ALEXION PHARMACEUTICALS INC
Form 10-Q
April 24, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

x Quarterly report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934
For the quarterly period ended March 31, 2015
or
¨ Transition report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934
For the transition period from to
Commission file number: 0-27756

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

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

352 Knotter Drive, Cheshire Connecticut 06410
(Address of Principal Executive Offices) (Zip Code)
203-272-2596
(Registrant's telephone number, including area code)
N/A
(Former name, former address, and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. Check One:

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨ (Do not check if a smaller reporting company) Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Common Stock, $0.0001 par value	199,576,769
Class	Outstanding as of April 21, 2015

Alexion Pharmaceuticals, Inc.
Contents

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

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

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

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

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

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

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

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

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

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Alexion Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(amounts in thousands)

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

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

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

1. Business

Alexion Pharmaceuticals, Inc. (Alexion, the Company, we, our or us) is a biopharmaceutical company focused on serving patients with severe and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Our marketed product Soliris is the first and only therapeutic approved for patients with either of two severe and ultra-rare disorders resulting from chronic uncontrolled activation of the complement component of the immune system: paroxysmal nocturnal hemoglobinuria (PNH), a life-threatening and ultra-rare genetic blood disorder, and atypical hemolytic uremic syndrome (aHUS), a life-threatening and ultra-rare genetic disease. We are also evaluating additional potential indications for Soliris in other severe and devastating diseases in which uncontrolled complement activation is the underlying mechanism, and we are progressing in various stages of development with additional product candidates as potential treatments for patients with severe and life-threatening ultra-rare disorders. We were incorporated in 1992 and began commercial sale of Soliris in 2007.

2. Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. These accounting principles were applied on a basis consistent with those of the consolidated financial statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014. In our opinion, the accompanying unaudited consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of our financial statements for interim periods in accordance with accounting principles generally accepted in the United States. The condensed consolidated balance sheet data as of December 31, 2014 was derived from audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2014 included in our Annual Report on Form 10-K. The results of operations for the three months ended March 31, 2015 are not necessarily indicative of the results to be expected for the full year.

The financial statements of our subsidiaries with functional currencies other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for stockholders' equity and weighted average exchange rates for operating results. Translation gains and losses are included in accumulated other comprehensive income (loss), net of tax, in stockholders' equity. Foreign currency transaction gains and losses are included in the results of operations in other income and expense.

The accompanying unaudited condensed consolidated financial statements include the accounts of Alexion Pharmaceuticals, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Our significant accounting policies are described in Note 1 of the Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2014.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2016 and allows for adoption using a full retrospective method, or a modified retrospective method. In April 2015, the FASB proposed a one year deferral of the effective date of this standard to annual periods ending after December 15, 2017, along with an option to permit companies to early adopt the standard for annual periods beginning after December 15, 2016. We are currently assessing the method of adoption and the expected impact the new standard has on our financial position and results of operations.

Alexion Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(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:

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

As of March 31, 2015 and December 31, 2014, we capitalized $23,377 and $22,005 of inventory produced for commercial sale for products awaiting regulatory approval, respectively. We recorded an expense of $24,352 in the first quarter of 2015 associated with a portion of a single manufacturing campaign at a third party manufacturer for Strensiq™ (asfotase alfa). The costs are comprised of raw materials, internal overhead and external production costs.

4. Intangible Assets and Goodwill

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

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

5. Debt

In February 2012, we entered into a credit agreement, as amended (the Credit Agreement) with a syndicate of banks that provides for a $240,000 senior secured term loan facility payable in equal quarterly installments of $12,000 starting June 30, 2012 and a $200,000 senior secured revolving credit facility through February 7, 2017. In addition to borrowings upon prior notice, the revolving credit facility includes borrowing capacity in the form of letters of credit up to $60,000 and borrowings on same-day notice, referred to as swingline loans, of up to $10,000. Borrowings can be used for working capital requirements, acquisitions and other general corporate purposes. With the consent of the lenders and the administrative agent and subject to satisfaction of certain conditions, we may increase the term loan facility and/or the revolving credit facility by an aggregate amount not to exceed $150,000.

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

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

6. Earnings Per Common Share

Basic earnings per common share (EPS) is computed by dividing net income by the weighted-average number of shares of common stock outstanding. For purposes of calculating diluted EPS, the denominator reflects the potential dilution that could occur if stock options, unvested restricted stock, unvested restricted stock units or other contracts to issue common stock were exercised or converted into common stock, using the treasury stock method.

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

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

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

7. Marketable Securities

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and estimated fair value of available-for-sale investments by type of security at March 31, 2015 and December 31, 2014 were as follows:

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

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

The aggregate fair value of available-for-sale securities in an unrealized loss position as of March 31, 2015 and December 31, 2014 was $359,768 and $472,241, respectively. These investments have been in a continuous unrealized loss

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position for less than 12 months. As of March 31, 2015, we believe that the cost basis of our available-for-sale investments is recoverable.

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

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

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

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

As of March 31, 2015 and December 31, 2014, the fair value of our trading securities was $6,547 and $4,277, respectively.

We utilize the specific identification method in computing realized gains and losses. Realized gains and losses on our available-for-sale and trading securities were not material for the three months ended March 31, 2015.

8. Derivative Instruments and Hedging Activities

We operate internationally and, in the normal course of business, are exposed to fluctuations in foreign currency exchange rates. The exposures result from portions of our revenues, as well as the related receivables, and expenses that are denominated in currencies other than the U.S. dollar, primarily the Euro and Japanese Yen. We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes.

We enter into foreign exchange forward contracts, with durations of up to 60 months, to hedge exposures resulting from portions of our forecasted revenues, including intercompany revenues, that are denominated in currencies other than the U.S. dollar. The purpose of the hedges of revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. These hedges are designated as cash flow hedges upon contract inception. At March 31, 2015, we have open contracts with notional amounts totaling $1,728,774 that qualified for hedge accounting.

The impact on accumulated other comprehensive income (AOCI) and earnings from foreign exchange contracts that qualified as cash flow hedges, for the three months ended March 31, 2015 and 2014 were as follows:

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

Assuming no change in foreign exchange rates from market rates at March 31, 2015, $112,908 of gain recognized in AOCI will be reclassified to revenue over the next 12 months.

We enter into foreign exchange forward contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities. We enter into these hedges to reduce the impact of fluctuating exchange rates

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(amounts in thousands, except per share amounts)

on our operating results. Hedge accounting is not applied to these derivative instruments as gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. As of March 31, 2015, the notional amount of foreign exchange contracts where hedge accounting is not applied was $187,976.
We recognized a gain of $6,423 and $2,289, in other income and expense, for the three months ended March 31, 2015 and 2014, respectively, associated with the foreign exchange contracts not designated as hedging instruments. These amounts were largely offset by gains or losses in monetary assets and liabilities.
The following tables summarize the fair value of outstanding derivatives at March 31, 2015 and December 31, 2014:

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

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

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

Although we do not offset derivative assets and liabilities within our condensed consolidated balance sheets, our International Swap and Derivatives Association (ISDA) agreements provide for net settlement of transactions that are due to or from the same counterparty upon early termination of the agreement due to an event of default or other termination event. The following tables summarize the potential effect on our condensed consolidated balance sheets of offsetting our foreign exchange forward contracts subject to such provisions:

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

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

9. Other Investments

Other investments include our investment of $37,500 in the preferred stock of Moderna LLC. Our investment is recorded at cost within other assets in our condensed consolidated balance sheets. The carrying value of this investment was not impaired as of March 31, 2015.

10. Stockholders' Equity

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

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

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(amounts in thousands, except per share amounts)

11. Other Comprehensive Income and Accumulated Other Comprehensive Income

The following tables summarize the changes in AOCI, by component, for the three months ended March 31, 2015 and 2014:

	Defined Benefit Pension Plans	Unrealized Gains (Losses) from Marketable Securities	Unrealized Gains (Losses) from Hedging Activities	Foreign Currency Translation Adjustment	Total Accumulated Other Comprehensive Income (Loss)
Balances, December 31, 2014	$(16,570)	$(234)	$87,308	$(13,719)	$ 56,785
Other comprehensive income before reclassifications	(488)	1,065	93,809	(5,388)	88,998
Amounts reclassified from other comprehensive income	236	(8)	(26,522)	—	(26,294)
Net other comprehensive income (loss)	(252)	1,057	67,287	(5,388)	62,704
Balances, March 31, 2015	$(16,822)	$823	$154,595	$(19,107)	$ 119,489

	Defined Benefit Pension Plan	Unrealized Gains (Losses) from Marketable Securities	Unrealized Gains (Losses) From Hedging Activities	Foreign Currency Translation Adjustment	Total Accumulated Other Comprehensive Income (Loss)
Balances, December 31, 2013	$(11,502)	(146)	$(3,827)	$(7,382)	$ (22,857)
Other comprehensive income before reclassifications	(72)	812	(3,944)	506	(2,698)
Amounts reclassified from other comprehensive income	72	(1)	(951)	—	(880)
Net other comprehensive income (loss)	—	811	(4,895)	506	(3,578)
Balances, March 31, 2014	$(11,502)	$665	$(8,722)	$(6,876)	$ (26,435)

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(amounts in thousands, except per share amounts)

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

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

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

12. Fair Value Measurement

Authoritative guidance establishes a valuation hierarchy for disclosure of the inputs to the valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value.

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

The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2015 and December 31, 2014, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

		Fair Value Measurement at March 31, 2015			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$192,281	$—	$192,281	$—
Cash equivalents	Commercial paper	$151,879	$—	$151,879	$—
Cash equivalents	Corporate bonds	$39,088	$—	$39,088	$—
Cash equivalents	Municipal bonds	$51,750	$—	$51,750	$—
Cash equivalents	Bank certificates of deposit	$57,002	$—	$57,002	$—
Cash equivalents	Other government-related obligations	$61,966	$—	$61,966	$—
Marketable securities	Mutual funds	$6,547	$6,547	$—	$—
Marketable securities	Commercial paper	$29,885	$—	$29,885	$—
Marketable securities	Corporate bonds	$501,100	$—	$501,100	$—
Marketable securities	Municipal bonds	$163,017	$—	$163,017	$—
Marketable securities	Other government-related obligations	$305,729	$—	$305,729	$—
Marketable securities	Bank certificates of deposit	$2,000	$—	$2,000	$—
Other current assets	Foreign exchange forward contracts	$116,092	$—	$116,092	$—
Other assets	Foreign exchange forward contracts	$125,374	$—	$125,374	$—
Other current liabilities	Foreign exchange forward contracts	$336	$—	$336	$—
Other liabilities	Foreign exchange forward contracts	$66	$—	$66	$—
Other current liabilities	Acquisition-related contingent consideration	$48,088	$—	$—	$48,088
Contingent consideration	Acquisition-related contingent consideration	$126,862	$—	$—	$126,862

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

There were no securities transferred between Level 1, 2 and 3 during the three months ended March 31, 2015.

Valuation Techniques
We classify mutual fund investments, which are valued based on quoted market prices in active markets with no valuation adjustment, as Level 1 assets within the fair value hierarchy.
Cash equivalents and marketable securities classified as Level 2 within the valuation hierarchy consist of institutional money market funds, commercial paper, municipal bonds, U.S. and foreign government-related debt, corporate debt securities and certificates of deposit. We estimate the fair values of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include market pricing based on real-time trade data

for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs. We validate the prices provided by our third-party pricing sources by understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances.

Our derivative assets and liabilities include foreign exchange derivatives that are measured at fair value using observable market inputs such as forward rates, interest rates, our own credit risk as well as an evaluation of our counterparties' credit risks. Based on these inputs, the derivative assets and liabilities are classified within Level 2 of the valuation hierarchy.

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

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As of March 31, 2015, there has not been any impact to the fair value of our derivative liabilities due to our own credit risk. Similarly, there has not been any significant adverse impact to our derivative assets based on our evaluation of our counterparties' credit risks.

Contingent Consideration

In connection with prior acquisitions, we may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory and reimbursement approvals or sales-based milestone events. We determine the fair value of these obligations on the acquisition date using various estimates that are not observable in the market and represent a Level 3 measurement within the fair value hierarchy. The resulting probability-weighted cash flows were discounted using a cost of debt of 4.8% for developmental milestones and a weighted average cost of capital ranging from 12% to 21% for sales-based milestones.

Each reporting period, we adjust the contingent consideration to fair value with changes in fair value recognized in operating earnings. Changes in fair values reflect new information about the probability and timing of meeting the conditions of the milestone payments. In the absence of new information, changes in fair value will only reflect the interest component of contingent consideration related to the passage of time as development work progresses towards the achievement of the milestones.

Estimated future contingent milestone payments related to prior business combinations range from zero if no milestone events are achieved, to a maximum of $876,000 if all development, regulatory and sales-based milestones are reached. As of March 31, 2015, the fair value of acquisition-related contingent consideration was $174,950. The following table represents a roll-forward of our acquisition-related contingent consideration:

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

13. Income Taxes

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

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

The tax provision for the three months ended March 31, 2015 and 2014 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. The tax provision for the three months ended March 31, 2014 also includes $2,652 attributable to our agreement with the French government that provided reimbursement for shipments of Soliris made prior to January 1, 2014. The remaining reduction in the effective tax rate for the three months ended March 31, 2015 as compared to the same period in the prior year is primarily attributable to an increase in our Federal Orphan Drug Credit and an increase in the amount of income taxed in jurisdictions with rates lower than the rate in the U.S.

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

14. Defined Benefit Plans

We maintain defined benefit plans for employees in certain countries outside the United States, including retirement benefit plans required by applicable local law. The plans are valued by independent actuaries using the projected unit credit method. The liabilities correspond to the projected benefit obligations of which the discounted net present value is calculated based on years of employment, expected salary increases, and pension adjustments.

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The components of net periodic benefit cost are as follows:

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

15. Leases

In November 2012, we entered into a lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. The term of the new lease will commence upon the landlord's substantial completion of the building and will expire 12 years later, with a minimum renewal option of 7 years and a maximum renewal option of 20 years, provided that we expand our lease to include all rentable space in the building. Although we will not legally own the premises, we are deemed to be the owner of the building during the construction period based on applicable accounting guidance for build-to-suit leases due to our involvement during the construction period. Accordingly, the landlord's costs of constructing the facility are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our condensed consolidated balance sheet.

Construction of the new facility began in June 2013 and is expected to be completed in late 2015. As of March 31, 2015, we recorded a construction-in-process asset of $148,470, inclusive of the landlord's costs as well as costs incurred by Alexion, and an offsetting facility lease obligation of $114,912 associated with the new facility.

16. License Agreements

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

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

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

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

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17. Commitments and Contingencies

Commitments

Lonza Agreement

We rely on Lonza Group AG and its affiliates (Lonza), a third party manufacturer, to produce a portion of commercial and clinical quantities of Soliris and for clinical and commercial quantities of Strensiq (asfotase alfa). We have various agreements with Lonza, with remaining total non-cancellable future commitments of approximately $413,150. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at Alexion Rhode Island Manufacturing Facility (ARIMF) and a payment with respect to sales of Soliris manufactured at Lonza facilities.

Contingent Liabilities

On an ongoing basis, we are involved in various claims and legal proceedings, none of which we deem material to our operations. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, we accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on our best estimates based on available information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, we may reassess the potential liability related to these matters and may revise these estimates, which could result in a material adverse adjustments to our operating results.

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

In March 2013, we received a Warning Letter (Warning Letter) from the U.S. Food and Drug Administration (FDA) regarding compliance with current Good Manufacturing Practices (cGMP) at ARIMF. The Warning Letter followed an FDA inspection which concluded in August 2012. At the conclusion of that inspection, the FDA issued a Form 483 Inspectional Observations, to which we responded in August 2012 and provided additional information to the FDA in September and December 2012. The observations relate to commercial and clinical manufacture of Soliris at ARIMF. We responded to the Warning Letter in a letter to the FDA dated in April 2013. At the conclusion of another inspection of ARIMF in August 2014, the FDA issued a Form 483 with three inspectional observations, none of which was designated as a repeat observation to the Warning Letter. The observations are inspectional and do not represent a final FDA determination of compliance. We continue to manufacture products, including Soliris, in this facility. While the resolution of the issues raised in the Warning Letter is difficult to predict, we do not currently believe a loss related to this matter is probable or that the potential magnitude of such loss or range of loss, if any, can be reasonable estimated. To the extent that circumstances related to this matter change, the impact could have a material adverse effect on our financial operations.

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18. Restructuring

In the fourth quarter 2014, we announced plans to relocate our European headquarters from Lausanne to Zurich, Switzerland. The relocation of the European headquarters will support our operational needs based on growth in the European region. The activities primarily occurring at our Lausanne site will be relocated to our Zurich, Cheshire, Connecticut, and Dublin, Ireland locations. As a result of this action, we recorded restructuring expenses of $15,365 related to employee costs in the fourth quarter of 2014. During the three months ended March 31, 2015 we incurred additional restructuring costs of $7,052. The following table presents a reconciliation of the restructuring reserve for the three months ended March 31, 2015:

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

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

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

Note Regarding Forward-Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management's beliefs, and certain assumptions made by our management, and may include, but are not limited to, statements regarding the potential benefits and commercial potential of Soliris® (eculizumab) for its approved indications and any expanded uses, timing and effect of sales of Soliris in various markets worldwide, pricing for Soliris, level of insurance coverage and reimbursement for Soliris, level of future Soliris sales and collections, timing regarding development and regulatory approvals for additional indications or in additional territories for Soliris, the medical and commercial potential of additional indications for Soliris, failure to satisfactorily address the issues raised by the U.S. Food and Drug Administration (FDA) in the March 2013 Warning Letter and Form 483 issued by the FDA in August 2014, costs, expenses and capital requirements, cash outflows, cash from operations, status of reimbursement, price approval and funding processes in various countries worldwide, progress in developing commercial infrastructure and interest about Soliris and our drug candidates in the patient, physician and payer communities, the safety and efficacy of Soliris and our product candidates, estimates of the potential markets and estimated commercialization dates for Soliris and our drug candidates around the world, sales and marketing plans, any changes in the current or anticipated market demand or medical need for Soliris or our drug candidates, status of our ongoing clinical trials for eculizumab, asfotase alfa and our other product candidates, commencement dates for new clinical trials, clinical trial results, evaluation of our clinical trial results by regulatory agencies, the adequacy of our pharmacovigilance and drug safety reporting processes, prospects for regulatory approval of Strensiq (asfotase alfa) and our other product candidates, need for additional research and testing, the uncertainties involved in the drug development process and manufacturing, performance and reliance on third party service providers, our future research and development activities, plans for acquired programs, our ability to develop and commercialize products with our collaborators, assessment of competitors and potential competitors, the outcome of challenges and opposition proceedings to our intellectual property, assertion or potential assertion by third parties that the manufacture, use or sale of Soliris infringes their intellectual property, estimates of the capacity of manufacturing and other service facilities to support Soliris and our product candidates, potential costs resulting from product liability or other third party claims, the sufficiency of our existing capital resources and projected cash needs, the possibility that expected tax benefits will not be realized, assessment of impact of recent accounting pronouncements, declines in sovereign credit ratings or sovereign defaults in countries where we sell Soliris, delay of collection or reduction in reimbursement due to adverse economic conditions or changes in government and private insurer regulations and approaches to reimbursement, the short and long term effects of other government healthcare measures, and the effect of shifting foreign exchange rates. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this report under the section entitled "Risk Factors". Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in this and other reports or documents we file from time to time with the Securities and Exchange Commission.

Business

We are a biopharmaceutical company focused on serving patients with severe and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Our marketed product Soliris is the first and only therapeutic approved for patients with either of two severe and ultra-rare disorders resulting from chronic uncontrolled activation of the complement component of the immune system: paroxysmal nocturnal hemoglobinuria (PNH), a life-threatening and ultra-rare genetic blood disorder, and atypical hemolytic uremic syndrome (aHUS), a life-threatening and ultra-rare genetic disease. We are also evaluating additional potential indications for Soliris in severe and devastating diseases in which we believe that uncontrolled complement activation is the underlying mechanism, and we are progressing in various stages of development with additional biotechnology product candidates as treatments for patients with severe and life-threatening ultra-rare disorders. We were incorporated in 1992 and began commercial sale of Soliris in 2007.

Soliris is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation associated with chronic disorders in several therapeutic areas, including hematology, nephrology, transplant rejection and neurology. Soliris is a humanized monoclonal antibody that effectively blocks terminal complement activity at the doses currently prescribed. The initial indication for which we received approval for Soliris is PNH. PNH is a debilitating and life-threatening, ultra-rare genetic blood disorder defined by chronic uncontrolled complement activation leading to the

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destruction of red blood cells (hemolysis). The chronic hemolysis in patients with PNH may be associated with life-threatening thromboses, recurrent pain, kidney disease, disabling fatigue, impaired quality of life, severe anemia, pulmonary hypertension, shortness of breath and intermittent episodes of dark-colored urine (hemoglobinuria).
Soliris was approved for the treatment of PNH by the FDA and the European Commission (EC) in 2007 and by Japan's Ministry of Health, Labour and Welfare (MHLW) in 2010, and has been approved in several other territories. Additionally, Soliris has been granted orphan drug designation for the treatment of PNH in the United States, Europe, Japan and several other territories.
In September and November 2011, Soliris was approved by the FDA and EC, respectively, for the treatment of pediatric and adult patients with aHUS in the United States and Europe. In September 2013, the MHLW approved Soliris for the treatment of pediatric and adult patients with aHUS in Japan. aHUS is a severe and life-threatening genetic ultra-rare disease characterized by chronic uncontrolled complement activation and thrombotic microangiopathy (TMA), the formation of blood clots in small blood vessels throughout the body, causing a reduction in platelet count (thrombocytopenia) and life-threatening damage to the kidney, brain, heart and other vital organs. In addition, the FDA and EC have granted Soliris orphan drug designation for the treatment of patients with aHUS.

Products and Development Programs
We focus our product development programs on life-transforming therapeutics for severe and life-threatening ultra-rare diseases for which we believe current treatments are either non-existent or inadequate.
Marketed Products
Our marketed products include the following:

Product	Development Area	Indication	Development Stage
Soliris (eculizumab)	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Commercial
		PNH Registry	Phase IV
	Hematology/Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)	Commercial
		aHUS Registry	Phase IV

Paroxysmal Nocturnal Hemoglobinuria (PNH)
Soliris is the first and only therapy approved for the treatment of patients with PNH, a debilitating and life-threatening ultra-rare blood disorder in which an acquired genetic deficiency causes uncontrolled complement activation which leads to life-threatening complications. We continue to work with researchers to expand the base of knowledge in PNH and the utility of Soliris to treat patients with PNH. In 2013, the EC extended the Soliris label to include pediatric patients with PNH. The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommends that the renewal be granted with unlimited validity. We are sponsoring a multinational registry to gather information regarding the natural history of patients with PNH and the longer term outcomes during Soliris treatment. In April of 2014 the EC approved an update to the EU label that supports Soliris treatment for patients with PNH regardless of history of transfusion and additional updates to inform physicians to make treatment decisions based on elevated hemolysis and the presence of common symptoms associated with PNH.
Atypical Hemolytic Uremic Syndrome (aHUS)
aHUS is a chronic and life-threatening ultra-rare genetic disease in which uncontrolled complement activation causes blood clots in small blood vessels throughout the body or TMA leading to kidney failure, stroke, heart attack and death. Soliris is the first and only therapy approved for the treatment of pediatric and adult patients with aHUS. In May 2014, the FDA approved conversion of Soliris accelerated approval in aHUS to regular approval for the treatment of adult and pediatric patients with aHUS to inhibit complement-mediated TMA. In April of 2014 the EC approved an update to the EU label for Soliris treatment for patients with aHUS that included new efficacy data which specifies that longer-term treatment with Soliris is associated with a greater proportion of patients achieving clinically significant benefits, including complete TMA response and hematologic normalization, as well as the importance of sustained Soliris therapy.

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Clinical Development Programs

Our programs, including investigator sponsored clinical programs, include the following:

Product	Development Area	Indication	Development Stage
Soliris (eculizumab)	Neurology	Myasthenia Gravis (MG)	Phase III
		Neuromyelitis Optica (NMO)	Phase III
	Transplant	Delayed Kidney Transplant Graft Function	Phase III
		Antibody Mediated Rejection (AMR) Presensitized Renal Transplant - Living Donor	Phase II
		Antibody Mediated Rejection (AMR) Presensitized Renal Transplant - Deceased Donor	Phase II
		Treatment of Antibody Mediated Rejection (AMR) Following Renal Transplantation*	Phase II
Strensiq (asfotase alfa)	Metabolic Disorders	Hypophosphatasia (HPP)	Phase II
cPMP (ALXN 1101)	Metabolic Disorders	MoCD Type A	Phase II
ALXN 1007	Inflammatory Disorders	GI Graft versus Host Disease	Phase II
		Anti-phospholipid Syndrome	Phase II
ALXN 1210	Next Generation		Phase I
ALXN 5500	Next Generation		Phase I

*Investigator sponsored clinical program

Soliris (eculizumab)

Neurology

Myasthenia Gravis (MG)

MG is an ultra-rare autoimmune syndrome characterized by complement activation leading to the failure of neuromuscular transmission. Enrollment of patients in a Phase III multinational, placebo-controlled registration trial of eculizumab in patients with refractory generalized MG is ongoing and expected to be completed in 2015. The FDA, EC and MHLW have granted orphan drug designation for eculizumab as a treatment for patients with MG.

Neuromyelitis Optica (NMO)

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

Transplant

Delayed Kidney Transplant Graft Function (DGF)

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

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Antibody Mediated Rejection (AMR) in Presensitized Kidney Transplant Patients
AMR is the term used to describe a type of transplant rejection that occurs when the recipient has antibodies to the donor organ. Enrollment in a multi-national, multi-site controlled clinical trial of eculizumab in presensitized kidney transplant patients at elevated risk for AMR who received kidneys from deceased organ donors was completed in March 2013. The study was re-opened in October 2013 to enroll additional patients at the request of participating investigators. Enrollment and dosing in this expanded trial has been completed and patient follow-up in the trial is continuing. In September 2013, researchers presented positive preliminary data from the eculizumab deceased-donor AMR kidney transplant study at the European Society of Organ Transplant in Vienna, Austria.
In January 2015, we reported results from a randomized, open-label, multicenter Phase II clinical trial of eculizumab presensitized kidney transplant patients at an elevated risk of AMR who received kidneys from living donors. The primary composite endpoint of the trial did not reach statistical significance. Patient follow-up and data analyses are ongoing and based on discussions with regulators, we are developing plans to commence a clinical trial with eculizumab as a treatment for patients with AMR.
The EC granted orphan drug designation to eculizumab for the prevention of graft rejection following solid organ transplantation.

Strensiq (asfotase alfa)
Hypophosphatasia (HPP)
HPP is an ultra-rare, genetic, and life-threatening metabolic disease characterized by impaired phosphate and calcium regulation, leading to progressive damage to multiple vital organs including destruction and deformity of bones, profound muscle weakness, seizures, impaired renal function, and respiratory failure.
Strensiq (asfotase alfa), a targeted enzyme replacement therapy in Phase II clinical trials for patients with HPP, is designed to directly address underlying causes of HPP by aiming to restore the genetically defective metabolic process, thereby preventing or reversing the severe and potentially life-threatening complications in patients with HPP. In 2013, Strensiq (asfotase alfa) received Breakthrough Therapy Designation from the FDA. In September 2014, the MHLW granted orphan drug designation to Strensiq (asfotase alfa) for the treatment of patients with HPP.
In 2014, we filed for regulatory approval with the FDA, EMA and MHLW. In July 2014, the European Medicines Agency (EMA) validated our Marketing Authorization Application (MAA) for Strensiq (asfotase alfa) for the treatment of HPP. In March 2015, the FDA accepted for Priority Review our Biologics License Application (BLA) for Strensiq (asfotase alfa) for treatment of patients with infantile- and juvenile-onset HPP.

cPMP (ALXN 1101)
Molybdenum Cofactor Deficiency (MoCD) Disease Type A (MoCD Type A)
MoCD Type A is an ultra-rare metabolic disorder characterized by severe and rapidly progressive neurologic damage and death in newborns. MoCD Type A results from a genetic deficiency in cyclic Pyranopterin Monophosphate (cPMP), a molecule that enables the function of certain enzymes and the absence of which allows neurotoxic sulfite to accumulate in the brain. To date, there is no approved therapy available for MoCD Type A. There has been some early clinical experience with the recombinant cPMP replacement therapy in a small number of children with MoCD Type A, and we are conducting a natural history study in patients with MoCD Type A. In October 2013, cPMP received Breakthrough Therapy Designation from the FDA for the treatment of patients with MoCD Type A. Evaluation of our synthetic form of cPMP replacement therapy in a Phase I healthy volunteer study is complete. As a result, we are conducting a multi-center, multinational open-label clinical trial of synthetic cPMP in patients with MoCD Type A switched from treatment with recombinant cPMP.

ALXN 1007
ALXN 1007 is a novel humanized antibody designed to target rare and severe inflammatory disorders and is a product of our proprietary antibody discovery technologies. We have completed enrollment in both a Phase I single-dose, dose escalating safety and pharmacology study in healthy volunteers, as well as in a multi-dose, dose escalating safety and

pharmacology study in healthy volunteers. A proof-of-concept study in patients with an ultra-rare disorder, gastrointestinal graft versus host disease (GI-GVHD), is ongoing. Patients with GI-GVHD following bone marrow or hematopoietic stem cell transplant experience engrafted hematopoietic cells that attack host gastrointestinal tissues in the first 100 days post-transplant causing damage to the GI tract, liver and skin. In addition, enrollment is ongoing in a Phase II proof-of-concept study in patients with non-criteria manifestations of anti-phospholipid syndrome (APS). APS is an ultra-rare autoimmune, hypercoagulable state caused by antiphospholipid antibodies.

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Manufacturing

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

We have various agreements with Lonza through 2026, with remaining total non-cancellable commitments of approximately $413,150 through 2019. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangements. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at ARIMF and a payment with respect to sales of Soliris manufactured at Lonza facilities.

In March 2013, we received a Warning Letter (Warning Letter) from the FDA regarding compliance with current Good Manufacturing Practices (cGMP) at ARIMF. The Warning Letter followed an FDA inspection which concluded in August 2012. At the conclusion of that inspection, the FDA issued a Form 483 Inspectional Observations, to which we responded in August 2012 and provided additional information to the FDA in September and December 2012. The observations relate to commercial and clinical manufacture of Soliris at ARIMF. We responded to the Warning Letter in a letter to the FDA dated in April 2013. At the conclusion of another inspection of ARIMF in August 2014, the FDA issued a Form 483 with three inspectional observations, none of which were designated as a repeat observation to the Warning Letter. We continue to manufacture products, including Soliris at ARIMF. While the resolution of the issues raised in the Warning Letter is difficult to predict, we do not currently believe a loss related to this matter is probable or that the potential magnitude of such loss or range of loss, if any, can be reasonably estimated. To the extent that circumstances related to this matter change, the impact could have a material adverse effect on our financial operations.

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

In April 2014, we purchased a fill/finish facility in Athlone, Ireland. Following refurbishment of the facility, and after successful completion of the appropriate validation processes and regulatory approvals, the facility will become our first company-owned fill/finish facility for Soliris and other clinical and commercial products. We have also initiated the construction of office, laboratory and packaging facilities on property in Dublin, Ireland, which we purchased in April 2014.

Critical Accounting Policies and the Use of Estimates

The significant accounting policies and basis of preparation of our consolidated financial statements are described in Note 1, “Business Overview and Summary of Significant Accounting Policies” of the Consolidated Financial Statements included in our Form 10-K for the year ended December 31, 2014. Under accounting principles generally accepted in the United States, we are required to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingent assets and liabilities in our financial statements. Actual results could differ from those estimates.

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

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

For a complete discussion of these critical accounting policies, refer to “Critical Accounting Policies and Use of Estimates” within “Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations” included within our Form 10-K for the year ended December 31, 2014. We have reviewed our critical accounting policies as disclosed in our Form 10-K, and we have not noted any material changes.

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New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2016 and allows for adoption using a full retrospective method, or a modified retrospective method. In April 2015, the FASB proposed a one year deferral of the effective date of this standard to periods ending after December 15, 2017 along with an option to permit companies to early adopt the standard for annual periods beginning after December 15, 2016. We are currently assessing the method of adoption and the expected impact the new standard has on our financial position and results of operations.

Results of Operations

Net Product Sales

The following table summarizes net product sales for the three months ended March 31, 2015 and 2014:

	Three months ended March 31,		$
	2015	2014	Variance
Net product sales	$600,333	$566,616	$33,717

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 in years prior to January 1, 2014. As a result of this agreement, in the first quarter of 2014, we reduced the rebate payable and 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 in 2014 related to prior years, net product revenues increased by $121,547 for the three months ended March 31, 2015 compared to the three months ended March 31, 2014. The components of this increase in revenues, are as follows:

Components of change:		
Price	1.0	%
Volume	31.0	%
Foreign exchange	(7.0	)%
Total change in net product sales	25.0	%

The increase in net product sales for the three months ended March 31, 2015, as compared to the same period in 2014, was primarily due to an increase in unit volumes of 31.0%, due to increased physician demand globally for Soliris therapy for patients with PNH or aHUS during the respectively periods.

Price had a positive impact on net product sales of 1.0% for the three months ended March 31, 2015.

Foreign exchange had a negative impact of 7.0% for the three months ended March 31, 2015, as compared to the same period in 2014. The negative impact on foreign exchange of $31,400 or 7.0%, was due to changes in foreign currency exchange rates (inclusive of hedging activity) versus the U.S. dollar for the three months ended March 31, 2015. The negative impact was primarily due to the weakening of the Euro, Japanese Yen and Russian Ruble. Offsetting the impact of the stronger dollar, we recorded a gain in revenue of $29,082 and $1,266 related to our foreign currency cash flow hedging program for the three months ended March 31, 2015 and 2014, respectively. We expect the strong dollar compared to other currencies, especially the Euro, Japanese Yen and Russian Ruble, to continue to have a negative impact on revenue in 2015 compared to 2014.

Cost of Sales

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

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The following table summarizes cost of sales for the three months ended March 31, 2015 and 2014:

	Three months ended March 31,					
	2015		2014		Variance	
Cost of sales	$69,399		$32,939		$36,460	
Cost of sales as a percentage of net product sales	11.6	%	5.8	%	5.8	%

We recorded an expense of $24,352 in the first quarter of 2015 associated with a portion of a single manufacturing campaign at a third party manufacturer for Strensiq (asfotase alfa). The costs are comprised of raw materials, internal overhead and external production costs. We do not expect this expense will not impact the clinical supply of inventory or the expected commercial launch of Strensiq (asfotase alfa) later in 2015, and we do not expect further material financial impact related to this campaign.

In the first quarter 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, we recorded a reversal of accrued royalties of $5,124 as a reduction of cost of sales. Also, in the first quarter of 2014, we recorded the incremental impact in cost of sales of $2,055 for additional royalties related to the $87,830 of net product sales from prior year shipments.

Exclusive of the items mentioned above, cost of sales as a percentage of net product sales were 7.5% for the three months ended March 31, 2015 and 2014.

Research and Development Expense

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

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

All other R&D expenses consist of costs to compensate personnel, to maintain our facility, equipment and overhead and similar costs of our research and development efforts. These costs relate to efforts on our clinical and preclinical products, our product development and our discovery research efforts. These costs have not been allocated directly to each program.

The following table provides information regarding research and development expenses:

	Three months ended March 31,		$
	2015	2014	Variance
Clinical development	$29,007	$23,917	$5,090
Product development	21,326	13,039	8,287
Licensing agreements	112,500	101,925	10,575
Discovery research	6,044	2,581	3,463
Total external direct expenses	168,877	141,462	27,415
Payroll and benefits	44,492	44,019	473
Operating and occupancy	3,090	2,876	214
Depreciation and amortization	4,621	3,100	1,521

Total other R&D expenses	52,203	49,995	2,208
Research and development expense	$221,080	$191,457	$29,623

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For the three months ended March 31, 2015, the increase of $29,623 in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase of $5,090 in external clinical development expenses related primarily to an expansion of clinical studies (see table below).
- Increase of $8,287 in external product development expenses related primarily to an increase in costs associated with the manufacturing of material for increased clinical research activities and clinical studies as compared to the first quarter of 2014.
- Increase of $10,575 in upfront licensing agreement costs primarily due to the upfront payments of $112,000 in the first quarter of 2015 as compared to $100,000 in the first quarter of 2014.
- Increase of $3,463 in discovery research expenses primarily related to increases in external research expenses associated with our Moderna agreement.

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 March 31, 2015	2014	$ Variance
External direct expenses			
Eculizumab	$17,909	$15,496	$2,413
Asfotase alfa	4,271	4,242	29
cPMP	1,554	1,553	1
Other programs	2,956	1,601	1,355
Unallocated	2,317	1,025	1,292
	$29,007	$23,917	$5,090

The successful development of our drug candidates is uncertain and subject to a number of risks. We cannot guarantee that results of clinical trials will be favorable or sufficient to support regulatory approvals for our other programs. We could decide to abandon development or be required to spend considerable resources not otherwise contemplated. For additional discussion regarding the risks and uncertainties regarding our development programs, please refer to Item 1A "Risk Factors" in this Form 10-Q.

Selling, General and Administrative Expense

Our selling, general and administrative expense includes commercial and administrative personnel, corporate facility and external costs required to support the marketing and sales of our commercialized products. These selling, general and administrative costs include: corporate facility operating expenses and depreciation; marketing and sales operations in support of Soliris; human resources; finance, legal, information technology and support personnel expenses; and other corporate costs such as telecommunications, insurance, audit, government affairs and our global corporate compliance program.

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

	Three months ended March 31, 2015	2014	$ Variance
Salary, benefits and other labor expense	$124,103	$82,418	$41,685
External selling, general and administrative expense	63,013	46,873	16,140
Total selling, general and administrative expense	$187,116	$129,291	$57,825

For the three months ended March 31, 2015, the increase of $57,825 in selling, general and administrative expense, as compared to the same period in the prior year, was related to the following:

- Increase in salary, benefits and other labor expenses of $41,685. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of $11,400 related to our global commercial staff to support global expansion. This increase was also due to increases in payroll and benefits of $30,300 within our general and administrative functions to support our infrastructure growth as a global commercial entity including additional stock-based compensation of $15,300.

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- Increase in external selling, general and administrative expenses of $16,140. The increase was primarily due to an increase in marketing costs to support the continued growth in global sales of Soliris, increased costs associated with new product candidates, and an increase in other administrative costs to support our infrastructure growth.

Acquisition-related Costs

For the three months ended March 31, 2015 and 2014, acquisition-related costs consisted of changes in the fair value of contingent consideration of $11,979 and $(38), respectively. The increase in the fair value of contingent consideration is primarily due to increases in the likelihood of payments for contingent consideration.

Restructuring Expenses

In the fourth quarter of 2014, we announced plans to relocate our European headquarters from Lausanne, Switzerland to Zurich, Switzerland. The relocation of the European headquarters will support our operational needs based on growth in the European region. For the three months ended March 31, 2015 we incurred additional employee separation costs resulting in restructuring expenses of $7,052. We expect to pay all accrued amounts related to this restructuring activity in 2015.

Other Income and Expense

The following table provides information regarding other income and expense:

	Three months ended March 31,		$
	2015	2014	Variance
Investment income	$2,884	$2,213	$671
Interest expense	(651)	(1,063)	412
Foreign currency gain	1,005	1,258	(253)
Total other income and expense	$3,238	$2,408	$830

Income Taxes

During the three months ended March 31, 2015, we recorded an income tax provision of $15,622 and an effective tax rate of 14.6%, compared to an income tax provision of $52,557 and an effective tax rate of 24.8% for the three months ended March 31, 2014.

The tax provision for the three months ended March 31, 2015 and 2014 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. The tax provision for the three months ended March 31, 2014 also includes $2,652 attributable to our agreement with the French government that provided reimbursement for shipments of Soliris made prior to January 1, 2014. The remaining reduction in the effective tax rate for the three months ended March 31, 2015 as compared to the same period in the prior year is primarily attributable to an increase in our Federal Orphan Drug Credit and an increase in the amount of income earned in jurisdictions outside the U.S.

We continue to maintain a valuation allowance against certain other deferred tax assets where the realization is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized.

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Financial Condition, Liquidity and Capital Resources
The following table summarizes the components of our financial condition as of March 31, 2015 and December 31, 2014:

	March 31, 2015	December 31, 2014	$ Variance
Cash and cash equivalents	$916,814	$ 943,999	$(27,185)
Marketable securities	$1,008,278	$ 1,017,567	$(9,289)
Long-term debt (includes current portion)	$45,500	$ 57,500	$(12,000)
Current assets	$2,852,987	$ 2,796,029	$56,958
Current liabilities	580,439	606,740	(26,301)
Working capital	$2,272,548	$ 2,189,289	$83,259

The decrease in cash and cash equivalents was primarily attributable to purchases of marketable securities, payments on our outstanding term loan, purchases of property, plant and equipment, and the repurchase of common stock, offset by cash generated from operations, proceeds from the maturity or sale of available-for-sale securities, net proceeds from the exercise of stock options and a reduction of income taxes payable due to excess tax benefits from stock options.
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 is to preserve capital, provide liquidity consistent with forecasted cash flow requirements, maintain appropriate diversification and generate returns relative to these investment objectives and prevailing market conditions.
Financial instruments that potentially expose us to concentrations of credit risk are cash equivalents, marketable securities, accounts receivable and our foreign exchange derivative contracts. At March 31, 2015, four individual customers accounted for an aggregate of 55% of the accounts receivable balance, with individual customers ranging from 11% to 20% of the accounts receivable balance. At December 31, 2014, four individual customers accounted for an aggregate of 58% of the accounts receivable balance, with individual customers ranging from 10% to 23% of the accounts receivable balance. For the three months ended March 31, 2015, three customers accounted for an aggregate of 39% of our product sales, with individual customers ranging from 10% to 18% of our product sales. For the three months ended March 31, 2014 , one customer accounted for 16% of our product sales.
We continue to monitor economic conditions, including volatility associated with global 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. Although collection of our accounts receivables from certain countries may extend beyond our standard credit terms, we do not expect any such delays to have a material impact on our financial condition or results of operations.
We manage our foreign currency exposure within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk mitigation purposes, and we do not use derivatives for speculative trading

purposes. As of March 31, 2015, we have foreign exchange forward contracts with notional amounts totaling $1,916,750. These outstanding foreign exchange forward contracts had a net fair value of $241,064, of which an unrealized gain of $241,466 is included in other assets, offset by an unrealized loss of $402 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.

At March 31, 2015, 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

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through market corroboration, but substantially the full term of the financial instrument. Our Level 2 assets consist primarily of institutional money market funds, commercial paper, municipal bonds, U.S. and foreign government-related debt, corporate debt securities, certificates of deposit and foreign exchange forward contracts. Our Level 2 liabilities consist also of foreign exchange forward contracts. 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 an impact on our liquidity in the near-term, and, during the next 12 months, we expect to make milestone payments totaling approximately $50,000. 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.

Financing Lease Obligation

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

License Agreements

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

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

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

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

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 also 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

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March 31, 2015, we had $45,500 outstanding on the term loan of which $12,000 was paid in April 2015. As of March 31, 2015, we had open letters of credit of $9,938, and our borrowing availability under the revolving facility was $190,062 at March 31, 2015. We expect that cash generated from operations will be sufficient to meet debt service obligations.

Lonza Agreement

We have supply agreements with Lonza through 2026 relating to the manufacture of Soliris and Strensiq (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 non-cancellable commitments of approximately $413,150 through 2019. 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 ARIMF and a payment with respect to sales of Soliris manufactured at Lonza facilities.

Taxes

We do not record U.S. tax expense on the undistributed earnings of our controlled foreign corporation (CFC) subsidiaries because these earnings are intended to be permanently reinvested offshore. At December 31, 2014, the cumulative amount of these earnings was approximately $359,000. 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.

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 March 31, 2015, approximately $608,000 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, our Board of Directors authorized the repurchase of up to $400,000 of our common stock and in December 2014 they authorized the repurchase of an additional $500,000 of our common stock. The repurchase program does not have an expiration date, and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at the Company's discretion. We expect that cash generated from operations and our existing available cash and cash equivalents are sufficient to fund any share repurchases.

Under the program, we repurchased 334 and 137 shares of our common stock at a cost of $60,026 and $22,057 during the three months ended March 31, 2015 and 2014, respectively. As of March 31, 2015, there is a total of $459,686 remaining for repurchases under the program.

Subsequent to December 31, 2014, we repurchased 126 shares of our common stock under our repurchase program at a cost of $22,413.

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Cash Flows

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

	Three months ended March 31,		
	2015	2014	$ Variance
Net cash provided by (used in) operating activities	$23,034	$(31,055)	$54,089
Net cash used in investing activities	(48,423)	(90,197)	41,774
Net cash provided by financing activities	5,074	119,212	(114,138)
Effect of exchange rate changes on cash	(6,870)	468	(7,338)
Net change in cash and cash equivalents	$(27,185)	$(1,572)	$(25,613)

The decrease in cash and cash equivalents was primarily attributable to purchases of marketable securities, payments on our outstanding term loan, purchases of property, plant and equipment, and the repurchase of common stock, offset by cash generated from operations, proceeds from the maturity or sale of available-for-sale securities, net proceeds from the exercise of stock options and a reduction of income taxes payable due to excess tax benefits from stock options.

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 $91,323 and $159,354 for the three months ended March 31, 2015 and 2014, respectively. During the first quarter of 2015 we recorded expense of $112,000 for upfront payments associated with license agreements we entered into with a third parties. 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, and deferred taxes, and were increases (decreases) to reconcile net income to net cash flows from operating activities of $46,736 and $(17,005) for the three months ended March 31, 2015 and 2014, respectively.
- Non-cash items also included $52,521 and $130,407 of windfall tax benefits for three months ended March 31, 2015 and 2014, respectively. The amount of the windfall tax benefit was significantly higher for the three months ended March 31, 2014 due to an increased level of stock option exercises.
- Net cash outflow due to changes in operating assets and liabilities was $62,504 and $42,997 for the three months ended March 31, 2015 and 2014, respectively. The $62,504 change in operating assets and liabilities primarily relates to:
- Increase in accounts receivable of $58,918 due primarily to increasing revenue.

Increase of $38,980 in prepaid expenses and other assets related to increases in prepaid manufacturing costs and prepaid taxes.

- Decrease of $13,659 in accounts payable, accrued expenses and other liabilities primarily related to decreases in accrued compensation and accrued taxes, offset by increases in accrued distribution fees and trade accounts payable.
- Increase in deferred revenue of $46,427 due to increased shipments in advance of recognizing revenue.

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Investing Activities

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

- Purchases of available-for-sale marketable securities of $166,319 and $145,565 for the three months ended March 31, 2015 and 2014, respectively, offset by proceeds from the maturity or sale of available-for-sale marketable securities of $176,256 and $99,250 during the same periods.
- Additions to property, plant and equipment of $57,075 and $17,733 for the three months ended March 31, 2015 and 2014, respectively.

Financing Activities

Net cash flows from financing activities reflect proceeds from the exercise of stock options of $24,882 and $30,404 for the three months ended March 31, 2015 and 2014, respectively. Net cash flows from financing activities for the three months ended March 31, 2015 and 2014 also include $52,521 and $130,407 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.

During the three months ended March 31, 2015, we made payments of $12,000 against the term loan facility. The facility had $45,500 remaining outstanding as of March 31, 2015.

During the three months ended March 31, 2015 and 2014, we repurchased $60,026 and $22,057 worth of shares of our common stock under a repurchase program that was approved by our Board of Directors in November 2012. In December 2014, our Board of Directors approved an additional $500,000 for the repurchase of shares. As of March 31, 2015, there is a total of $459,686 remaining for repurchases under the repurchase 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, 2014, in the section titled “Management's Discussion and Analysis of Financial Condition and Results of Operations” under the caption “Contractual Obligations.”

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest Rate Risk

As of March 31, 2015, 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 increase. 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 length of time to maturity of our investments. If interest rates were to increase or decrease by 1%, the fair value of our investment portfolio would (decrease) increase by approximately $(11,230) and $7,723, 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. At March 31, 2015, we had approximately $45,500 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 $455.

Foreign Exchange Market Risk

Our operations include activities in many countries outside the United States, including countries in Europe, Latin America and Asia Pacific. As a result, our financial results are impacted by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets where we operate. We have exposure to movements in foreign currency exchange rates, the most significant of which are the Euro and Japanese Yen, against the U.S. dollar. We are a net recipient of many foreign currencies, and our consolidated financial results benefit from a weaker U.S. dollar and are adversely impacted by a stronger U.S. dollar relative to foreign currencies in which we sell our product.

Our monetary exposures on our balance sheet arise primarily from cash, accounts receivable, intercompany receivables and payables denominated in foreign currencies. Approximately 54% of our product sales were denominated in foreign currencies during the three months ended March 31, 2015, and our revenues are also exposed to fluctuations in the foreign currency exchange rates over time. In certain foreign countries, we may sell in U.S. Dollar, but our customers may be impacted adversely in fluctuations in foreign currency exchange rates which may also impact us in the future.

Both positive and negative impacts to our international product sales from movements in foreign currency exchange rates are only partially mitigated by the natural, opposite impact that foreign currency exchange rates have on our international operating expenses. Additionally, we have operations based in Switzerland, and accordingly, our expenses are 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) mitigate the foreign currency exposure of our monetary assets and liabilities on our balance sheet, using forward contracts with durations of up to 30 days and 2) hedge a portion of our forecasted product sales (in some currencies), including intercompany sales, using contracts with durations of up to 60 months. The objectives of this program are to reduce the volatility of our operating results due to fluctuation of foreign exchange and to increase the visibility of the foreign exchange impact on forecasted revenues. This program utilizes foreign exchange forward contracts intended to reduce, not eliminate, the volatility of operating results due to fluctuations in foreign exchange rates.

As of March 31, 2015 and December 31, 2014, we held foreign exchange forward contracts with notional amounts totaling $1,916,750 and $1,748,931, respectively. The increase in outstanding foreign exchange forward contracts resulted primarily from increases in forecasted revenues and, for certain currencies, extended duration of hedges. As of March 31, 2015 and December 31, 2014, our outstanding foreign exchange forward contracts had a net fair value of $241,064 and $135,166, respectively. The increase in the net fair value of outstanding foreign exchange forward contracts is primarily due to the strengthening of the U.S. dollar in 2015.

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 March 31, 2015, 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 $147,794 at March 31, 2015. 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. Although collection of our accounts receivables from certain countries may extend beyond our standard credit terms, we currently do not expect 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, or the Exchange Act) as of March 31, 2015. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2015, 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 March 31, 2015 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 Products
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 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, including the U.S., certain European countries, or Japan. 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 and aHUS in new territories, and the maintenance of marketing approvals in the United States, the European Union, Japan and other territories;
- 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 our commercial manufacturing capabilities ourselves or through third-party manufacturers;
- 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 aHUS, and successful launch in countries where we have not yet obtained, or only recently obtained, marketing approval or commenced sales;
- 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 and 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.

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 in foreign countries, 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. Third party

payers decide which drugs they will pay for and establish reimbursement and co-payment levels. Government and other third-party payers in the United States and the European Union member states are increasingly challenging the prices charged for health care products, examining the cost effectiveness of drugs in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement for prescription drugs.
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 "Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy and Government initiatives that affect coverage and reimbursement of drug products may impact our business in ways that we cannot currently predict and these changes could adversely affect our business and financial condition" and "The credit and financial market conditions may aggravate certain risks affecting our business." 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.
Payers in the U.S. also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price (ASP), average manufacturer price, and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. The Centers for Medicare and Medicaid Services (CMS), the federal agency that administers Medicare and the Medicaid Drug Rebate Program, has begun posting drafts of this retail survey price information on at least a monthly basis in the form of draft National Average Drug Acquisition Cost (NADAC) files, which reflect retail community pharmacy invoice costs, and National Average Retail Price (NARP) files, which reflect retail community pharmacy prices to consumers. In July 2013, CMS suspended the publication of draft NARP data, pending funding decisions. In November 2013, CMS moved to publishing final rather than draft NADAC data and has since made updated NADAC data publicly available on a weekly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payers to cover 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 through related charitable purposes. We are not able to predict the financial impact of the support we may provide for these and other charitable purposes; however, substantial support could have a material adverse effect on our profitability in the future.
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 in this Quarterly Report on Form 10-Q. As Soliris is approved by regulatory agencies for indications other than PNH and aHUS, 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, aHUS 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 maintain market acceptance of Soliris among the medical community or patients, or gain market acceptance of our products in the future, which could prevent us from maintaining profitability or growth.
We cannot be certain that Soliris will 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. Physicians' willingness to prescribe, and patients' willingness to accept, our products, such as Soliris, depends on many factors, including prevalence and severity of adverse side effects in both clinical trials and commercial use, the timing of the market introduction of competitive drugs, lower demonstrated clinical safety and efficacy compared to other drugs, perceived lack of cost-effectiveness, pricing and lack of availability of reimbursement from third-party payers, convenience and ease of administration, effectiveness of our marketing strategy, publicity concerning the product, our other product candidates or competing products, and availability of alternative treatments, including bone marrow transplant as an alternative treatment for PNH. The likelihood of physicians to prescribe Soliris for patients with aHUS may also depend on how quickly Soliris can be delivered to the hospital or clinic and our distribution methods may not be sufficient to satisfy this need. In addition, we are aware that medical doctors have determined not to continue Soliris treatment for some patients with aHUS.

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 products 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 our products, including 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.

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 any third party manufacturer or provider fails to provide sufficient quantities of Soliris or our product candidates, including Soliris for new indications, we could experience product shortages, our commercialization of Soliris may be stopped or delayed, our clinical trials could be disrupted or regulatory approvals could be delayed.

Soliris is manufactured by Alexion at ARIMF and by Lonza. We depend on a very limited number of third party providers for the manufacture and supply of Soliris and our product candidates. The manufacture of Soliris and our product candidates is difficult, requiring a multi-step controlled process and even minor problems or deviations could result in defects or failures. Manufacture of our products, including Soliris, is highly technical, and only a small number of companies have the ability and capacity to manufacture our products for our development and commercialization needs. Due to the highly technical requirements of manufacturing our products and the strict quality and control specifications, we and our third party providers may be unable to manufacture or supply our products despite our and their efforts. 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 our products in accordance with regulatory requirements and to our quality specifications and volume requirements.

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 for any reason, including due to the loss of approvals, 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. See also our Risk Factor "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 or our product candidates, and our business would be seriously harmed." 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. The failure to manufacture appropriate supplies of our product candidates, on a timely basis, or at all, may prevent or interrupt clinical development of our products, including Soliris for new indications. If we are forced to find an alternative supplier or other third party providers, in addition to loss of sales and disruption to patients, we may also incur significant costs and experience significant delay in establishing a new arrangement.

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

We have obtained marketing approval for Soliris for the treatment of patients with aHUS in the United States, the European Union, Japan and other territories. 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 filling, finishing, packaging, and labeling. We have changed or added third party fill/finish providers in the past in order to support uninterrupted supply, and may do so in the future. We currently rely on three third party fill/finish providers to support our commercial requirements in the United States and the European Union, and two to support requirements in Japan. No guarantee can be made that regulators will approve additional third party fill/finish providers in a timely manner or at all, or that any third party fill/finish providers 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 with respect to recalls initiated in 2013 and 2014.

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 in 2013 and 2014 due to the presence of visible particles in a limited number of vials in specific lots. Even if we are able to find alternatives they may ultimately be insufficient for our needs.

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.

In April 2014, we acquired a fill/finish facility in Ireland to support global distribution of Soliris and Alexion's other clinical and commercial products. To date, we have relied entirely on third party fill/finish providers and have never operated our own fill/finish facility. We 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 fill/finish 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.

If we or our contract manufacturers fail to comply with United States and foreign regulations, we or our manufacturers could lose our approvals to market Soliris or our product candidates, 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 governmental authorities around the world, including the FDA, EMA, the competent authorities of the European Union member states, and MHLW. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us. For example, in March 2013, we received the Warning Letter from the FDA relating to compliance with cGMP at ARIMF. In August 2014 we announced that we received a Form 483 with three observations following an FDA inspection at ARIMF. If we do not resolve outstanding concerns expressed by the FDA in the Warning Letter and the August 2014 Form 483 to the satisfaction of the FDA, EMA or any other regulatory agency, or we or our third-party providers, including our product fill/finish providers, packagers and labelers, fail to comply fully with applicable regulations then we may be required to initiate a recall or withdrawal of our products.

The safety profile of any product continues to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. Regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, finishing, filling, labeling, advertising, promotion, risk mitigation, adverse event reporting requirements, and export of biologics. For example, the risk management program established in 2007 upon the FDA's approval of Soliris for the treatment of PNH was replaced with a Risk Evaluation and Mitigation Strategy (REMS) program, approved by the FDA in 2010. 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. In November 2014, we met with the FDA Drug Safety and Risk Management Advisory Committee to discuss adjustments to the REMS with elements to assure safe use (ETASU). A majority of the Committee favored revising the REMS and made suggestions for streamlining prescriber assessments and broadening the program's educational outreach. Changes to the Soliris REMS could be costly and burdensome to implement.

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.

The FDA requires reporting of certain information on side effects and adverse events reported during clinical studies and after marketing approval. Non-compliance with safety reporting requirements could result in regulatory action that may include civil action or criminal penalties.

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

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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.

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 (FCA), the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind to induce, or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federal health care programs. This statute has been interpreted to apply broadly to arrangements between pharmaceutical manufacturers on the one hand and prescribers, patients, purchasers and formulary managers on the other. Liability may be established without a person or entity having actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the PPACA), amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the FCA. A conviction for violation of the Anti-kickback Statute requires mandatory exclusion from participation in federal health care programs. 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 to those who prescribe, purchase, or recommend pharmaceutical products, including certain discounts, education and research grants, purchase of speaking or consulting services, and patient assistance programs, 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 FCA prohibits any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim. Pharmaceutical companies have been investigated and have reached substantial financial settlements with the Federal government under the FCA for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees and other benefits to physicians to induce them to prescribe products; 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.

The majority of states also have statutes similar to the federal anti-kickback law and false claims laws that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. In addition, 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. Some state laws prohibit certain marketing-related activities including the provision of gifts, meals or other items to certain health care providers. Similar legislation is being considered in other states. Additionally, PPACA enacted the Physician Payment Sunshine Act, being implemented as the Open Payments program, that requires manufacturers to track and report to the federal government, for public dissemination, payments and other transfers of value made to physicians and teaching hospitals. Many of these requirements are new and there is limited guidance on many aspects of how they will be interpreted, implemented and enforced. 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.

Sanctions under these federal and state fraud and abuse laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, monetary damages, criminal fines, and imprisonment. Efforts to ensure that our business arrangements continue to comply with applicable healthcare laws and regulations could be costly. 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. 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 could also harm our financial condition. Responding to government investigations or whistleblower lawsuits, defending any claims raised, and any resulting fines, damages, penalties, settlement payments or administrative actions, as well as any related actions brought by stockholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business.

Although physicians in the United States are permitted to, based on their medical judgment, prescribe products for indications other than those cleared or approved by the FDA, manufacturers are prohibited from promoting their products for such off-label uses. In the United States, we market 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 or state enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false or fraudulent claims for payment of government funds. 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.

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 medicinal product which does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the European Union and in other territories. The promotion of medicinal products that are not subject to a marketing authorization is also prohibited in the European Union. Laws in the European Union, including in the individual European Union member states, also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal 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 medicinal 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. These rules have been supplemented by provisions of related industry codes. Additional countries may consider or implement similar laws and regulations. Violations of these rules could lead to reputational risk, public reprimands, and/or the imposition of fines or imprisonment.

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 that generally prohibit companies and their intermediaries from making improper payments to government officials and/or other persons for the purpose of obtaining or retaining business. Worldwide regulators are increasing their regulatory and enforcement efforts in this area. For example, the Bribery Act in the United Kingdom, effective as of 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.

Recent years have seen a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice ("DOJ") and the U.S. Securities and Exchange Commission (SEC), increased enforcement activity by non-U.S. regulators, and increases in criminal and civil proceedings brought against companies and individuals. Our policies mandate compliance with these anti-bribery laws. We may operate in many parts of the world that are recognized as having a greater potential for governmental and commercial corruption. We cannot assure that our policies and procedures will always protect us from reckless or criminal acts committed by our employees or third-party intermediaries. From time-to-time, we may conduct internal investigations and compliance reviews, the findings of which could negatively impact our business. Any determination that our operations or activities are not, or were not, in compliance with existing United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence. Violations of these laws may result in criminal or civil sanctions, which could disrupt our business and result in a material adverse effect on our reputation, business, results of operations or financial condition. Increasing regulatory scrutiny of the promotional activities of pharmaceutical companies also has been observed in a number of European Union member states.

Laws, including those governing promotion, marketing and anti-kickback/anti-bribery provisions, and industry regulations are often strictly enforced. In the United States, additional governmental resources are being added to enforce these laws and to prosecute companies and individuals believed to be violating them. For example, PPACA included a number of provisions aimed at strengthening the government’s ability to pursue anti-kickback and false claims cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers for government authorities, and amendments to the FCA that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations. We anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and whistleblower lawsuits. Responding to a government investigation or whistleblower lawsuit would be expensive and time-consuming, and could have a material adverse effect on our business and financial condition and growth prospects.

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, including asfotase alfa and Soliris for other indications, 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. Although we are preparing for a commercial launch of Strensiq (asfotase alfa) for the treatment of hypophosphatasia, we do not know when or if Strensiq (asfotase alfa) will be approved by the FDA, EMA or any other regulatory agency. We completed a rolling submission of our BLA for Strensiq (asfotase alfa) in the U.S., which allowed completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. While the FDA accepted the application in March 2015, 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. Unfavorable clinical trial results, failure to comply with regulatory requirements, resolve pending concerns described in the Warning Letter, and inadequate manufacturing processes are examples of 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. Data obtained from preclinical studies and clinical trials are subject to varying interpretations that could delay, limit or prevent regulatory approval. Data that we believe is highly clinically significant, including the results of our HPP trials, could be interpreted differently by the FDA or other regulatory agencies. The results generated in clinical studies of Strensiq (asfotase alfa) which we believe to be positive, do not ensure that the product will be approved and the FDA or other regulatory agency could require additional preclinical or clinical data. If the design or results achieved in our clinical trials are insufficient to proceed to further trials or to regulatory approval of our product candidates, our company could be materially adversely affected. Failure of a clinical trial to achieve its pre-specified primary endpoint, such as the Phase II Soliris trial for AMR that we announced in January 2015, generally increases the likelihood that additional studies or trials will be required if we determine to continue development of the product candidate, reduces the likelihood of timely development of and regulatory approval to market the product candidate, and may decrease the chances for successfully achieving the primary endpoint in scientifically similar indications.

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.

In March 2015, the FDA accepted our application for Strensiq (asfotase alfa) as a treatment for patients with HPP. In July 2014, the MAA for Strensiq (asfotase alfa) was validated by the EMA. In October 2014, Alexion submitted a New Drug Application for Strensiq (asfotase alfa) to Japan’s MHLW.

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, such as Strensiq (asfotase alfa), 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. For example, the EMA transitioned the MAA for Strensiq (asfotase alfa) from an accelerated assessment to a regular assessment. 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 or post-marketing obligations;
- 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.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that is not desirable for the successful commercialization of that product candidate. In addition, if our product candidate produces undesirable side effects or safety issues, the FDA may require the establishment of REMS or a comparable foreign regulatory authority may require the establishment of a similar strategy, that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us. Any of the foregoing scenarios could materially harm the commercial prospects of our product candidates.

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 molecules 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 molecules 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 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 our drug candidates, such as asfotase alfa, and for Soliris in additional territories and other indications, our ability to successfully market Soliris in additional territories, 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 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.

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 are seeking to expand our business through acquisitions and we may not realize the benefits of such acquisitions.

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.

A substantial portion of our strategic efforts are focused on opportunities for rare disorders and life-saving therapies. The availability of such development opportunities is limited. We may not be able to identify opportunities that are acceptable to us or our shareholders. Several 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 or our shareholders find acceptable, or at all. 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.

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

To effectively manage our current and future potential growth, we must continue to effectively grow and manage our global employee base, and enhance our operational and financial processes. Supporting our growth strategy will require significant capital expenditures and management resources, including investments in research and development, sales and marketing, manufacturing and other areas of our operations. If we do not successfully manage our current growth and do not successfully execute our strategy, then our business and financial results may be adversely affected and we may incur asset impairment or restructuring charges.

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.

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

As a company with international operations, we are subject to income taxes, as well as non-income based taxes, in both the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities. Although we believe our estimates are reasonable, the ultimate outcome with respect to the taxes we owe may differ from the amounts recorded in our financial statements. If the Internal Revenue Service, or other taxing authority, disagrees with the positions we take, we could have additional tax liability, and this could have a material impact on our results of operations and financial position. Our effective tax rate could be adversely affected by changes in the mix of earnings in countries with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in tax laws and regulations, changes in interpretations of tax laws, including pending tax law changes, changes in our manufacturing activities and changes in our future levels of research and development spending.

We have designed our corporate structure, the manner in which we develop and use our intellectual property, and our intercompany transactions between our affiliates in a way that is intended to enhance our operational and financial efficiency and increase our overall profitability. The application of the tax laws and regulations of various countries in which we operate and to our global operations is subject to interpretation. We also must operate our business in a manner consistent with our corporate structure to realize such efficiencies. The tax authorities of the countries in which we operate may challenge our methodologies for valuing developed technology or for transfer pricing. If tax authorities determine that the manner in which we operate results in our business not achieving the intended tax consequences, our effective tax rate could increase and harm our financial position and results of operations.

In addition, the United States government and other governments are considering and may adopt tax reform measures that significantly increase our worldwide tax liabilities. The U.S. Congress, the Organization for Economic Co-operation and Development and other government agencies in countries where we and our affiliates operate have focused on issues related to the taxation of multinational corporation, including, for example, in the area of “base erosion and profit shifting,” where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. We established operations in Ireland in 2013 and recently, Ireland tax authorities announced changes to the treatment of non-resident Irish entities. The changes are not expected to impact existing non-resident Irish entities, such as ours, until after December 31, 2020. These changes and other prospective changes in the United States and other countries in which we and our affiliates operate could increase our effective tax rate, and harm our financial position and results of operations.

Our sales and operations are subject to 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 and we are exposed to fluctuations in foreign currency exchange rates in the normal course of our business. See also Risk Factor "Currency fluctuations and changes in exchange rates could adversely affect our revenue growth, increase our costs and negatively affect our profitability."

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

Sales of Soliris and other products are or will be 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 our products, including Soliris, in the future, which could have a material adverse effect on our business and results of operations. 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.

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.

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

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 and we expect these exposures to increase during 2015 if the strengthening of the U.S. dollar continues. The exposures result from portions of our revenues, as well as the related receivables, and expenses that are denominated in currencies other than the U.S. dollar, including the Euro, Japanese Yen, British Pound, Swiss Franc, and Russian Ruble. We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. We enter into foreign exchange forward contracts, with durations of up to 60 months, to hedge exposures resulting from portions of our forecasted revenues, including intercompany revenues, that are denominated in currencies other than the U.S. dollar. The purpose of the hedges of revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. 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.

Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy and coverage and reimbursement of drug products may impact our business in ways that we cannot currently predict and these changes could adversely affect our business and financial condition.

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, the PPACA was adopted in the United States in March 2010. This law substantially changes the way healthcare is financed by both governmental and private insurers in the U.S., and significantly impacts the pharmaceutical industry. PPACA contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under health insurance exchanges, expansion of the 340B program, expansion of state Medicaid programs, and fraud and abuse enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

PPACA contains several provisions that have or could potentially impact our business. PPACA made significant changes to the Medicaid Drug Rebate Program. Effective March 23, 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. With regard to the amount of the rebates owed, PPACA increased the minimum Medicaid rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, PPACA and subsequent legislation changed the definition of average manufacturer price. Finally, PPACA requires pharmaceutical manufacturers of branded prescription drugs, such as Soliris, to pay a branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2014 (and set to increase in ensuing years), based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Sales of "orphan drugs"-those designated under section 526 of the FDCA, like Soliris-are excluded from this fee as long as no non-orphan indications have been approved for the orphan drug.

In 2012, CMS issued proposed regulations to implement the changes to the Medicaid Drug Rebate Program under PPACA but has not yet issued final regulations. CMS is currently expected to release the final regulations in 2015. Moreover, in the future, Congress could enact legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate Program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate Program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Additional provisions of PPACA, some of which became effective in 2011, may negatively affect our revenues in the future. For example, as part of PPACA's provisions closing a coverage gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole.

PPACA also expanded the Public Health Service's 340B drug pricing discount program. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. PPACA expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by PPACA. PPACA exempts "orphan drugs"-those designated under section 526 of the FDCA, such as Soliris-from the ceiling price requirements for these newly-eligible entities. On July 21, 2014, the Health Resources and Services Administration (HRSA) which administers the 340B program, issued an interpretive rule to implement the orphan drug exception which interprets the orphan drug exception narrowly. It exempts orphan drugs from the ceiling price requirements for the newly-eligible entities only when the orphan drug is used for its orphan indication. The newly-eligible entities are entitled to purchase orphan drugs at the ceiling price when the orphan drug is not used for its orphan indication. A manufacturer trade group has filed a lawsuit challenging the interpretive rule as inconsistent with the statutory language. That challenge remains ongoing. The uncertainty regarding how the statutory orphan drug exception will be applied will increase the complexity of compliance, will make compliance more time-consuming, and could negatively impact our results of operations. If HRSA's narrow interpretation of the scope of the orphan drug exemption prevails, it could potentially negatively impact the price we are paid for Soliris by certain entities for some uses and increase the complexity of compliance with the 340B program.

In addition, our industry may be affected by broader legislation addressing federal spending, including, for example, a sequester required by the Budget Control Act of 2011, Pub. L. No. 112-25, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240, that took effect in April 2013 and was expended by the Bipartisan Budget Act of 2013, Pub. L. No. 113-67. Under the sequestration, Medicare payments for all items and services, including drugs and biologicals, have been reduced by 2%. This 2% reduction in Medicare payments affects all Parts of the Medicare program and could impact sales of Soliris. 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.

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

Medicare is a U.S. federal government insurance program that covers individuals aged 65 years or older, certain younger individuals with certain disabilities, and individuals with End-Stage Renal Disease. The primary Medicare programs that may affect reimbursement for Soliris are Medicare Part B, which covers physician services and outpatient care, and Medicare Part D, which provides a voluntary outpatient prescription drug benefit. Medicare Part B provides limited coverage of certain outpatient drugs and biologicals that are reasonable and necessary for diagnosis or treatment of an illness or injury. Under Part B, reimbursement is based on a fixed percentage of the applicable product's ASP. Manufacturers calculate ASP based on a statutory formula and must report ASP information to the CMS, the federal agency that administers Medicare and the Medicaid Drug Rebate Program, on a quarterly basis.

Medicaid is a government health insurance program for low-income children, families, pregnant women, and people with disabilities. It is jointly funded by the federal and state governments, and it is administered by individual states within parameters established by the federal government. Coverage and reimbursement for drugs and biologicals thus varies by state. Drugs and biologicals may be covered under the medical or pharmacy benefit. State Medicaid programs may impose utilization management controls, such as prior authorization, step therapy, or quantity limits on drugs and biologicals. Medicaid also includes the Medicaid Drug Rebate Program, under which we are required to pay a rebate to each state Medicaid program for quantities of Soliris that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for Soliris under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS. These data include the average manufacturer price and the best price for Soliris.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer price and best price for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug discount program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price, ASP, or best price information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. If we are found to have made a misrepresentation in the reporting of our ASP, the Medicare statute provides for civil monetary penalties of up to $10,000 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly average manufacturer price, ASP, and best price data on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

In September 2010, CMS and the Office of Inspector General (OIG) indicated that they intend to pursue more aggressively those companies who fail to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

Federal law requires that for a company to be eligible to have its products paid for with federal funds under the Medicaid program as well as to be purchased by certain federal agencies and grantees, it also must participate in the Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program. To participate, we are required to enter into an FSS contract with the VA, under which we must make our innovator "covered drugs" available to the "Big Four" federal agencies - the VA, the Department of Defense (DoD) the Public Health Service, and the Coast Guard - at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992 (VHCA). The FCP is based on a weighted average non-federal average manufacturer price (Non-FAMP) which manufacturers are required to report on a quarterly and annual basis to the VA. If a company misstates Non-FAMPs or FCPs it must restate these figures. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of $100,000 for each item of false information.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an agreed "tracking customer." Further, in addition to the "Big Four" agencies, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies "negotiated pricing" for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor's commercial "most favored customer" pricing. We offer dual pricing on our FSS contract.

In addition, pursuant to regulations issued by the DoD TRICARE Management Activity, now the Defense Health Agency, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, each of our covered drugs is listed on a Section 703 Agreement under which we have agreed to pay rebates on covered drug prescriptions dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. Companies are required to list their innovator products on Section 703 Agreements in order for those products to be eligible for DoD formulary inclusion. The formula for determining the rebate is established in the regulations and our Section 703 Agreement and is based on the difference between the annual Non-FAMP and the FCP (as described above, these price points are required to be calculated by us under the VHCA).

If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

We are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., some of the laws that may apply include state security breach notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure and transmission of personal information. Each of these laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions. Accordingly, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by the federal Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA) or for aiding and abetting the violation of HIPAA.

In addition, the receipt of personal health information in connection with our clinical trial initiatives is subject to state and federal human subject protection laws. These laws could create liability for us if one of our research collaborators were to use or disclose research subject information without consent and in violation of applicable laws.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. European Union member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from different EU member states may interpret the EU Data Protection Directive and national laws differently, which adds to the complexity of processing personal data in the EU, and guidance on implementation and compliance practices are often updated or otherwise revised. The EU Data Protection Directive prohibits the transfer of personal data to countries outside of the EU member states that are not considered by the European Commission to provide an adequate level of data protection. These countries include the United States. Any failure to comply with the rules arising from the EU Data Protection Directive and related national laws of European Union member states could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results

A proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, is currently under consideration. The EU Data Protection Regulation is expected to introduce new data protection requirements in the EU and substantial fines for breaches of the data protection rules. If the draft EU Data Protection Regulation is adopted in its current form, it may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules.

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

We collect, store, and transmit sensitive information including intellectual property, proprietary business information and personal information in connection with business operations. We have implemented information security measures to protect patients’ personal information against the risk of inappropriate and unauthorized external use and disclosure. However, despite these measures, and due to the ever changing information cyber-threat landscape, we may be subject to data breaches through cyber-attacks perpetrated by individuals that attempt to compromise our security controls. If our systems were to fail or be disrupted for an extended period of time we could lose product sales and our revenue and reputation would suffer. In the event our systems were to be breached by an unauthorized third-party, they could potentially access confidential personal information, which could cause us to suffer reputational damage and loss of customer confidence. Such incidents would result in notification obligations to affected individuals and government agencies, legal claims or proceedings, and liability under federal and state laws that protect the privacy and security of personal information. Any one of these events could cause our business to be materially harmed and our results of operations would be adversely impacted.

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 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 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.

Our Board of Directors decided to accelerate the expiration of our shareholder rights plan after reviewing our governance profile and current practices, considering the vote results on a related non-binding shareholder proposal presented at our 2014 annual meeting of shareholders, and determining that it was in the best interests of Alexion and our shareholders. The shareholder rights plan expired in March 2015.

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 first quarter of 2015:

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

January 1-31, 2015	61	$177.71	61	$508,857
February 1-28, 2015	127	$178.04	127	$486,233
March 1-31, 2015	146	$181.82	146	$459,686
Total	334	$179.63	334	

On November 8, 2012, we announced that our Board of Directors authorized the repurchase of up to $400,000 of our common stock. On December 15, 2014 we announced that our Board of Directors authorized the repurchase of up to an additional $500,000 of our common stock. The 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 March 31, 2015 formatted in eXtensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets at March 31, 2015 and December 31, 2014, (ii) the Condensed Consolidated Statements of Operations for the three months ended March 31, 2015 and 2014, (iii) the Condensed Consolidated Statements of Comprehensive Income for the three months ended March 31, 2015 and 2014, (iv) the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014, 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.

Date: April 24, 2015	By: /s/ David Hallal David Hallal Chief Executive Officer (principal executive officer)
Date: April 24, 2015	By: /s/ Vikas Sinha Vikas Sinha, M.B.A., C.A., C.P.A. Executive Vice President and Chief Financial Officer (principal financial officer)