer accounted for 21% of the global accounts receivable balance. We expect such customer concentration to continue for the foreseeable future. We typically sell Soliris to third party distributors, such as specialty pharmacies, who in turn sell to patient health care providers. We do not promote Soliris to these distributors, and they do not set or determine demand for Soliris. Our ability to successfully commercialize Soliris will depend, in part, on the extent to which we are able to provide adequate distribution of Soliris to patients. Although a number of specialty distributors and specialty pharmacies, which supply physician office clinics, hospital outpatient clinics, infusion clinics, home health care providers, and governmental organizations, distribute Soliris, they generally carry a very limited inventory and may be reluctant to distribute Soliris in the future if demand for the product does not increase. Further, it is possible that our distributors could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to distribute smaller volume products such as Soliris, or cause higher product distribution costs, lower margins or the need to find alternative methods of distributing our product. Although we believe we can find alternative distributors on a relatively short notice, our revenue during that period of time may suffer and we may incur additional costs to replace a distributor. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us or any failure to pay for the products we have shipped to them could materially and adversely affect our results of operations and financial condition.

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

We are marketing and selling Soliris ourselves in the United States, Europe, Japan and several other territories. If we are unable to establish and/or expand our capabilities to sell, market and distribute Soliris for the treatment of PNH, aHUS or, if approved by the necessary regulatory agencies, other future indications, either through our own capabilities or by entering into agreements with others, or to maintain such capabilities in countries where we have already commenced commercial sales, we will not be able to successfully sell Soliris. In that event, we will not be able to generate significant revenues. We cannot guarantee that we will be able to establish and maintain our own

capabilities or enter into and maintain any marketing or distribution agreements with third-party providers on acceptable terms, if at all. Even if we hire the qualified sales and marketing personnel we need to support our objectives, or enter into marketing and distribution agreements with third parties on acceptable terms, we may not do so in an efficient manner or on a timely basis. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell Soliris. Establishing and maintaining sales, marketing and distribution capabilities are expensive and time-consuming. Our expenses associated with building up and maintaining the sales force and distribution capabilities around the world may be disproportionate compared to the revenues we may be able to generate on sales of Soliris. We cannot guarantee that we will be successful in commercializing Soliris.

If we market Soliris in a manner that violates health care fraud and abuse laws and other laws regulating marketing and promotion, we may be subject to investigations and civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care “fraud and abuse” laws, such as the Federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, patients, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing, or recommending may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor. We seek to comply with the anti-kickback laws and with the available statutory exemptions and safe harbors. However, our practices may not in all cases fit within the safe harbors, and our practices may therefore be subject to case-by-case scrutiny.

The Federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the Federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been investigated and have reached substantial financial settlements with the Federal government under this Act for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees and other benefits to physicians to induce them to prescribe products; reporting inflated prices to private publications that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or "off-label" uses, that caused claims to be submitted to Federal programs for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program.

Although physicians are permitted to, based on their medical judgment, prescribe products for indications other than those cleared or approved by the FDA, manufacturers are prohibited from promoting their products for such off-label uses. In the United States, we market Soliris for PNH and aHUS and provide promotional materials and training programs to physicians regarding the use of Soliris for PNH and aHUS. Although we believe our marketing materials and training programs for physicians do not constitute off-label promotion of Soliris, the FDA, the U.S. Justice Department, or other federal or state government agencies may disagree. If the FDA or other government agencies determine that our promotional materials, training or other activities constitute off-label promotion of Soliris, it could request that we modify our training or promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is later determined we are not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our position and have to divert significant management resources from other matters.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors and because government scrutiny in this area is high, it is possible that some of our business activities could come under that scrutiny.

Several U.S. states and localities have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Additionally, as part

of the Patient Protection and Affordable Care Act, the Federal government has enacted the Physician Payment Sunshine provisions, which requires manufacturers to publicly report gifts and payments made to physicians and teaching hospitals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Similar strict restrictions are imposed on the promotion and marketing of drug products in the European Union, where a large portion of our non-U.S. business is conducted, and other territories. Laws in the European Union, including in the individual European Union member states, require promotional materials and advertising for drug products to comply with the

product's Summary of Product Characteristics (SmPC), which is approved by the competent authorities. Promotion of a drug product which does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of drug products is prohibited in the European Union and in other territories. Laws in the European Union, including in the individual European Union member states, also prohibit the direct-to-consumer advertising of prescription-only drug products. Violations of the rules governing the promotion of drug products in the European Union and in other territories could be penalized by administrative measures, fines and imprisonment.

Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual European Union member states. The provision of any inducements to physicians to prescribe, recommend, endorse, order, purchase, supply, use or administer a drug product is prohibited. A number of European Union member states have introduced additional rules requiring pharmaceutical companies to publicly disclose their interactions with physicians and to obtain approval from employers, professional organizations and/or competent authorities before entering into agreements with physicians. Additional countries may consider or implement similar laws and regulations. Violations of these rules could lead to the imposition of fines or imprisonment.

Laws, including those governing promotion, marketing and anti-kickback provisions, industry regulations and professional codes of conduct are often strictly enforced. Increasing regulatory scrutiny of the promotional activities of pharmaceutical companies has been observed in a number of European Union member states. We are also subject to the United States Foreign Corrupt Practices Act (FCPA), the U.K. Bribery Act, and other anti-corruption laws and regulations pertaining to our financial relationships with government officials. Worldwide regulators are increasing their regulatory and enforcement efforts in this area. For example, the Bribery Act in the United Kingdom entered into force in July 2011 applies to any company incorporated in or "carrying on business" in the United Kingdom, regardless of the country in which the alleged bribery activity occurs and even if the inappropriate activity is undertaken by our international distribution partners.

Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candidates

None of our product candidates except for Soliris has received regulatory approvals. Soliris has not been approved for any indication other than for the treatment of patients with PNH and aHUS. If we are unable to obtain regulatory approvals to market one or more of our product candidates, our business may be adversely affected.

All of our product candidates except Soliris and asfotase alfa are in early stages of development, and we do not expect our early stage product candidates to be commercially available for several years, if at all. Similarly, Soliris has not been approved for any indication other than for the treatment of patients with PNH in the United States, the European Union, Japan and other territories, and for patients with aHUS in the United States, the European Union and Japan. Although we are preparing for a commercial launch of asfotase alfa for the treatment of hypophosphatasia, we do not know when or if asfotase alfa will be approved by the FDA, EMA or any other regulatory agency. We have commenced a rolling submission of our BLA for asfotase alfa, which allows completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. While we believe a rolling submission will allow us to expedite the review of the application, we cannot predict how long the approval process will take or when we will receive approval, if at all. We do not know when or if our other product candidates will be approved. Our product candidates are subject to strict regulation by regulatory authorities in the United States, in the European Union and in other territories. We cannot market any product candidate until we have completed all necessary preclinical studies and clinical trials and have obtained the necessary regulatory approvals. We do not know whether regulatory agencies will grant approval for any of our product candidates. Even if we complete preclinical studies and clinical trials successfully, we may not be able to obtain regulatory approvals or we may not receive approvals to make claims about our products that we believe to be necessary to effectively market our products. Data obtained from preclinical studies and clinical trials are subject to varying interpretations that could delay, limit or prevent regulatory approval, failure to comply with regulatory requirements, resolve pending concerns described in the Warning Letter, and inadequate manufacturing processes are examples of other problems that could prevent approval. In addition, we may encounter delays or rejections due to additional government regulation from future legislation, administrative action or changes in the FDA policy. Even if the FDA approves a product, the approval will be limited to those indications covered in the approval.

Outside the United States, our ability to market any of our potential products is dependent upon receiving marketing approvals from the appropriate regulatory authorities. These foreign regulatory approval processes include all of the risks associated with the FDA approval process described above. If we are unable to receive regulatory approvals, we will be unable to commercialize our product candidates, and our business may be adversely affected.

Completion of preclinical studies or clinical trials does not guarantee advancement to the next phase of development. Completion of preclinical studies or clinical trials does not guarantee that we will initiate additional studies or trials for our product candidates, that if further studies or trials are initiated what the scope and phase of the trial will be or that they will

be completed, or that if these further studies or trials are completed, that the design or results will provide a sufficient basis to apply for or receive regulatory approvals or to commercialize products. Results of clinical trials could be inconclusive, requiring additional or repeat trials. If the design or results achieved in our clinical trials are insufficient to proceed to further trials or to regulatory approval of our product candidates, our company could be materially adversely affected. Failure of a clinical trial to achieve its pre-specified primary endpoint generally increases the likelihood that additional studies or trials will be required if we determine to continue development of the product candidate, reduces the likelihood of timely development of and regulatory approval to market the product candidate, and may decrease the chances for successfully achieving the primary endpoint in scientifically similar indications.
There are many reasons why drug testing could be delayed or terminated.
For human trials, patients must be recruited and each product candidate must be tested at various doses and formulations for each clinical indication. In addition, to ensure safety and effectiveness, the effect of drugs often must be studied over a long period of time, especially for the chronic diseases that we are studying. Many of our programs focus on diseases with small patient populations and insufficient patient enrollment in our clinical trials could delay or cause us to abandon a product development program. We may decide to abandon development of a product candidate at any time due to unfavorable results or other reasons, or we may have to spend considerable resources repeating clinical trials or conducting additional trials, either of which would increase costs and delay any revenue from those product candidates, if any.
Additional factors that can cause delay, impairment or termination of our clinical trials or our product development efforts include:

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

The regulatory approval process is costly and lengthy and we may not be able to successfully obtain all required regulatory approvals.

The preclinical development, clinical trials, manufacturing, marketing and labeling of pharmaceuticals are all subject to extensive regulation by numerous governmental authorities and agencies in the United States, the European Union and other territories. We must obtain regulatory approval for each of our product candidates before marketing or selling any of them. It is not possible to predict how long the approval processes of the FDA or any other applicable federal or foreign regulatory authority or agency for any of our product candidates will take or whether any such approvals ultimately will be granted. The FDA and foreign regulatory agencies have substantial discretion in the drug approval process, and positive results in preclinical testing or early phases of clinical studies offer no assurance of success in later phases of the approval process. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. Generally, preclinical and clinical testing of product candidates can take many years and require the expenditure of substantial resources, and the data obtained from these tests and trials can be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. If we encounter significant delays in the regulatory process, this may prevent us from continuing to develop our product candidates due to excessive costs or otherwise. Any delay in obtaining, or failure to obtain, approvals could adversely affect the marketing of our products and our ability to generate product revenue. The risks associated with the approval process include:

- failure of our product candidates to meet a regulatory agency's requirements for safety, efficacy and quality;
- disagreement over interpretation of data from preclinical studies or clinical trials;
- restricted distribution or limitation on the indicated uses for which a product may be marketed;
- unforeseen safety issues or side effects and potential requirements to establish REMS;
- disapproval of the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- governmental or regulatory delays and changes in regulatory requirements and guidelines.

Even if our product candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients and health care payers.

Physicians may elect not to recommend our drugs even if they receive marketing approval for a variety of reasons, including the timing of the market introduction of competitive drugs; lower demonstrated clinical safety and efficacy compared to other drugs; perceived lack of cost-effectiveness; lack of availability of reimbursement from third-party payers; convenience and ease of administration; prevalence and severity of adverse side effects; other potential advantages of alternative treatment methods; and ineffective marketing and distribution support. Sales of pharmaceutical products depend in significant part on the coverage and reimbursement policies of government programs, including Medicare and Medicaid in the United States and similar programs in other countries, and other third-party payers. These health insurance programs may restrict coverage of some products by using payer formularies under which only selected drugs are covered, variable co-payments that make drugs that are not preferred by the payer more expensive for patients, and by using utilization management controls, such as requirements for prior authorization or failure on another type of treatment. Payers may especially impose these obstacles to coverage for higher-priced drugs, and consequently our drug candidates may be subject to payer-driven restrictions. In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, European Union member states may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. A European Union member state may approve a specific price or level of reimbursement for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. The reimbursement or budget identified by a government or non-government payer for Soliris in a new indication, if obtained, may be adversely affected by the reimbursement or budget for Soliris in previously approved indications and/or adversely affect the reimbursement or budget for Soliris in such previously approved indication by that payer.

Inability to contract with third party manufacturers and other third party providers on commercially reasonable terms, or failure or delay by us or our third party manufacturers or other third party providers to provide services with respect to our drug products in the volumes and quality required, would have a material adverse effect on our business. Clinical quantities of eculizumab are manufactured by us at ARIMF and by Lonza. Clinical quantities of our other product candidates are manufactured by us at ARIMF or by a third party. We also depend on a very limited number of third party providers for other services with respect to our clinical and commercial requirements, including product finishing, packaging, filling and labeling. We have changed or added third party fillers in the past in order to support uninterrupted

supply, and may do so in the future. No guarantee can be made that regulators will approve additional third party fillers in a timely manner or at all, or that any third party filler will be able to perform such services for sufficient product volumes for any country or territory. A regulator may also refuse to approve a BLA if the manufacturing facility or service provider for the relevant product candidate is not approved. Manufacture of our drug products is highly technical, and only a small number of companies have the ability and capacity to manufacture our drug products for our development and commercialization needs. Due to the highly technical requirements of manufacturing our drug products and the strict quality and control specifications, we and our third party providers may be unable to manufacture or supply our drug products despite our and their efforts. In addition, we cannot be certain that any third party will be able or willing to honor the terms of its agreement, including any obligations to manufacture the drug products in accordance with regulatory requirements and to our quality specifications and volume requirements. Further, we have limited experience manufacturing the drug candidates that we acquired from third parties. We cannot guarantee that we or any third party provider will be able to manufacture or supply such drug candidates, or that we or a third party provider will be able to manufacture or supply sufficient quantities to satisfy our requirements.

Manufacture of drug products, including the need to develop and utilize manufacturing processes that consistently produce our drug products to their required quality specifications, is highly regulated by the FDA, EMA and other domestic and foreign authorities. Regulatory authorities must approve the facilities in which our products are manufactured vialed, packaged and labeled prior to granting marketing approval for any product candidate. Such facilities are also subject to ongoing inspections, and minor changes in manufacturing or other related processes may require additional regulatory approvals. For example, if future inspections by regulatory authorities of our facilities or the facilities of our third party providers identify issues, including issues similar to those raised in the Warning Letter, then manufacture of some of our product candidates and our business may be adversely affected. Further, we cannot assure you that we or our third party providers will successfully comply with all requirements and regulations. In the past we have had to write-off and incur other charges and expenses for production that failed to meet requirements and in 2013 and 2014 we instituted voluntary recalls due to the presence of visible particles in a limited number of vials in specific lots. Failure to comply with all requirements and regulations by third parties in the future could have a material adverse effect on our business.

We can provide no assurance that we will be able to successfully manufacture our drug products in volumes that would be necessary to support commercial sales. We acquired ARIMF in July 2006. The EC, the FDA and MHLW have approved the use of ARIMF for the production of Soliris, and we are authorized to sell Soliris manufactured in ARIMF in the United States, the European Union, Japan and certain other territories. We are entirely dependent on only one third party provider for commercial filling in certain territories, including Japan. We have limited experience in developing commercial-scale manufacturing. We can provide no assurance that we will be able to manufacture our drug products at ARIMF under conditions required by the FDA or foreign regulatory agencies on a timely basis, if at all. ARIMF is subject to approval by other national and regional regulatory agencies before we can begin sales of Soliris or other drug products manufactured in this facility in the applicable countries or regions, and we will continue to be subject to ongoing regulatory inspections thereafter.

We, and our third party providers, may experience higher failure rates than in the past if and when we attempt to increase production volume. If we experience interruptions in the manufacture or supply of our products, our drug development and commercialization efforts will be delayed. If any of our outside third party providers stops manufacturing or supplying our products or reduces the amount manufactured or supplied, or is otherwise unable to provide our required amounts at our required quality, we may need to find other alternatives, which is likely to be expensive and time consuming, and also may result in reduced revenue during this period. Even if we are able to find alternatives they may ultimately be insufficient for our needs. As a result, our ability to conduct testing and drug trials and our plans for commercialization could be materially adversely affected. Submission of products and new development programs for regulatory approval, as well as our plans for commercialization, would be delayed or suspended. Our competitive position and our prospects for achieving or maintaining profitability could be materially and adversely affected.

Due to the nature of the current market for third-party commercial manufacturing, many arrangements require substantial penalty payments by the customer for failure to use the manufacturing capacity for which it contracted.

Penalty payments under these agreements typically decrease over the life of the agreement, and may be substantial initially and de minimis or non-existent in the final period. The payment of a substantial penalty could harm our financial condition.

Risks Related to Intellectual Property

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

In order to protect our drugs and technology more effectively, we need to obtain and maintain patents covering the drugs and technologies we develop. We have and may in the future obtain patents or the right to practice patents through ownership or license. Our patent applications may not result in the issue of patents in the United States or other countries. Our patents may not afford adequate protection for our products. Third parties may challenge our patents, and have challenged our patents

in the past. If any of our patents are narrowed, invalidated or become unenforceable, competitors may develop and market products similar to ours that do not conflict with or infringe our patents rights, which could have a material adverse effect on our financial condition. We may also finance and collaborate in research conducted by government organizations, hospitals, universities or other educational or research institutions. Such research partners may be unwilling to grant us exclusive rights to technology or products developed through such collaborations. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties.
Soliris and our drug candidates are expensive and time-consuming to test and develop. Even if we obtain and maintain patents, our business may be significantly harmed if the patents are not broad enough to protect our drugs from copycat products.
In addition, our business requires using sensitive technology, techniques and proprietary compounds that we protect as trade secrets. However, we may also rely heavily on collaboration with, or discuss the potential for collaboration with, suppliers, outside scientists and other drug companies. Collaboration and discussion of potential collaboration present a strong risk of exposing our trade secrets. If our trade secrets were exposed, it would help our competitors and adversely affect our business prospects.
If we are found to be infringing on patents owned by others, we may be forced to pay damages to the patent owner and/or obtain a license to continue the manufacture, sale or development of our drugs. If we cannot obtain a license, we may be prevented from the manufacture, sale or development of our drugs, including Soliris, which would adversely affect our business.
Parts of our technology, techniques and proprietary compounds and potential drug candidates, including those which are or may be in-licensed, may be found to infringe patents owned by or granted to others. We previously reported that Novartis and other third parties have filed civil lawsuits against us claiming infringement of their intellectual property rights. Each of these matters has been resolved, however, additional third parties may claim that the manufacture, use or sale of Soliris or other drugs under development infringes patents owned or granted to such third parties. In addition to the civil actions referenced above, 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 or some of our drug candidates. We are aware of patents owned by third parties that might be claimed by such third parties to be infringed by the development and commercialization of Soliris and some of our drug candidates. In respect to some of these patents, we have obtained licenses, or expect to obtain licenses. However, with regard to such other patents, we have determined in our judgment that:

- Soliris and our product candidates do not infringe the patents;
- the patents are not valid; or
- we have identified and tested or are testing various modifications that we believe should not infringe the patents and which should permit commercialization of our product candidates.

Any holder of these patents or other patents covering similar technology could sue us for damages and seek to prevent us from manufacturing, selling or developing our drugs. Legal disputes can be costly and time consuming to defend. If we cannot successfully defend against any future actions or conflicts, if they arise, we may incur substantial legal costs and may be liable for damages, be required to obtain costly licenses or need to stop manufacturing, using or selling Soliris, which would adversely affect our business. We may seek to obtain a license prior to or during legal actions in order to reduce further costs and the risk of a court determination that our product infringes the third party's patents. A required license may be costly or may not be available on acceptable terms, if at all. A costly license, or inability to obtain a necessary license, could have a material adverse effect on our business.
There can be no assurance that we would prevail in a patent infringement action or that we would be able to obtain a license to any third-party patent on commercially reasonable terms or any terms at all; successfully develop non-infringing alternatives on a timely basis; or license alternative non-infringing technology, if any exists, on commercially reasonable terms. Any impediment to our ability to manufacture, use or sell approved forms of Soliris or our product candidates could have a material adverse effect on our business and prospects.
It is possible that we could lose market exclusivity for a product earlier than expected, which would harm our competitive position.
In our industry, much of an innovative product’s commercial value is realized while it has market exclusivity. When market exclusivity expires and biosimilar or generic versions of the product are approved and marketed, there can be

substantial decline in the innovative product's sales.

Market exclusivity for Soliris is based upon patent rights and certain regulatory forms of exclusivity. The scope of Soliris patent rights vary from country to country and are dependent on the availability of meaningful legal remedies in each country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or loss of such rights, could be

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

Risks Related to Our Operations

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

Until the quarter ended June 30, 2008, we had never been profitable since we were incorporated in January 1992. We have maintained profitability on a quarterly basis since the quarter ended June 30, 2008 and on an annual basis beginning with the year ended December 31, 2008. We believe that we formulate our annual operating budgets with reasonable assumptions and targets, however we cannot guarantee that we will be able to generate sufficient revenues or control expenses to achieve our financial goals, including continued profitability. Even if we do achieve profitability in any subsequent quarters, we may not be able to sustain or increase profitability on a quarterly or annual basis. You should not consider our revenue growth in recent periods as indicative of our future performance. Our revenue in future periods could decline. We may make errors in predicting and reacting to relevant business trends or our business may be subject to factors beyond our control, which could harm our operations. Since we began our business, we have focused on research and development of product candidates. We launched Soliris for sale for the treatment of patients with PNH in the United States and Europe during 2007. We obtained marketing approval from the FDA and the EC for Soliris for the treatment of patients with aHUS in September and November 2011, respectively. In September 2013, the MHLW approved Soliris for the treatment of patients with aHUS in Japan. We have not obtained marketing approval for aHUS in any other country or territory. We cannot guarantee that we will be successful in marketing and selling Soliris on a continued basis in countries or regions where we have obtained marketing approval, including the United States, Europe and Japan, and we do not know when we will have Soliris available for sale in territories where we have applied or will apply for marketing approval, if ever. We will have substantial expenses as we continue our research and development efforts, continue to conduct clinical trials and continue to develop manufacturing, sales, marketing and distribution capabilities in the United States and abroad. The achievement of our financial goals, including the extent of our future profitability, depends on many factors, including our ability to successfully market Soliris in the United States, the European Union and Japan and other territories, our ability to obtain regulatory, pricing, coverage, and reimbursement approvals of Soliris in additional countries and regions and for aHUS and other indications, our ability to successfully market Soliris in additional countries and regions, our ability to successfully manufacture and commercialize our drug candidates and our ability to successfully bring our other product candidates to the major commercial markets throughout the world.

If our competitors get to the marketplace before we do, or with better or less expensive drugs, it may not be profitable to continue to produce Soliris and our product candidates.

The FDA, EC and the MHLW granted orphan drug designation for Soliris in the treatment of PNH and the FDA and EC granted orphan drug designation for aHUS. Orphan drug status entitles Soliris to market exclusivity for a total of seven years in the United States and for ten years in the European Union and Japan. However, if a competitive product that is the same as or similar to Soliris, as defined under the applicable regulations, is shown to be clinically superior to Soliris in the treatment of PNH or aHUS, or if a competitive product is different from Soliris, as defined under the applicable regulations, the orphan drug exclusivity we have obtained may not block the approval of such competitive product. Several biotechnology and pharmaceutical companies throughout the world have programs to develop complement inhibitor therapies or have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. Pharmaceutical companies have publicly announced intentions to establish or develop rare disease programs and these companies may introduce products that are competitive with ours. These and other companies, many of which have significantly greater resources than us, may develop, manufacture, and market better or cheaper drugs than Soliris or our product candidates. They may establish themselves in the marketplace before us for Soliris for other indications or for any of our other product candidates. Other pharmaceutical companies also compete with us to attract academic research institutions as drug development

partners, including for licensing these institutions' proprietary technology. If our competitors successfully enter into such arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may not be able to find equivalent opportunities elsewhere.

If we fail to satisfy our debt service obligations or obtain the capital necessary to fund our operations, we will be unable to continue the commercialization of Soliris or continue or complete our product development.

We have used our cash on hand and incurred debt under the terms of a senior secured credit facility to finance acquisitions and collaborations. In addition, we are party to definitive agreements relating to these transactions that include significant contingent payments that will become payable if and when certain development and commercial milestones are achieved. We have also entered into strategic license agreements that require us to make significant payments if and when research, development or commercial milestones are achieved. We expect to enter into similar agreements in the future. In May 2012, Alexion issued 5,000 shares of its common stock in a public offering resulting in net proceeds of approximately $462,000. We believe that revenues and collections from sales of Soliris along with our existing cash and cash equivalents will provide sufficient capital to satisfy our debt service obligations and the contingent consideration required by the acquisitions, and to fund our operations and product development for at least 12 months. We may need to raise additional capital before or after that time to complete or continue the development or commercialization of our products and product candidates or for other purposes. We are currently selling or preparing for the commercialization of Soliris in the United States, the European Union, Japan, and several other territories, evaluating and preparing regulatory submissions for Soliris in several countries, and conducting, preparing or evaluating several clinical trials. Funding needs may shift between projects and potentially accelerate and increase as we continue launch and commercialization activities throughout the world and as we initiate or continue clinical trials for our product candidates.

Additional financing could take the form of public or private debt or equity offerings, equity line facilities, bank loans, including additional borrowing under our existing credit facility, collaborative research and development arrangements with corporate partners and/or the sale or licensing of some of our property. The amount of capital we may need depends on many factors, including:

- the cost necessary to sell, market and distribute Soliris;
- the rate of new patient sales and drug utilization by treated patients;
- the time and cost necessary to obtain and maintain regulatory approvals for Soliris in multiple countries;
- the ability to obtain and maintain reimbursement approvals and funding for Soliris and the time necessary to obtain such approvals and funding;
- the time and cost necessary to develop sales, marketing and distribution capabilities outside the United States;
- the time and cost necessary to purchase or to further develop manufacturing processes, arrange for contract manufacturing or build manufacturing facilities and obtain and maintain the necessary regulatory approvals for those facilities;
- changes in applicable governmental regulatory policies or requests by regulatory agencies for additional information or data;
- the progress, timing and scope of our research and development programs;
- the progress, timing and scope of our preclinical studies and clinical trials;
- any new collaborative, licensing or other commercial relationships that we may establish; and
- the cost of any acquisition.

We may not receive additional funding when we need it or funding may only be available on unfavorable terms. Financial markets in the United States, Europe and the rest of the world have been experiencing significant volatility in security prices, substantially diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. There can be no assurance that we will be able to access additional credit or the equity markets in order to finance our operations, grow our operations in any territory, or expand development programs for our product candidates, or that there will not be a further deterioration in financial markets and confidence in economies. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back or eliminate our research and development activities or future operations. We might have to license our technology to others or relinquish commercialization rights. This could result in sharing revenues that we might otherwise retain for ourselves. Any of these actions would harm our business.

If we fail to recruit and retain personnel, we may not be able to implement our business strategy.

We are highly dependent upon the efforts of our executive officers, and other key personnel in our commercial and technical organizations. There is intense competition in the biopharmaceutical industry for qualified commercial and

technical personnel. Our business is specialized and global and we must attract and retain highly qualified individuals across many

geographies. We may not be able to continue to attract and retain the qualified personnel necessary for developing, manufacturing and commercializing our products and product candidates.

The terms of our Credit Agreement may restrict our current and future operations, including our ability to respond to changes or to take certain actions.

We and certain of our wholly-owned subsidiaries are party to a Credit Agreement with a syndicate of banks. The Credit Agreement provides for a $240,000 senior secured term loan facility and a $200,000 senior secured revolving credit facility, which includes up to a $60,000 sublimit for letters of credit and a $10,000 sublimit for swingline loans. Our obligations under the credit facilities are unconditionally guaranteed, jointly and severally, by certain of our existing domestic subsidiaries and are required to be guaranteed by certain of our future domestic subsidiaries. The obligations of the foreign borrowers under the credit facilities are unconditionally guaranteed, jointly and severally, by us, certain of our existing domestic subsidiaries, and certain of our foreign subsidiaries, and are required to be guaranteed by certain of our future subsidiaries. All obligations of each borrower under the credit facilities, and the guarantees of those obligations, are secured, subject to certain exceptions, by substantially all of each borrower's assets and the assets of certain guarantors, including the pledge of the equity interests of certain of our subsidiaries and real estate located in Smithfield, Rhode Island, but excluding intellectual property and assets of certain foreign subsidiaries.

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, engage in certain investment, acquisition and disposition transactions, pay dividends, repurchase capital stock and enter into transactions with affiliates. 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.

The credit facilities, and the contingent consideration payable in connection with our acquisitions and collaborations remain outstanding or available, and the degree to which we are leveraged could, among other things:

- make it difficult for us to make payments on the credit facilities;
- make it difficult for us to obtain financing for additional acquisitions or in-licensing opportunities or other purposes on favorable terms, if at all;
- make us more vulnerable to industry downturns and competitive pressures; and
- limit our flexibility in planning for, or reacting to changes in, our business.

Our ability to meet our debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control. A breach of the covenants under the Credit Agreement could result in an event of default. 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 Credit Agreement. Furthermore, if we were unable to repay the amounts due and payable under our Credit Agreement, those lenders could proceed against the collateral granted to them to secure that indebtedness, which could force us into bankruptcy or liquidation. In the event our administrative agent or lenders accelerate the repayment of our borrowings, we and our subsidiaries may not have sufficient assets to repay that indebtedness.

We are subject to environmental laws and potential exposure to environmental liabilities.

We are subject to various federal, state and local environmental laws and regulations that govern our operations, including our manufacturing operations at ARIMF and in Ireland, the handling and disposal of non-hazardous and hazardous wastes, such as medical and biological wastes, and emissions and discharges into the environment, such as air, soils and water sources. Failure to comply with such laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We also are subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs of remediating its property or locations to which wastes were sent from its facilities, without regard to whether the owner or operator knew of, or necessarily caused, the contamination. Such obligations and liabilities, which to date have not been material, could

have a material impact on our business and financial condition.

We may expand our business through acquisitions or in-licensing opportunities that could disrupt our business and harm our financial condition.

Our business strategy includes expanding our products and capabilities. We may seek additional acquisitions or in-licensing of businesses or products to expand our products and capabilities. Acquisitions of new businesses or products and in-licensing of new products may involve numerous risks, including:

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

We have limited experience in the acquisition and integration of other companies. We cannot assure you that any acquisition or in-licensing of new products will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or an acquired or in-licensed product. In addition, the future success of such transactions would depend in part on our ability to manage the rapid growth associated with any such acquisitions or in-licensing. We cannot assure you that we will be able to make the combination of our business with that of any acquired businesses or companies work or be successful.

We compete with pharmaceutical companies that have significantly greater resources than we for many of the same acquisition and in-licensing opportunities. Such pharmaceutical companies may be less leveraged and have better access to capital resources that may preclude us from completing any acquisition or in-licensing. In addition, several pharmaceutical companies have publicly announced intentions to establish or develop rare disease programs. For these and other reasons, we may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all. Furthermore, the development or expansion of our business, any acquired business or any acquired or in-licensed products may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our capital stock, which could dilute current stockholders' ownership interest in our company, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest in our company upon conversion.

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

We operate in many jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, Qui Tam, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment, and other claims and legal proceedings which may arise from conducting our business. Legal proceedings, government investigations and enforcement actions can be expensive and time consuming. An adverse outcome could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations.

We may have exposure to additional tax liabilities which could have a material impact on our results of operations and financial position.

As a company with international operations, we are subject to income taxes, as well as non-income based taxes, in both the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities. Although we believe our estimates are reasonable, the ultimate outcome with respect to the taxes we owe may differ from the amounts recorded in our financial statements. If the Internal Revenue Service, or other taxing authority, disagrees with the positions we take, we could have additional tax liability, and this could have a material impact on our results of operations and financial position. Our effective tax rate could be adversely affected

by changes in the mix of earnings in countries with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in tax laws and regulations, changes in interpretations of tax laws, including pending tax law changes, changes in our manufacturing

activities and changes in our future levels of research and development spending. In addition, the United States government and other governments are considering and may adopt tax reform measures that significantly increase our worldwide tax liabilities. There are several proposals under consideration in the United States to reform tax law, including proposals that may reduce or eliminate the deferral of U.S. income tax on our unrepatriated foreign earnings. A significant change to U.S. tax policy, such as a change to the taxation of income earned outside the United States, could have a material and adverse effect on our business, financial condition and results of operations.

Our sales and operations are subject to the economic, political, legal and business conditions in the countries in which we do business, and our failure to operate successfully or adapt to changes in these conditions could cause our sales and operations to be limited or disrupted.

Since 2007, we have significantly expanded our operations and expect to continue to do so in the future. Our operations in foreign countries subject us to the following additional risks:

- fluctuations in currency exchange rates;
- political or economic determinations that adversely impact pricing or reimbursement policies;
- economic problems or political instability that disrupt health care payment systems;
- difficulties or inability to obtain financing in markets;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- difficulties enforcing contractual and intellectual property rights;
- changes in laws, regulations or enforcement practices with respect to our business, including without limitation laws relating to reimbursement, competition, pricing and sales and marketing of our products;
- trade restrictions and restrictions on direct investments by foreign entities;
- compliance with tax, employment and labor laws;
- costs and difficulties in recruiting and retaining qualified managers and employees to manage and operate the business in local jurisdictions;
- costs and difficulties in managing and monitoring international operations; and
- longer payment cycles.

Our business and marketing methods are also subject to regulation by the governments of the countries in which we operate. The FCPA and similar anti-bribery laws in other countries prohibit companies and their representatives from offering, promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business. We have policies and procedures designed to help ensure that we and our representatives, including our employees, comply with such laws, however we cannot guarantee that these policies and procedures will protect us against liability under the FCPA or other anti-bribery laws for actions taken by our representatives. Failure to comply with the laws and regulations of the countries in which we operate could materially harm our business.

We conduct, or anticipate that we will conduct, a substantial portion of our business in currencies other than the U.S. dollar. We are exposed to fluctuations in foreign currency exchange rates in the normal course of our business. 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, Japanese Yen, British Pound and Swiss Franc. 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 36 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. Further, we enter into foreign exchange forward contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results. Gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. While we attempt to hedge certain currency risks, currency fluctuations between the U.S. dollar and the currencies in which we do business have, in the past, caused foreign currency transaction gains and losses and have also impacted the amounts of revenues and expenses calculated in U.S. dollars and will likely do so in the future. Likewise, past currency fluctuations have at times resulted in foreign currency transaction gains, and there can be no assurance that these gains can be reproduced. See also Footnote 8, Derivative

Instruments and Hedging Activities, in the Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q.

The credit and financial market conditions may aggravate certain risks affecting our business.

Sales of Soliris are dependent, in large part, on reimbursement from government health administration organizations and private and governmental third-party payers, and also co-payments from individual patients in certain situations. As a result of adverse credit and financial market conditions, and the overall financial climate, these governmental organizations and payers, and/or individuals, may reduce or delay initiation of treatment, may be unable to satisfy their reimbursement obligations, may delay payment or may seek to reduce reimbursement for Soliris in the future, which could have a material adverse effect on our business and results of operations. For example, in July 2011, we received non-interest bearing bonds issued by the Greek government that mature in 2012 and 2013 for payment on receivables from 2008 and 2009 as part of the Greek government's plan repayment of its debt to international pharmaceutical companies. We sold the associated bonds in July 2011 and recorded expense of approximately $4,100 through December 31, 2011 related to the reduction of value of the Greek bonds and other delays impacting the book value of our accounts receivable in other countries. Soliris is approved for the treatment of patients with PNH and aHUS in the United States, the European Union and Japan and for the treatment of PNH in several other territories. If Soliris is approved in additional territories for PNH, aHUS, or for additional indications that are under clinical development, the reimbursement risks and uncertainties associated with adverse credit and financial market conditions may be exacerbated due to increases in the number of patients receiving Soliris that require reimbursement. Payment defaults by a government payer could require us to expense previously recorded revenue as uncollectible, and might cause us to end or restrict sales to patients in that country. Further, the risk of payment default by a government payer could require us to revise our revenue recognition policies in regard to that payer, causing revenue to be recorded only on a cash basis, and we may be required to end or restrict sales to patients in that country.

We continue to monitor economic conditions, including volatility associated with U.S. and international economies, associated impacts on the financial markets and our business, and the sovereign debt issues in Europe. The credit and economic conditions in Greece, Italy and Spain, among other members of the European Union have deteriorated over the last several years. These conditions have in the past resulted in an increase in the average length of time it takes to collect our outstanding accounts receivable in these countries. We have recorded an allowance related to all or a portion of receivables in each of Greece, Italy and Spain that have been outstanding for greater than one year as of June 30, 2014.

We may not be able to successfully mitigate or prevent our exposures to volatile economic and financial conditions and our failure to operate successfully or adapt to changes in these conditions could cause our sales and operations to be limited or disrupted or otherwise harm our business.

Additionally, we rely upon third-parties for certain parts of our business, including Lonza, licensees, wholesale distributors of Soliris, contract clinical trial providers, contract manufacturers and other third-party suppliers and financial institutions. Because of the volatility in the financial markets, there may be a disruption or delay in the performance or satisfaction of commitments to us by these third parties which could have a material adverse effect on our business and results of operations.

Government initiatives that affect coverage and reimbursement of drug products could adversely affect our business.

Governments in countries where we operate have adopted or have shown significant interest in pursuing legislative initiatives to reduce costs of health care. Any such government-adopted health care measures could adversely impact the pricing of Soliris or the amount of coverage and reimbursement available for Soliris from governmental agencies or other third-party payers. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the PPACA), substantially changes the way healthcare is financed by both governmental and private insurers in the U.S., and significantly impacts the pharmaceutical industry. PPACA contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under health insurance exchanges, and fraud and abuse enforcement. While the constitutionality of key provisions of PPACA have been upheld by the Supreme Court, legislative changes remain possible. In addition, our industry may be affected by broader legislation addressing federal spending, including, for example, a sequester that

took effect in March 2013 and cuts to most Medicare spending by 2%. As another example, the governments of Germany and Spain each approved increases to mandatory rebates on the sales of pharmaceutical products.

We expect that the implementation of current laws and policies, the amendment of those laws and policies in the future, as well as the adoption of new laws and policies, could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales or successfully commercialize our product candidates, or could limit or eliminate our future spending on development projects. In many cases, these government initiatives, even if enacted into law, are subject to

future rulemaking by regulatory agencies. Although we have evaluated these government initiatives and the impact on our business, we cannot know with certainty whether any such law, rule or regulation will adversely affect coverage and reimbursement of Soliris, or to what extent, until such laws, rules and regulations are promulgated, implemented and enforced. The announcement or adoption of regulatory or legislative proposals could delay or prevent our entry into new markets, affect our reimbursement or sales in the markets where we are already selling Soliris and materially harm our business, financial condition and results of operations.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, customers and business partners, and personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

Natural disasters, acts of war or terrorism, shipping embargoes, labor unrest or political instability, could adversely affect our operations, including our ability to supply and commercialize Soliris.

Natural disasters such as earthquakes, hurricanes, tsunamis or other adverse weather and climate conditions, whether occurring in the U.S. or abroad, and the effects of these natural disasters, as well as acts of war or terrorism, shipping embargoes, labor unrest or political instability could disrupt our operations, or the operations of our vendors and other suppliers. Such events could adversely impact our facilities, or interfere with the manufacture or distribution of Soliris and our product candidates.

Risks Related to Our Common Stock

If the trading price of our common stock continues to fluctuate in a wide range, our stockholders will have uncertainty with respect to an investment in our common stock.

The trading price of our common stock has been volatile and may continue to be volatile in the future. Factors such as announcements of fluctuations in our or our competitors' operating results or clinical or scientific results, fluctuations in the trading prices or business prospects of our competitors and collaborators, changes in our prospects, particularly with respect to sales of Soliris, failure to resolve, delays in resolving or other developments with respect to the issues raised in the Warning Letter, and market conditions for biopharmaceutical stocks in general could have a significant impact on the future trading prices of our common stock. In particular, the trading price of the common stock of many biopharmaceutical companies, including ours, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of the companies whose stocks were affected. This is due to several factors, including general market conditions, sales of Soliris, the announcement of the results of our clinical trials or product development and the results of our efforts to obtain regulatory approval for our products. While we cannot predict our future performance, if our stock price continues to fluctuate in a wide range, an investment in our common stock may result in considerable uncertainty for an investor.

Anti-takeover provisions of Delaware law, provisions in our charter and bylaws and our stockholders' rights plan, or poison pill, could make a third-party acquisition of us difficult and may frustrate any attempt to remove or replace our current management.

Because we are a Delaware corporation, the anti-takeover provisions of Delaware law could make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to stockholders. We are subject to the provisions of Section 203 of the Delaware General Laws, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our corporate charter and by-law provisions and stockholder rights plan may discourage certain types of transactions involving an actual or potential change of control that might be beneficial to us or our stockholders. Our bylaws

provide that special meetings of our stockholders may be called only by the Chairman of the Board, the President, the Secretary, or a majority of the Board of Directors, or upon the written request of stockholders who together own of record 50% of the outstanding stock of all classes entitled to vote at such meeting. Our bylaws also specify that the authorized number of

directors may be changed only by resolution of the board of directors. Our charter does not include a provision for cumulative voting for directors, which may have enabled a minority stockholder holding a sufficient percentage of a class of shares to elect one or more directors. Under our charter, our board of directors has the authority, without further action by stockholders, to designate up to 5,000 shares of preferred stock in one or more series. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any class or series of preferred stock that may be issued in the future.

Pursuant to our stockholder rights plan, each share of common stock has an associated preferred stock purchase right. The rights will not trade separately from the common stock until, and are exercisable only upon, the acquisition or the potential acquisition through tender offer by a person or group of 20% or more of the outstanding common stock. The rights are designed to make it more likely that all of our stockholders receive fair and equal treatment in the event of any proposed takeover of us and to guard against the use of partial tender offers or other coercive tactics to gain control of us. These provisions could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices. These provisions could also limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and could adversely affect the price of our common stock.

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

ISSUER PURCHASE OF EQUITY SECURITIES (amounts in thousands except per share amounts)

The following table summarizes our common stock repurchase activity during the second quarter of 2014:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Dollar Value of Shares that May Yet Be Purchased Under the Program
April 1-30, 2014	547	$149.34	547	$218,500
May 1-31, 2014	255	$157.10	255	$178,439
June 1-30, 2014	210	$164.97	210	$143,796
Total	1,012	$154.54	1,012	

On November 8, 2012, we announced that our Board of Directors authorized the repurchase of up to $400,000 of our common stock. This repurchase program does not have an expiration date.

Item 5. OTHER INFORMATION.

None.

Item 6. EXHIBITS.

(a) Exhibits:

31.1	Certificate of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002.
31.2	Certificate of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
32.1	Certificate of Chief Executive Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.
32.2	Certificate of Chief Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act.
101	The following materials from the Alexion Pharmaceuticals, Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 formatted in eXtensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets at June 30, 2014 and December 31, 2013, (ii) the Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2014 and 2013, (iii) the Condensed Consolidated Statements of Comprehensive Income for the three and six months ended June 30, 2014 and 2013, (iv) the Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2014 and 2013, and (v) Notes to Condensed Consolidated Financial Statements.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALEXION PHARMACEUTICALS, INC.

By: /s/ Leonard Bell
Leonard Bell, M.D.
Date: July 25, 2014 Chief Executive Officer, Treasurer and Director (principal executive officer)

By: /s/ Vikas Sinha
Vikas Sinha, M.B.A., C.A.
Date: July 25, 2014 Executive Vice President and Chief Financial Officer (principal financial officer)