ALEXION PHARMACEUTICALS INC
Form 10-Q
October 29, 2012

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 September 30, 2012
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	194,285,561
Class	Outstanding at October 23, 2012

Alexion Pharmaceuticals, Inc.
Contents

PART I.		FINANCIAL INFORMATION	Page
	Item 1.	Condensed Consolidated Financial Statements (Unaudited)	
		Condensed Consolidated Balance Sheets as of September 30, 2012 and December 31, 2011	2
		Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2012 and 2011	3
		Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2012 and 2011	4
		Notes to Condensed Consolidated Financial Statements	5
	Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	19
	Item 3.	Quantitative and Qualitative Disclosures about Market Risk	33
	Item 4.	Controls and Procedures	34
PART II.		OTHER INFORMATION	35
	Item 1.	Legal Proceedings	35
	Item 1A.	Risk Factors	35
	Item 5.	Other Information	54
	Item 6.	Exhibits	54
SIGNATURES			

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

	September 30, 2012	December 31, 2011
Assets		
Current Assets:		
Cash and cash equivalents	$905,526	$540,865
Trade accounts receivable, net	311,369	244,288
Inventories	90,049	81,386
Deferred tax assets	19,177	19,132
Prepaid expenses and other current assets	84,270	55,599
Total current assets	1,410,391	941,270
Property, plant and equipment, net	165,047	165,852
Intangible assets, net	648,306	91,604
Goodwill	253,839	79,639
Deferred tax assets	14,509	103,868
Other assets	13,516	12,518
Total assets	$2,505,608	$1,394,751
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$21,962	$16,029
Accrued expenses	247,885	183,624
Deferred revenue	35,070	17,905
Current portion of long-term debt	48,000	—
Other current liabilities	9,025	10,227
Total current liabilities	361,942	227,785
Long-term debt, less current portion	113,000	—
Contingent consideration	139,453	18,120
Other liabilities	18,778	14,354
Total liabilities	633,173	260,259
Commitments and contingencies (Note 14)		
Stockholders' Equity:		
Preferred stock, $0.0001 par value; 5,000 shares authorized, no shares issued or outstanding	—	—
Common stock, $0.0001 par value; 290,000 shares authorized; 194,333 and 185,616 shares issued at September 30, 2012 and December 31, 2011, respectively	19	19
Additional paid-in capital	1,827,517	1,261,589
Treasury stock, at cost	(2,676)	(2,676)
Accumulated other comprehensive income	2,345	4,179
Retained earnings (deficit)	45,230	(128,619)
Total stockholders' equity	1,872,435	1,134,492
Total liabilities and stockholders' equity	$2,505,608	$1,394,751

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

2

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

	Three months ended		Nine months ended	
	2012	2011	2012	2011
Net product sales	$294,136	$204,047	$813,588	$555,872
Cost of sales:				
Cost of sales	33,186	23,369	93,067	64,342
Gain on intellectual property settlement	(53,377)	—	(53,377)	—
Total cost of sales	(20,191)	23,369	39,690	64,342
Operating expenses:				
Research and development	54,280	36,567	159,323	103,023
Selling, general and administrative	89,957	77,572	272,054	221,609
Acquisition-related costs	967	236	19,447	11,164
Impairment of acquired in-process research and development	26,300	—	26,300	—
Amortization of purchased technology	104	104	312	278
Total operating expenses	171,608	114,479	477,436	336,074
Operating income	142,719	66,199	296,462	155,456
Other income and expense:				
Investment income	317	523	872	1,691
Interest expense	(1,855)	(204)	(6,220)	(605)
Foreign currency loss	(416)	(841)	(817)	(952)
Income before income taxes	140,765	65,677	290,297	155,590
Income tax provision	48,586	107	116,446	28,445
Net income	$92,179	$65,570	$173,851	$127,145
Earnings per common share				
Basic	$0.48	$0.36	$0.92	$0.70
Diluted	$0.46	$0.34	$0.88	$0.66
Shares used in computing earnings per common share				
Basic	193,353	183,706	189,219	182,805
Diluted	201,142	192,161	197,635	191,267
Comprehensive income	$77,982	$82,093	$172,017	$131,181

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

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

	Nine months ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net income	$173,851	$127,145
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	17,613	13,202
Impairment of acquired in-process research and development	26,300	—
Change in fair value of contingent consideration	4,333	1,117
Share-based compensation expense	40,322	34,426
Deferred taxes	57,674	15,169
Unrealized foreign currency (gain) loss	(5,405)	3,415
(Gains) losses on forward contracts	(202)	3,044
Other	18	318
Changes in operating assets and liabilities, excluding the effect of acquisitions:		
Accounts receivable	(65,299)	(52,332)
Inventories	(3,467)	(10,863)
Prepaid expenses and other assets	(17,065)	(21,029)
Accounts payable, accrued expenses and other liabilities	59,945	54,488
Deferred revenue	17,038	11,197
Net cash provided by operating activities	305,656	179,297
Cash flows from investing activities:		
Proceeds from maturity or sale of marketable securities	—	87,100
Purchases of property, plant and equipment	(14,257)	(15,241)
Payments for acquisitions of businesses, net of cash acquired	(605,735)	(105,886)
Increase in restricted cash	(3)	(351)
Net cash used in investing activities	(619,995)	(34,378)
Cash flows from financing activities:		
Debt issuance costs	(6,184)	—
Payments on capital leases	(638)	(640)
Proceeds from revolving credit facility	115,000	60,000
Payments on revolving credit facility	(115,000)	(60,000)
Proceeds from term loan	240,000	—
Payments on term loan	(79,000)	—
Excess tax benefit from stock options	7,582	2,306
Net proceeds from issuance of common stock	462,212	—
Net proceeds from the exercise of stock options	54,910	24,531
Net cash provided by financing activities	678,882	26,197
Effect of exchange rate changes on cash	118	(107)
Net change in cash and cash equivalents	364,661	171,009
Cash and cash equivalents at beginning of period	540,865	267,145
Cash and cash equivalents at end of period	$905,526	$438,154
Supplemental cash flow disclosures from investing and financing activities:		
Conversion of convertible debt	$718	$3,012
Contingent consideration issued in acquisitions	117,000	16,720

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

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

1. Business

Alexion Pharmaceuticals, Inc. (Alexion, the Company, we, our or us) is a biopharmaceutical company focused on serving patients with severe and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Our marketed product Soliris® (eculizumab) is the first and only therapeutic approved for patients with 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 blood disorder, and atypical hemolytic uremic syndrome (aHUS), a life-threatening and ultra-rare genetic disease. We are also evaluating additional potential indications for Soliris in severe and ultra-rare diseases in which chronic 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 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, 2011. 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, 2011 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, 2011 included in our Annual Report on Form 10-K. The results of operations for the three and nine months ended September 30, 2012 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, 2011.

New Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board issued a new standard on the presentation of comprehensive income. The new standard eliminated the alternative to report other comprehensive income and its components in the

statement of changes in equity. Under the new standard, companies can elect to present items of net income and other comprehensive income in one continuous statement or in two separate, but consecutive statements. We adopted the provisions of this guidance during the first quarter 2012.

3. Acquisitions

Acquisition of Enobia Pharma Corp.

On February 7, 2012, we acquired Enobia Pharma Corp. (Enobia), a privately held clinical-stage biotechnology company based in Montreal, Canada and Cambridge, Massachusetts, in a transaction accounted for under the acquisition method of accounting for business combinations. Under the acquisition method of accounting, the assets acquired and liabilities assumed of Enobia were recorded as of the acquisition date at their respective fair values. The reported consolidated financial condition after completion of the acquisition reflects these fair values. Enobia's results of operations are included in the consolidated

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

financial statements from the date of acquisition. The acquisition is intended to further our objective to develop and commercialize therapies for patients with severe, ultra-rare and life-threatening disorders. Enobia's lead product candidate asfotase alfa, is a human recombinant targeted alkaline phosphatase enzyme-replacement therapy for patients suffering with hypophosphatasia (HPP), an ultra-rare, life-threatening, genetic metabolic disease for which there are no approved treatments.

We made an upfront cash payment of $623,876 for 100% of Enobia's capital stock. Additional contingent payments of up to an aggregate of $470,000 would be due upon reaching various regulatory and sales milestones. We financed the acquisition with existing cash and proceeds from our new credit facility (Note 7).

A reconciliation of upfront payments in accordance with the purchase agreement to the total purchase price is presented below:

	Enobia
Base payment per agreement	$610,000
Cash acquired	18,141
Working capital adjustment	(4,265)
Upfront payment in accordance with agreement	623,876
Estimated fair value of contingent consideration	117,000
Total purchase price	$740,876

The initial estimate of fair value of contingent consideration was $117,000, which was recorded as a noncurrent liability. We determined the fair value of these obligations to pay additional milestone payments using various estimates, including probabilities of success, discount rates and amount of time until the conditions of the milestone payments are met. This fair value measurement is based on significant inputs not observable in the market, representing a Level 3 measurement within the fair value hierarchy (described further in Note 11). The resulting probability-weighted cash flows were discounted using a cost of debt rate of 5.2% for developmental milestones and a weighted average cost of capital rate of 13.0% for commercial milestones. These rates are representative of market participant assumptions. The range of estimated milestone payments is from zero if no clinical milestones are achieved for any product to $470,000 if various regulatory and sales milestones are achieved.

Subsequent to the acquisition date, we have adjusted 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. At September 30, 2012, the fair value of the contingent consideration for Enobia was $122,444. Changes in fair value of the consideration for Enobia were $1,932 and $5,444 for the three and nine months ended September 30, 2012, respectively.

The fair values of acquired assets and liabilities are based on preliminary estimates and are subject to change. The following table summarizes the estimated fair values of assets acquired and liabilities assumed:

	Enobia
Cash and cash equivalents	$18,141
Current assets	5,536
In-process research and development	587,000
Other noncurrent assets	910
Assets acquired	611,587

Deferred tax liability	(31,665)
Other liabilities assumed	(13,246)
Liabilities assumed	(44,911)
Goodwill	174,200
Net assets acquired	$740,876

Asset categories acquired in the Enobia acquisition included working capital, fixed assets, deferred tax assets and in-process research and development (IPR&D). The fair value of working capital was determined to approximate book values. The fair value assigned to the assets acquired and liabilities assumed has been prepared on a preliminary basis, and changes to

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

that allocation may occur as additional information becomes available related to working capital adjustments, indemnification assets and deferred taxes.

Intangible assets associated with IPR&D projects relate to Enobia's lead product candidate, asfotase alfa. The estimated fair value of $587,000 was determined using the multi-period excess earnings method, a variation of the income approach. The multi-period excess earnings method estimates the value of an intangible asset equal to the present value of the incremental after-tax cash flows attributable to that intangible asset. The fair value using the multi-period excess earnings method was dependent on an estimated weighted average cost of capital for Enobia of 13.0%, which represents a rate of return that a market participant would expect for these assets. Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment on an annual basis, as well as between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their estimated useful lives at that point in time.

The excess of purchase price over the fair value amounts of the assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. We do not expect any portion of this goodwill to be deductible for tax purposes. The goodwill attributable to our acquisition of Enobia has been recorded as a noncurrent asset and is not amortized, but is subject to an annual review for impairment. The factors that contributed to the recognition of goodwill included the synergies that are specific to our business and not available to market participants, including our unique ability to commercialize therapies for rare diseases, our skills and relationships related to biologics manufacturing, our existing relationships with specialty physicians who can identify patients with HPP and a global distribution network to facilitate immediate drug delivery.

We recorded a net deferred tax liability of $31,665. This amount was primarily comprised of $78,620 related to IPR&D, offset by acquired net operating losses and research credit carryovers totaling $46,955.

For the nine months ended September 30, 2012, we recorded $6,794 of expenses associated with the operations of Enobia from February 7, 2012 through March 31, 2012 in our condensed consolidated statement of comprehensive income. Effective April 1, 2012, the operations of Enobia were integrated into our operations.

Pro forma financial information (unaudited)

The following unaudited pro forma information presents the combined results of operations for the three months ended September 30, 2011 and for the nine months ended September 30, 2012 and 2011 as if the acquisition of Enobia had been completed on January 1, 2011. The pro forma results do not reflect operating efficiencies or potential cost savings which may result from the consolidation of operations. The pro forma results have been adjusted to remove costs associated with changes in the fair value of Enobia's preferred stock. Included in the pro forma net income for the nine months ended September 30, 2012, are approximately $20,600 and $7,900 of Alexion and Enobia acquisition-related costs, respectively, which are not expected to have an ongoing impact.

	Three months ended	Nine months ended	
	September 30,	September 30,	
	2011	2012	2011
Revenues	$204,047	$813,588	$555,872
Net income	50,567	155,437	91,592

Earnings per common share			
Basic	$0.28	$0.82	$0.50
Diluted	$0.26	$0.79	$0.48

Other Acquisitions

Taligen Therapeutics, Inc.

On January 28, 2011, we acquired all of the outstanding capital stock of Taligen Therapeutics, Inc. (Taligen) in a transaction accounted for under the acquisition method of accounting for business combinations. We made initial payments of $111,773 in cash and may make additional future payments of up to $367,000 in contingent milestone payments upon achievement of various development and commercial milestones. The range of estimated milestone payments is from zero if

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

no clinical milestones are achieved for any product to $367,000 if six products gain both U.S. and European marketing approval.

The initial estimate of fair value of contingent consideration was $11,634. Subsequent to the acquisition date, we have adjusted the contingent consideration to fair value with changes in fair value recognized in operating earnings. At September 30, 2012, the fair value of the contingent consideration for Taligen was $9,615. Changes in fair value of the consideration for Taligen were $(4,224) and $149 for the three months ended September 30, 2012 and 2011, respectively and $(3,069) and $899 for the nine months ended September 30, 2012 and 2011, respectively. Included in this change in fair value of the Taligen for the three and nine months ended September 30, 2012 is a gain of $4,331 related to the decrease in the fair value of the contingent consideration related to this acquisition. The decrease in fair value was a result of a decreased likelihood of payments for contingent consideration due to the negative scientific findings, decrease in value and related deprioritization of the age-related macular degeneration program (Note 6).

Orphatec Pharmaceuticals GmbH

On February 8, 2011, we acquired certain patents and assets from Orphatec Pharmaceuticals GmbH (Orphatec) related to an investigational therapy for patients with molybdenum cofactor deficiency (MoCD) Type A, an ultra-rare genetic disorder characterized by severe brain damage and rapid death in newborns. We made initial payments of $3,050 in cash and may make additional future payments of up to $42,000 in contingent milestone payments upon various development, regulatory and commercial milestones. The range of estimated milestone payments is from zero if no products gain market approval to $42,000 if all indications for up to two products gain both U.S. and European marketing approval and reach applicable sales levels.

The initial estimate of fair value of contingent consideration was $5,086. Subsequent to the acquisition date, we have measured the contingent consideration arrangement at fair value with changes in fair value recognized in operating earnings. At September 30, 2012, the fair value of the contingent consideration for Orphatec was $7,394. Changes in fair value of the consideration for Orphatec were $1,750 and $87 for the three months ended September 30, 2012 and 2011, respectively and $1,958 and $218 for the nine months ended September 30, 2012 and 2011, respectively.

Acquisition-Related Costs

Acquisition-related costs for the three and nine months ended September 30, 2012 and 2011 include the following:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Separately-identifiable employee costs	$457	$—	$3,552	$6,597
Professional fees	1,052	—	11,562	3,450
Changes in fair value of contingent consideration	(542)	236	4,333	1,117
	$967	$236	$19,447	$11,164

During the three and nine months ended September 30, 2012, we incurred approximately $3,400 and $20,600, respectively, in costs related to the Enobia acquisition, which are included in this table above.

4. Revenue and Accounts Receivable

Revenue

Our principal source of revenue is product sales. We recognize revenue from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or

determinable, collection from the customer is reasonably assured and we have no further performance obligations. Revenue is recorded upon receipt of the product by the end customer, which is typically a hospital, physician's office, private or government pharmacy or other health care facility. Amounts collected from customers and remitted to governmental authorities, such as value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in our statements of operations and do not impact net product sales.

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

Because of factors such as the pricing of Soliris, the limited number of patients, the short period from product sale to patient infusion and the lack of contractual return rights, Soliris customers often carry limited inventory. We also monitor inventory within our sales channels to determine whether deferrals are appropriate based on factors such as inventory levels, contractual terms, and reliance on a single distributor in a market and financial strength of distributors.

We have entered into volume-based arrangements with governments in certain countries in which reimbursement is limited to a contractual amount. We estimate incremental discounts resulting from these contractual limitations, based on estimated sales during the limitation period, and we apply the discount percentage to product shipments as a reduction of revenue. In addition to sales in countries where Soliris is commercially available, we have also recorded revenue on sales for patients receiving Soliris treatment through named-patient programs. The relevant authorities or institutions in those countries have agreed to reimburse for product sold on a named-patient basis where Soliris has not received final approval for commercial sale.

We record estimated rebates payable under governmental programs, including Medicaid in the United States and other programs outside the United States, as a reduction of revenue at the time of product sale. Our calculations related to these rebate accruals require analysis of historical claim patterns and estimates of customer mix to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period and record any necessary adjustments, which may have an impact on revenue in the period in which the adjustment is made. Generally, the length of time between product sale and the processing and reporting of the rebates is three to six months.

We record distribution and other fees paid to our customers as a reduction of revenue, unless we receive an identifiable and separate benefit for the consideration and we can reasonably estimate the fair value of the benefit received. If both conditions are met, we record the consideration paid to the customer as an operating expense. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

We enter into foreign exchange forward contracts to hedge exposures resulting from portions of our forecasted intercompany revenues that are denominated in currencies other than the U.S. dollar. These hedges are designated as cash flow hedges upon inception. We record the effective portion of these cash flow hedges to revenue in the period in which the sale is made to an unrelated third party and the derivative contract is settled.

Accounts Receivable

Our standard credit terms vary based on the country of sale and range from 30 to 120 days. Our consolidated average days' sales outstanding ranges from 80 to 100 days. We sell Soliris to a limited number of customers, and we evaluate the creditworthiness of each such customer on a regular basis. In certain European countries, sales by us are subject to payment terms that are statutorily determined. This is primarily the case in countries where the payor is government-owned or government-funded and we consider to be creditworthy. The length of time from sale to receipt of payment in certain countries typically exceeds our credit terms. In countries in which collections from customers extend beyond normal payment terms, we seek to collect interest. We record interest on customer receivables as interest income when collected. For non-interest bearing receivables with an estimated payment beyond one year, we discount the accounts receivable to present value at the date of sale, with a corresponding adjustment to revenue. If creditworthiness declines further, subsequent adjustments for further declines in credit rating are recorded as bad debt expense as a component of selling, general and administrative expense. We also use judgments as to our ability to collect outstanding receivables and provide allowances for the portion of receivables if and when collection becomes doubtful.

We continue to monitor economic conditions, including volatility associated with international economies and the sovereign debt crisis in Europe, and the associated impacts on the financial markets and our business. The credit and economic conditions in Greece, Italy and Spain, among other members of the European Union, have deteriorated throughout 2011 and into 2012. These conditions have resulted in, and may continue to result in, an increase in the average length of time it takes to collect our outstanding accounts receivable in these countries. 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. Our exposure to the sovereign debt crisis in Greece is limited, as we do not have a material amount of accounts receivable in Greece.

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

As of September 30, 2012, our gross accounts receivable in Italy and Spain were approximately $86,100. Approximately $25,300 of this amount has been outstanding for greater than one year, and we have recorded an allowance of approximately $2,500 related to these gross receivables as of September 30, 2012. During the three and nine months ended September 30, 2012, we have recorded expense of approximately $115 and $1,580, respectively, related to the expectation of delayed payment from these countries. Our net accounts receivable from these countries as of September 30, 2012 are summarized as follows:

	Total Accounts Receivable, net	Accounts Receivable, net > one year
Italy	$35,836	$6,805
Spain	$47,785	$17,130

5. 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:

	September 30, 2012	December 31, 2011
Raw materials	$8,879	$9,677
Work-in-process	30,367	37,000
Finished goods	50,803	34,709
	$90,049	$81,386

6. Intangible Assets and Goodwill

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

	September 30, 2012	December 31, 2011
Licenses, patents and purchased technology, net	$ 20,056	$ 24,054
Acquired IPR&D	628,250	67,550
Intangible assets	$ 648,306	$ 91,604
Goodwill	$ 253,839	$ 79,639

During the three months ended September 30, 2012, we reviewed for impairment the value of an early stage, preclinical indefinite-lived intangible asset related to the Taligen acquisition. We initiated such review based on our evaluation of negative scientific findings associated with our development of a different asset for the treatment of age-related macular degeneration, the likelihood of success for ophthalmic use and the value that can be obtained from a market participant in an arm's length transaction. These developments led us to deprioritize the development of this acquired asset. As a result, we recognized an impairment charge of $26,300 to write-down this asset to fair value, which, as of September 30, 2012 was determined to be de minimis based on the value of the asset to a market

participant in an arm's length transaction. The fair value of this IPR&D asset was determined using the income approach, which used significant unobservable (Level 3) inputs. These unobservable inputs included, among other things, risk-adjusted forecast future cash flows to be generated by this asset, contributory asset charges for other assets employed in this IPR&D project and the determination of an appropriate discount rate based on a weighted average cost of capital of 22.0% to be applied in calculating the present value of future cash flows. The impairment charge was recorded in operating expenses in our condensed consolidated statements of comprehensive income for the three and nine months ended September 30, 2012.

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

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

Balance at December 31, 2011	$79,639
Goodwill resulting from the Enobia acquisition	174,200
Balance at September 30, 2012	$253,839

7. Debt

On February 7, 2012, we and our wholly-owned Swiss subsidiary, Alexion Pharma International Sàrl, entered into a Credit Agreement (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.

We may elect that the loans under the Credit Agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.25% to 2.00% depending on our consolidated leverage ratio (as calculated in accordance with the Credit Agreement), or (ii) in the case of loans denominated in U.S. dollars, a Base Rate equal to the higher of the (A) Prime Rate then in effect, (B) Federal Funds Rate then in effect plus 0.50%, and (C) Eurodollar Rate then in effect plus 1.00%, plus in each case of (A), (B) or (C), 0.25% to 1.00% depending on our consolidated leverage ratio (as calculated in accordance with the Credit Agreement). Interest is payable quarterly for Base Rate loans and, in the case of LIBOR-based loans, at the end of the applicable interest period, with the principal due on February 7, 2017, the maturity date.

Our obligations under the credit facilities are unconditionally guaranteed, jointly and severally, by certain of our existing domestic subsidiaries and are required to be guaranteed by certain of our future domestic subsidiaries. The obligations of Alexion Pharma International Sàrl under the credit facilities are unconditionally guaranteed, jointly and severally, by us, certain of our existing domestic subsidiaries, and certain of our foreign subsidiaries, and are required to be guaranteed by certain of our future subsidiaries. All obligations of each borrower under the credit facilities, and the guarantees of those obligations, are secured, subject to certain exceptions, by substantially all of each borrower's assets and the assets of certain guarantors, including the pledge of the equity interests of certain of our subsidiaries and real estate located in Smithfield, Rhode Island, but excluding intellectual property and assets of certain foreign subsidiaries.

The Credit Agreement requires us to comply with certain financial covenants on a quarterly basis. Further, the Credit Agreement includes negative covenants, subject to exceptions, restricting or limiting our ability and the ability of our subsidiaries to, among other things, incur additional indebtedness, grant liens, engage in certain investment, acquisition and disposition transactions, pay dividends, repurchase capital stock and enter into transactions with affiliates. The Credit Agreement also contains customary representations and warranties, affirmative covenants and events of default, including payment defaults, breach of representations and warranties, covenant defaults and cross defaults. If an event of default occurs, the interest rate would increase and the administrative agent would be entitled to take various actions, including the acceleration of amounts due under the loan.

In connection with entering into the Credit Agreement, we paid $6,184 in financing costs which are being amortized as interest expense over the life of the debt.

In connection with the acquisition of Enobia in February 2012, we borrowed $240,000 under the term loan facility and $80,000 under the revolving facility, and we used our available cash for the remaining purchase price. During the quarter ended June 30, 2012, we repaid the revolving facility in full. In the third quarter 2012, we repaid $67,000 of the term loan, and we had $161,000 outstanding on the term loan at September 30, 2012. As of September 30, 2012, we had open letters of credit of $9,918, and our borrowing availability under the revolving facility was $190,082.
The fair value of our long term debt, which is measured using Level 2 inputs, approximates book value.
On February 7, 2012, the Second Amended and Restated Credit Agreement (Prior Credit Agreement), dated March 7, 2011 was terminated. All outstanding borrowings under the Former Credit Agreement were canceled. The Former Credit Agreement was terminated in connection with, and simultaneously with, execution of the Credit Agreement described above.

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

8. Earnings Per Common Share

Basic earnings per common share (EPS) are computed by dividing net income by the weighted-average number of shares of common stock outstanding. For purposes of calculating diluted EPS, net income is adjusted for the after-tax amount of interest and deferred financing costs associated with our convertible debt, and 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, as well as the potential dilution if the remaining convertible notes were converted to common stock.

The following table summarizes the calculation of basic and diluted EPS for the three and nine months ended September 30, 2012 and 2011:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Net income used for basic calculation	$92,179	$65,570	$173,851	$127,145
Weighted-average effect of dilutive securities:				
Interest expense and debt financing cost amortization, net of tax, related to our 1.375% convertible senior notes	—	5	—	23
Net income used for diluted calculation	$92,179	$65,575	$173,851	$127,168
Shares used in computing earnings per common share—basic	193,353	183,706	189,219	182,805
Weighted-average effect of dilutive securities:				
Shares issuable upon the assumed conversion of our 1.375% convertible senior notes	—	92	11	234
Stock awards	7,789	8,363	8,405	8,228
Dilutive potential common shares	7,789	8,455	8,416	8,462
Shares used in computing earnings per common share—diluted	201,142	192,161	197,635	191,267
Earnings per common share:				
Basic	$0.48	$0.36	$0.92	$0.70
Diluted	$0.46	$0.34	$0.88	$0.66

The following table represents the potentially dilutive shares excluded from the calculation of EPS for the three and nine months ended September 30, 2012, and 2011 because their effect is anti-dilutive:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Potentially dilutive securities:				
Options to purchase common stock	226	1,430	1,561	1,905
Unvested restricted stock and restricted stock units	—	8	44	13
	226	1,438	1,605	1,918

9. Derivative Instruments and Hedging Activities

We operate internationally and, in the normal course of business, are exposed to fluctuations in foreign currency exchange rates. The exposures result from portions of our revenues, as well as the related receivables, and expenses

that are denominated in currencies other than the U.S. dollar, primarily the Euro, Japanese Yen and Swiss Franc. We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes.

We enter into foreign exchange forward contracts, with durations of up to 36 months, to hedge exposures resulting from portions of our forecasted intercompany revenues that are denominated in currencies other than the U.S. dollar. The purpose of

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

the hedges of intercompany 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 September 30, 2012, we have open contracts with notional amounts totaling $768,382 that qualified for hedge accounting.

The impact on accumulated other comprehensive income (AOCI) and earnings from foreign exchange contracts that qualified as cash flow hedges, for the three and nine months ended September 30, 2012 and 2011 are as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Gain (loss) recognized in AOCI, net of tax	$(10,873)	$17,569	$7,025	$4,252
Gain (loss) reclassified from AOCI to net product sales (effective portion)	$4,810	$(3,315)	$8,885	$(5,391)
Gain (loss) reclassified from AOCI to other income and expense (ineffective portion)	$(501)	$222	$(585)	$(864)

Assuming no change in foreign exchange rates from market rates at September 30, 2012, $8,853 of a gain recognized in AOCI to be reclassified to revenue over the next 12 months.

We enter into foreign exchange forward contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results. These derivative instruments do not qualify for hedge accounting; however, gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. As of September 30, 2012, the notional amount of foreign exchange contracts that do not qualify for hedge accounting was $176,938.

We recognized a gain (loss) of $(3,470) and $(10,149), in other income and expense, for the three months ended September 30, 2012 and 2011, respectively, and $787 and $(22,539), for the nine months ended September 30, 2012 and 2011, respectively, associated with the foreign exchange contracts not designated as hedging instruments under the guidance. 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 September 30, 2012 and December 31, 2011:

	September 30, 2012			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	$13,289	Other current liabilities	$3,888
Foreign exchange forward contracts	Other non-current assets	5,959	Other non-current liabilities	4,173

Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	692	Other current liabilities	4,008
Total fair value of derivative instruments		$19,940		$12,069

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

	December 31, 2011			
	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	$14,118	Other current liabilities	$5,889
Foreign exchange forward contracts	Other non-current assets	6,465	Other non-current liabilities	2,552
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	4,745	Other current liabilities	2,033
Total fair value of derivative instruments		$25,328		$10,474

10. Stockholders' Equity

In May 2012, in conjunction with our addition into the S&P 500 Index, we completed the sale of 5,000 shares of our common stock in a public offering. The net proceeds from the sale of shares in the offering were $462,212.

11. Fair Value Measurement

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

The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2012 and December 31, 2011, and indicate the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

		Fair Value Measurement at September 30, 2012			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$778,311	$—	$778,311	$—
Other current assets	Foreign exchange forward contracts	$13,981	$—	$13,981	$—
Other assets		$5,959	$—	$5,959	$—

	Foreign exchange forward contracts				
Other current liabilities	Foreign exchange forward contracts	$7,896	$—	$7,896	$—
Other liabilities	Foreign exchange forward contracts	$4,173	$—	$4,173	$—
Contingent consideration	Acquisition-related contingent consideration	$139,453	$—	$—	$139,453

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

		Fair Value Measurement at December 31, 2011			
Balance Sheet Classification	Type of Instrument	Total	Level 1	Level 2	Level 3
Cash equivalents	Institutional money market funds	$428,431	$—	$428,431	$—
Other current assets	Foreign exchange forward contracts	$18,863	$—	$18,863	$—
Other assets	Foreign exchange forward contracts	$6,465	$—	$6,465	$—
Other current liabilities	Foreign exchange forward contracts	$7,922	$—	$7,922	$—
Other liabilities	Foreign exchange forward contracts	$2,552	$—	$2,552	$—
Contingent consideration	Acquisition-related contingent consideration	$18,120	$—	$—	$18,120

The following table represents a roll-forward of the fair value of Level 3 instruments, comprised solely of acquisition-related contingent consideration:

	September 30, 2012
Balance at beginning of period	$(18,120)
Amounts acquired or issued	(117,000)
Changes in fair value	(4,333)
Balance at end of period	$(139,453)

Valuation Techniques
Items classified as Level 2 within the valuation hierarchy, consisting of an institutional money market fund held at a multinational financial institution, are valued based upon pricing of securities with similar investment characteristics and holdings. 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 and our counterparties' credit risks. Based on these inputs, the derivative assets and liabilities are classified within Level 2 of the valuation hierarchy. Items classified as Level 3 within the valuation hierarchy, consisting of contingent consideration liabilities related to acquisitions, were valued based on various estimates, including probability of success, discount rates and amount of time until the conditions of the milestone payments are met.
As of September 30, 2012, 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.

12. Income Taxes
We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax basis of

assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. We provide a valuation allowance when it is more likely than not that deferred tax assets will not be realized. We recognize the benefit of an uncertain tax position that has been taken or we expect to take on income tax returns if such tax position is more likely than not to be sustained.

We continue to maintain a valuation allowance against certain other deferred tax assets where 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.

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

The following table provides a comparative summary of our income tax provision and effective tax rate for the three and nine months ended September 30, 2012 and 2011:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Provision for income taxes	$48,586	$107	$116,446	$28,445
Effective tax rate	34.5 %	0.2 %	40.1 %	18.3 %

The tax provision for the three and nine months ended September 30, 2012 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations and the tax expense associated with the settlement and non-exclusive license agreement with a third party of $22,673 (described further in Note 14). Additionally, included in the nine months ended September 30, 2012 is the impact of the tax expense of $21,812 associated with the structuring of the Enobia business.

The tax provision for the three and nine months ended September 30, 2011 is principally attributable to the U.S. federal, state and foreign income taxes on our profitable operations. In September 2011, we completed our assessment of the impact the election to claim federal foreign tax credits and the federal orphan drug credits would have on our historical tax returns. Based on this assessment, management elected to claim both the foreign tax credit for the tax year ended December 31, 2010 and federal orphan drug credit for the tax years ended December 31, 2010 and 2009. The net federal income tax benefit recorded during the three months ended September 30, 2011 as a result of the election to claim the federal foreign tax credit for 2010 and the federal orphan drug credit for 2010 and 2009 was approximately $14,800. In addition, the Company also revised its estimate of the federal orphan drug credit benefit for 2011, which resulted in a $1,500 benefit in the quarter ended September 30, 2011.

The Internal Revenue Service (IRS) continues their examination of our U.S. income tax returns for 2008 and 2009, and we anticipate this examination to be completed within the next twelve months. If the IRS examination produces a substantial adjustment for those and other periods, the impact on our income tax provision may be significant and could have an impact on our results of operations.

13. Employee Benefit Plans

Defined Contribution Plan

We have one qualified 401(k) plan covering all eligible employees. Under the plan, employees may contribute up to the statutory allowable amount for any calendar year. We make matching contributions equal to:

- $1.00 for each dollar contributed up to the first 4% of an individual's base salary and incentive cash bonus; and
- $0.50 for each dollar contributed of the next 2% of such compensation.

For the three months ended September 30, 2012, and 2011, we recorded matching contributions of approximately $798, and $601, respectively. For the nine months ended September 30, 2012, and 2011, we recorded matching contributions of approximately $2,853 and $2,206, respectively.

Defined Benefit Plans

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

16

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

The components of net periodic benefit cost are as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Service cost	$1,061	$1,133	$3,422	$3,197
Interest cost	110	106	338	294
Expected return on plan assets	(125)	(108)	(385)	(307)
Employee contributions	(283)	(274)	(868)	(781)
Amortization	73	64	224	182
Total net periodic benefit cost	$836	$921	$2,731	$2,585

14. Commitments and Contingencies

Commitments

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 quantities of asfotase alfa, and we have contracted and expect to continue contracting for product finishing, vial filling and packaging through third parties. We have various agreements with Lonza, with remaining total commitments of approximately $190,000 through 2018. Such commitments may be canceled only in limited circumstances. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at Alexion Rhode Island Manufacturing Facility (ARIMF).

Contingent Liabilities

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

In October 2012, we entered into a settlement and non-exclusive license agreement with a third party. Under the terms of the agreement, we will make an upfront payment of approximately $38,000 in the fourth quarter of 2012 and will pay royalties on sales of Soliris in accordance with the terms of the agreement.

As a result of the settlement and non-exclusive license agreement noted above, we reduced our estimate for probable contingent liabilities and have recorded a gain in cost of sales of $53,377 in the third quarter 2012. At September 30, 2012 and December 31, 2011, we have recorded $55,758 and $82,010 respectively, in accrued expenses for probable contingent liabilities and royalties, which includes the upfront payment noted above and royalties owed to third parties.

On January 26, 2011, Novartis Vaccines & Diagnostics, Inc. (Novartis) filed a civil action against us and other biopharmaceutical companies in the U.S. District Court for the District of Delaware. Novartis claims willful infringement by us of U.S. Patent No. 5,688,688. Novartis seeks, among other things, monetary damages. If it is

finally determined that we infringe the Novartis patent, we may be required to pay royalties to Novartis on sales of Soliris regarding certain manufacturing technology. Although we do not believe that the manufacture of Soliris infringes a valid patent claim owned by Novartis, we cannot guarantee that we will be successful in defending against such action. Given the stage of this litigation, management does not currently believe a loss related to this matter is probable or that the potential magnitude of such loss or range of loss, if any, can be reasonably estimated.

In addition to the Novartis claim, other 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. We are aware of broad patents owned by others relating to the manufacture, use and sale of recombinant humanized antibodies, recombinant human antibodies, and recombinant human single chain antibodies. Soliris and many of our product candidates are genetically engineered antibodies, including recombinant humanized antibodies, recombinant human antibodies, or recombinant human single chain antibodies. In addition to the action described above, we have received notices from the owners of some of these patents claiming that their patents may be infringed by the development, manufacture or sale of Soliris or some of our drug candidates. We are also aware

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

of other 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. We estimate our obligations for probable contingent liabilities based on our assessment of estimated royalties potentially owed to other third parties. A costly license, or inability to obtain a necessary license, could have a material adverse effect on our business. However, the amount of such loss or a range of loss, if any, beyond amounts currently accrued cannot be reasonably estimated.

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

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, 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 payor 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, prospects for regulatory approval, need for additional research and testing, the uncertainties involved in the drug development process and manufacturing, performance and reliance on third party service providers, our future research and development activities, plans for acquired companies and programs, 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 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, 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 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

Overview

We are a biopharmaceutical company focused on serving patients with severe and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Our marketed product Soliris® (eculizumab) is the first and only therapeutic approved for patients with 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 blood disorder, and atypical hemolytic uremic syndrome (aHUS), a life-threatening and ultra-rare genetic disease. We are also evaluating additional potential indications for Soliris in severe and ultra-rare diseases in which chronic 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 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 the therapeutic areas of 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 an ultra-rare, debilitating and life-threatening, deficiency blood disorder defined by chronic uncontrolled complement activation leading to the

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

destruction of red blood cells, or 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 U.S. Food and Drug Administration (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, in 2003 Soliris was granted orphan drug designation for the treatment of PNH in the United States, Europe, Japan and several other territories.
aHUS is a genetic ultra-rare disease characterized by chronic uncontrolled complement activation and thrombotic microangiopathy, 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 September 2011, Soliris was approved by the FDA for the treatment of pediatric and adult patients with aHUS. Also in November 2011, the EC granted marketing authorization for Soliris to treat pediatric and adult patients with aHUS in Europe. In 2009, the FDA and EC granted Soliris orphan drug designation for the treatment of patients with aHUS.

Recent Developments

Enobia Acquisition
On February 7, 2012, we acquired Enobia Pharma Corp. (Enobia), a privately held clinical-stage biotechnology company based in Montreal, Canada and Cambridge, Massachusetts, in a transaction accounted for under the acquisition method of accounting for business combinations. Enobia's lead product candidate, asfotase alfa, is a human recombinant targeted alkaline phosphatase enzyme-replacement therapy for patients suffering with hypophosphatasia (HPP), an ultra-rare, life-threatening, genetic metabolic disease for which there are no approved treatments. We agreed to make an upfront payment of $610,000 subject to purchase price adjustments, which resulted in us making an upfront cash payment of $623,876 for 100% of Enobia's capital stock. Additional contingent payments of up to an aggregate of $470,000 would be due upon reaching various regulatory and sales milestones. We financed the acquisition with existing cash and proceeds from our new credit facility.

Credit Facilities
On February 7, 2012, we and our wholly-owned Swiss subsidiary, Alexion Pharma International Sàrl, entered into a Credit Agreement (Credit Agreement) with the lenders party thereto, Bank of America, N.A., as administrative agent, Merrill Lynch, Pierce, Fenner & Smith Incorporated and J.P. Morgan Securities LLC, as joint lead arrangers and joint book managers, JPMorgan Chase Bank, N.A., as syndication agent and RBS Citizens, National Association and Suntrust Bank as co-documentation agents. The Credit Agreement provides for a $240,000 senior secured term loan facility and a $200,000 senior secured revolving credit facility, which includes up to a $60,000 sublimit for letters of credit and a $10,000 sublimit for swingline loans. Alexion used the facilities to pay a portion of the consideration for the acquisition of Enobia. The facilities can also be used for working capital requirements, acquisitions and other general corporate purposes. At the same time, we terminated our Second Amended and Restated Credit Agreement, dated March 7, 2011.

Common Stock Offering
In May 2012, in conjunction with our addition into the S&P 500 Index, we completed the sale of 5,000 shares of our common stock in a public offering. The net proceeds from the sale of shares in the offering were $462,212.

Clinical
We have focused certain of our product development programs on life transforming therapeutics for diseases for which we believe current treatments are either non-existent or inadequate. Eculizumab is a humanized antibody known as a C5 terminal complement inhibitor (C5 Inhibitor), which is designed to selectively block the production of inflammation-causing proteins of the complement cascade. We believe that selective suppression of this immune

response may provide a significant therapeutic advantage relative to existing therapies. In addition to PNH and aHUS, for which the use of eculizumab has been approved in the United States and Europe and for PNH in several other territories, we believe that C5 Inhibitors may be useful in the treatment of a variety of other serious diseases and conditions resulting from uncontrolled complement activation.

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

Our clinical programs, including investigator initiated clinical programs, are as follows:

Product	Development Area	Indication	Development Stage
Soliris (eculizumab)	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Commercial
		PNH Registry	Phase IV
		Cold Agglutinin Disease (CAD)*	Phase II
	Hematology/Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)	Commercial
		aHUS - Pediatric	Phase IV
		aHUS - Adult	Phase IV
	Nephrology	Shiga-toxin producing E. Coli Hemolytic Uremic Syndrome (STEC-HUS)	Phase II
		MPGN II (Dense Deposit Disease or DDD)*	Phase II
		Presensitized Renal Transplant - Living Donor	Phase II
		Presensitized Renal Transplant - Deceased Donor	Phase II
		ABO Incompatible Renal Transplant*	Phase II
	Neurology	Myasthenia Gravis (MG)	Phase II
		Neuromyelitis Optica (NMO)*	Phase II
Asfotase alfa	Metabolic Disorders	Hypophosphatasia (HPP)	Phase II
cPMP	Metabolic Disorders	MoCD Type A	Preclinical
ALXN 1102/1103	Hematology	PNH	Phase I
ALXN 1007	Inflammatory Disorders		Phase I
Samalizumab	Oncology	Chronic Lymphocytic Leukemia (CLL)	Phase I

*Investigator Initiated Trial

Our most advanced programs focus on two therapeutic areas: hematology and nephrology. We are also advancing our pipeline programs with a focus primarily on neurology and metabolic disorders.

Soliris (eculizumab)
Hematology
Paroxysmal Nocturnal Hemoglobinuria (PNH)
Our marketed product Soliris® (eculizumab) is the first and only therapy approved for the treatment of patients with PNH, a debilitating, life-threatening and ultra-rare blood disorder in which an acquired genetic deficiency causes uncontrolled complement activation which leads to life-threatening complications. We continue to work with researchers to expand the base of knowledge in PNH and the utility of Soliris to treat patients with PNH. Additionally, we are sponsoring multinational registries to gather information regarding the natural history of patients with PNH and the longer term outcomes during Soliris treatment.
Cold Agglutinin Disease (CAD)

We are aware that dosing is ongoing in an investigator initiated Phase II study of eculizumab in patients for the treatment of CAD. CAD is a severe, ultra-rare complement-mediated autoimmune disease characterized by the presence of high concentrations of circulating complement-activating antibodies directed against red blood cells. As observed with PNH patients, CAD patients also suffer from the clinical consequences of severe hemolysis.

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

Hematology/Nephrology
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 (thrombotic microangiopathy, or TMA) leading to kidney failure, stroke, heart attack and death. As a post market requirement, we have now completed enrollment in a prospective open-label trial in adult aHUS and, separately, enrollment has been completed in a prospective pediatric aHUS study.

Nephrology

Shiga-toxin producing E. Coli Hemolytic Uremic Syndrome (STEC-HUS)

STEC-HUS is a life-threatening, complement-mediated ultra-rare disorder that results from exposure to Enterohemorrhagic E.Coli, (EHEC). Our STEC-HUS development program was initiated in connection with the widespread outbreak of EHEC in Germany in May and June 2011. Many EHEC patients rapidly progressed to STEC-HUS during this outbreak. As in several other conditions with severe and uncontrolled complement activation, including aHUS, complement activation in STEC-HUS results in TMA. Although aHUS and STEC-HUS exhibit similar life-threatening TMA manifestations, aHUS and STEC-HUS are different disorders. aHUS is a chronic genetic disease of uncontrolled complement activation, while STEC-HUS is not genetic and follows an isolated episode of infection. STEC-HUS is an ultra-rare disorder, comprising only a small sub-set of the already rare population of patients with EHEC. Following an authorization by the Paul-Ehrlich-Institut, Germany's health care regulatory body for biologics, and an access program for patients initiated in May 2011, we initiated an open-label clinical trial to investigate eculizumab as a treatment for patients with STEC-HUS. Enrollment in this trial has been completed. The EC has granted orphan designation for eculizumab as a treatment for patients with STEC-HUS.
Dense Deposit Disease (DDD)
We are aware that independent investigators have completed enrollment in studies aimed at evaluating eculizumab in patients with DDD as well as patients with a similar disease referred to as C3nef nephropathy. DDD, also called Type II membrano-proliferative glomerulonephritis (MGPN II), is an ultra-rare form of glomerulonephritis, associated with genetic mutations in complement inhibitor genes leading to sustained uncontrolled complement activation and inflammation. Clinically, this disease is characterized by the onset of severe proteinuria (excess protein in the urine), often accompanied by nephrotic syndrome which is refractory to immunosuppressant therapy. In most cases, the disease progresses to chronic renal failure, requiring dialysis and renal transplantation.
Acute Humoral Rejection (AHR) in Presensitized Kidney Transplant Patients
We initiated enrollment in a multi-national, multi-site controlled clinical trials of eculizumab in presensitized renal transplant patients at elevated risk for AHR who will receive living donor grafts, and we have initiated enrollment in a multi-national, multi-site controlled clinical trial of eculizumab in presensitized renal transplant patients at elevated risk for AHR who will receive deceased donor grafts. We are also aware that an independent investigator has also started enrolling patients in a clinical trial to evaluate eculizumab in kidney transplant patients sensitized to their donor kidney due to an ABO blood group mismatch between donor and recipient.
Neurology
Myasthenia Gravis (MG)
Myasthenia Gravis is an ultra-rare autoimmune disease characterized by uncontrolled complement activation leading to the failure of neuromuscular transmission. Preliminary data from a Phase II trial evaluating the safety and efficacy of eculizumab in patients with severe, refractory MG demonstrated an encouraging disease improvement signal and was presented at the Myasthenia Gravis Foundation Annual Meeting in September 2011.
Neuromyelitis Optica (NMO)
Neuromyelitis optica is a severe and ultra-rare autoimmune disease of the central nervous system (CNS) that primarily affects the optic nerves and spinal cord. Preliminary data from the investigator-initiated Phase II clinical trial of

eculizumab in severe and relapsing NMO patients was presented to the American Neurological Association (ANA) meeting in October 2012. The study was reported to have achieved its primary efficacy endpoint with a high degree of clinical and statistical significance and several key secondary endpoints were also achieved.

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

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. The severe manifestations of the genetic deficiency in HPP affect people of all ages, and approximately 50% of infants with the disease do not survive past one year of age. HPP is caused by mutations in the gene encoding the enzyme Tissue Nonspecific Alkaline Phosphatase. This enzyme normally breaks down metabolic substrates such as inorganic pyrophosphate and pyridoxal phosphate.
Asfotase alfa, a targeted enzyme replacement therapy in Phase II clinical trials for patients with HPP, is designed to directly address the morbidities and mortality of HPP by targeting alkaline phosphatase directly to the deficient tissue. In this way, asfotase alfa is designed to normalize the genetically defective metabolic process and prevent or reverse the severe, crippling and life-threatening complications of dysregulated mineral metabolism in patients with HPP. Initial studies with asfotase alfa in HPP patients indicate that the treatment significantly decreases the levels of targeted metabolic substrates. We have initiated a natural history study in infants with HPP. We acquired asfotase alfa in February 2012 in connection with our acquisition of Enobia.

cPMP
Molybdenum Cofactor Deficiency (MoCD) Disease Type A (MoCD Type A)
MoCD Type A is a rare metabolic disorder characterized by severe and rapidly progressive neurologic damage and death in newborns. MoCD Type A results from a genetic deficiency in cyclic Pyranopterin Monophosphate (cPMP), a molecule that enables production of certain enzymes, the absence of which allows neurotoxic sulfite to accumulate in the brain. To date, there is no approved therapy available for MoCD Type A. We acquired assets related to a cPMP replacement therapy from Orphatec Pharmaceuticals GmbH in February 2011. There has been some early clinical experience with the cPMP replacement therapy in a small number of children with MoCD Type A. We are currently conducting pre-IND toxicology studies with cPMP replacement therapy.

ALXN 1102/1103
ALXN 1102/1103 is a novel alternative pathway complement inhibitor with a mechanism of action unique from Soliris. We acquired a portfolio of preclinical product candidates, including ALXN 1102, in January 2011 in connection with the purchase of all of the equity interests of Taligen. ALXN 1102 is currently being investigated in a Phase I single dose, dose escalating safety and pharmacology study. ALXN 1103 is being dosed in the same Phase I trial as a subcutaneous formulation.

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. ALXN 1007 is currently being investigated in a Phase I single dose, dose escalating safety and pharmacology study in healthy volunteers.
Samalizumab

Samalizumab is our proprietary humanized monoclonal antibody directed against the cell surface protein CD200. Samalizumab is designed to modulate the immune system and destroy tumors expressing the CD200 protein.
The FDA authorized our IND to evaluate the activity of samalizumab, an antibody to the immune regulator CD200, in patients with chronic lymphocytic leukemia (CLL). CLL is a type of cancer of the blood and bone marrow. CLL most commonly affects older adults, though it may occur at any age and rarely can affect children.
Enrollment and dosing was completed in our Phase I dose-escalation clinical study of samalizumab in patients with treatment refractory CLL or multiple myeloma. The trial enrolled 26 patients, and positive interim results from this trial were reported at the 2010 American Society for Hematology meeting.

Manufacturing

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

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

depend on a limited number of third party providers for other services with respect to our clinical and commercial requirements, including product finishing, packaging, vialing and labeling.

We have various agreements with Lonza, with remaining total commitments of approximately $190,000 through 2018. Such commitments may be canceled only in limited circumstances. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at ARIMF.

Critical Accounting Policies and the Use of Estimates

The significant accounting policies and basis of preparation of our consolidated financial statements are described in Note 1, “Business Overview and Summary of Significant Accounting Policies,” of our financial statements included in our Form 10-K for the year ended December 31, 2011. 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;
- Research and development expenses;
- Share-based compensation;
- Valuation of goodwill, acquired intangible assets and in-process research and development (IPR&D);
- Valuation of contingent consideration; and
- Income taxes.

For a complete discussion of these critical accounting policies, refer to “Critical Accounting Policies and Use of Estimates” within “Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations” included within our Form 10-K for the year ended December 31, 2011. We have reviewed our critical accounting policies as disclosed in our Form 10-K, and we have not noted any material changes.

New Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board issued a new standard on the presentation of comprehensive income. The new standard eliminated the current option to report other comprehensive income and its components in the statement of changes in equity. Under the new standard, companies can elect to present items of net income and other comprehensive income in one continuous statement or in two separate, but consecutive statements. We adopted the provisions of this guidance during the first quarter 2012.

Results of Operations

Net Product Sales

The following table summarizes net product sales for the three and nine months ended September 30, 2012 and 2011:

	Three months ended September 30,			Nine months ended September 30,		
	2012	2011	$ Variance	2012	2011	$ Variance
Net product sales	$294,136	$204,047	$90,089	$813,588	$555,872	$257,716

The increase in revenue for the three and nine months ended September 30, 2012, as compared to the same periods in 2011, was primarily due to an increased number of patients treated with Soliris globally. The increase in treated patients was due to physicians requesting Soliris therapy for additional patients, as well as reimbursement and price

approvals in additional territories, including approval for PNH in certain provinces in Canada in the third quarter of 2011 and approval and

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

reimbursement for aHUS in the United States and some countries in Europe in late 2011. We also recognized $3,300 related to an agreement reached with a payor in the second quarter 2012 related to product shipped during 2011.

The increase in revenues was offset by the negative impact of approximately $6,323 and $15,591 for the three and nine months ended September 30, 2012, respectively, due to changes in foreign currency exchange rates (inclusive of hedging activity) versus the dollar for the three and nine months ended September 30, 2011. The negative impact was primarily due to the Euro, the British Pound and the Australian Dollar offset by a positive impact of the Japanese Yen.

Cost of Sales

In October 2012, we entered into a settlement and non-exclusive license agreement with a third party. Under the terms of the agreement, we will make an upfront payment of approximately $38,000 in the fourth quarter of 2012 and will pay royalties on sales of Soliris in accordance with the terms of the agreement. As a result of this settlement and non-exclusive license agreement, we reduced our estimate for probable contingent liabilities and have recorded a gain in cost of sales of $53,377 in the third quarter 2012.

Exclusive of the settlement noted above, cost of sales were $33,186 and $23,369 for the three months ended September 30, 2012 and 2011, respectively and $93,067 and $64,342 for the three and nine months ended September 30, 2012 and 2011, respectively. Cost of sales as a percentage of net revenue was 11.3% and 11.5% for the three months ended September 30, 2012 and 2011, respectively and 11.4% and 11.6%, for the nine months ended September 30, 2012, respectively. Cost of sales includes manufacturing costs as well as actual and estimated royalty expenses associated with sales of Soliris.

Research and Development Expense

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

External direct expenses are comprised of costs paid to outside parties for clinical development, product development and discovery research. 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. 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 September 30,		$	Nine months ended September 30,		$
	2012	2011	Variance	2012	2011	Variance
Clinical development	$10,274	$9,249	$1,025	$33,133	$27,206	$5,927
Product development	11,292	5,579	5,713	40,552	14,367	26,185
Discovery research	2,174	1,092	1,082	5,774	2,485	3,289
Total external direct expenses	23,740	15,920	7,820	79,459	44,058	35,401
Payroll and benefits	25,400	16,919	8,481	68,972	48,203	20,769
Operating and occupancy	3,029	2,257	772	5,608	6,509	(901)
Depreciation and amortization	2,111	1,471	640	5,284	4,253	1,031
Total other R&D expenses	30,540	20,647	9,893	79,864	58,965	20,899
Research and development expense	$54,280	$36,567	$17,713	$159,323	$103,023	$56,300

For the three months ended September 30, 2012, the increase of $17,713 in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase of $5,713 in external product development expenses related primarily to the production of clinical amounts of asfotase alfa.

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

- Increase of $8,481 in research and development payroll and benefit expense related primarily to global expansion of staff supporting our increasing number of clinical and development programs.

For the nine months ended September 30, 2012, the increase of $56,300 in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase of $5,927 in external clinical development expenses related primarily to an expansion of studies of eculizumab and our asfotase alfa program acquired in February 2012, as well as an increase in costs related to other clinical programs (see table below).
- Increase of $26,185 in external product development expenses related primarily the production of clinical amounts of asfotase alfa.
- Increase of $20,769 in research and development payroll and benefit expense related primarily to global expansion of staff supporting our increasing number of clinical and development programs.

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

	Three months ended September 30,		$	Nine months ended September 30,		$
	2012	2011	Variance	2012	2011	Variance
External direct expenses						
Eculizumab	$7,986	$8,888	$(902)	$26,753	$25,726	$1,027
Asfotase alfa	794	—	794	2,249	—	2,249
Other Programs	1,584	222	1,362	3,760	849	2,911
Unallocated	(90)	139	(229)	371	631	(260)
	$10,274	$9,249	$1,025	$33,133	$27,206	$5,927

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 the 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 and legal expenses.

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

	Three months ended September 30,		$	Nine months ended September 30,		$
	2012	2011	Variance	2012	2011	Variance
Salary, benefits and other labor expense	$52,117	$45,396	$6,721	$161,327	$134,953	$26,374
External selling, general and administrative expense	37,840	32,176	5,664	110,727	86,656	24,071
Total selling, general and administrative expense	$89,957	$77,572	$12,385	$272,054	$221,609	$50,445

For the three months ended September 30, 2012, the increase of $12,385 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase in salary, benefits and other labor expenses of $6,721. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of $4,900 related to our

26

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

global commercial staff to support global expansion. This increase was also due to increases in payroll and benefits of $1,800 within our general and administrative functions to support our infrastructure growth as a global commercial entity.

- Increase in external selling, general and administrative expenses of $5,664. The increase was primarily due to costs associated with marketing and professional services of $2,300 and an increase of $3,000 in other administrative costs incurred in connection with our infrastructure growth.

For the nine months ended September 30, 2012, the increase of $50,445 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase in salary, benefits and other labor expenses of $26,374. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of $20,100 related to our global commercial staff to support global expansion. This increase was also due to increases in payroll and benefits of $6,300 within our general and administrative functions to support our infrastructure growth as a global commercial entity.
- Increase in external selling, general and administrative expenses of $24,071. This increase was primarily due to costs associated with marketing and professional services of $10,900, increased distribution costs of $2,500, charitable contributions of $1,200, occupancy costs of $3,100 due to expansion of current facilities in the United States and Switzerland and new facilities associated with the acquisition of Enobia, and an increase of $4,700 in other administrative costs incurred in connection with our infrastructure growth.

Acquisition-related Costs

Acquisition-related costs for the three and nine months ended September 30, 2012 and 2011 associated with our acquisitions included the following:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Separately-identifiable employee costs	$457	$—	$3,552	$6,597
Professional fees	1,052	—	11,562	3,450
Changes in fair value of contingent consideration	(542)	236	4,333	1,117
	$967	$236	$19,447	$11,164

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

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Enobia	$3,441	$—	$20,558	$—
Taligen	(4,224)	149	(3,069)	10,224
Orphatec	1,750	87	1,958	940
	$967	$236	$19,447	$11,164

Included in this change in fair value of the Taligen contingent consideration for the three and nine months ended September 30, 2012 is a gain of $4,331 related to the decrease in the fair value of the contingent consideration related to this acquisition. The decrease in fair value was a result of a decreased likelihood of payments for contingent consideration due to the negative scientific findings, decrease in value and related deprioritization of the age-related macular degeneration program as noted below.

Impairment of In-Process Research and Development

During the three months ended September 30, 2012, we reviewed for impairment the value of an early stage, preclinical indefinite-lived intangible asset related to the Taligen acquisition. We initiated such review based on our evaluation of negative scientific findings associated with our development of a different asset for the treatment of age-related macular degeneration, the likelihood of success for ophthalmic use and the value that can be obtained from

a market participant in an arm's length transaction. These developments led us to deprioritize the development of this acquired asset. As a result, in the third quarter

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

2012, we recognized an impairment charge of $26,300 to write-down this asset to fair value, which was determined to be de minimis.

Other Income and Expense

Foreign currency transaction gains and losses relate to changes in the fair value of monetary assets and liabilities denominated in foreign currencies. The foreign currency transaction losses totaled $416 and $841, for the three months ended, and $817 and $952, for the nine months ended September 30, 2012 and 2011, respectively. The losses recorded in these periods were a result of the costs of hedging our exposures, as well as the fluctuation in exchange rates on the portion of our monetary assets and liabilities that were not fully hedged as part of our hedging programs.

We recognize investment income primarily from our portfolio of cash equivalents and marketable securities. Investment income was $317 and $523, for the three months ended, and $872 and $1,691 for the nine months ended September 30, 2012 and 2011, respectively.

We incur interest on our term notes, revolving credit facility, convertible notes and capital lease obligations. Interest expense was $1,855 and $204, for the three months ended, and $6,220 and $605 for the nine months ended September 30, 2012 and 2011, respectively. The increase in interest expense is primarily due to interest on our borrowing under our new credit facility used in the acquisition of Enobia in February 2012.

Income Taxes

During the three and nine months ended September 30, 2012, we recorded an income tax provision of $48,586 and $116,446 and an effective tax rate of 34.5% and 40.1%, compared to an income tax provision of $107 and $28,445 and an effective tax rate of 0.2% and 18.3% for the three and nine months ended September 30, 2011. The tax provision for the three and nine months ended September 30, 2012 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations and the tax expense associated with the settlement and non-exclusive license agreement with a third party of $22,673. Additionally, included in the nine months ended September 30, 2012 is the impact of the tax expense of $21,812 associated with the structuring of the Enobia business.

The tax provision for the three and nine months ended September 30, 2011 is principally attributable to the U.S. federal, state and foreign income taxes on our profitable operations. In September 2011, we completed our assessment of the impact the election to claim federal foreign tax credits and the federal orphan drug credits would have on our historical tax returns. Based on this assessment, management elected to claim both the foreign tax credit for the tax year ended December 31, 2010 and federal orphan drug credit for the tax years ended December 31, 2010 and 2009. The net federal income tax benefit recorded during the three months ended September 30, 2011 as a result of the election to claim the federal foreign tax credit for 2010 and the federal orphan drug credit for 2010 and 2009 was approximately $14,800. In addition, the Company also revised its estimate of the federal orphan drug credit benefit for 2011, which resulted in a $1,500 benefit in the quarter ended September 30, 2011.

At the end of the third quarter of 2012, 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.

Financial Condition, Liquidity and Capital Resources

The following table summarizes the components of our financial condition as of September 30, 2012 and December 31, 2011:

	September 30, 2012	December 31, 2011	$ Variance
Cash and cash equivalents	$905,526	$540,865	$364,661
Long-term debt (includes current portion)	$161,000	$—	$161,000
Current assets	$1,410,391	$941,270	$469,121
Current liabilities	361,942	227,785	134,157
Working capital	$1,048,449	$713,485	$334,964

The increase in cash and cash equivalents was primarily attributable to the net proceeds received from the common stock offering completed in May 2012, proceeds from our new credit facility, net proceeds from the exercise of stock options and cash generated from operations, offset by cash used for the Enobia acquisition.

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

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 for the foreseeable future.

Since the commercial launch of Soliris in 2007, we have financed our operations and capital expenditures primarily through positive cash flows from operations. We expect to continue to be able to fund for the foreseeable future, 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 and high quality commercial, corporate and U.S. government and agency bonds and commercial paper 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 the Company to concentrations of credit risk are limited to cash equivalents, accounts receivable and our foreign exchange derivative contracts. At September 30, 2012, two individual customers accounted for 19% and 11% of the accounts receivable balance. At December 31, 2011, two individual customers accounted for 18% and 13% of the accounts receivable balance. For the three and nine months ended September 30, 2012, two customers accounted for 21% and 12% of our product sales, respectively. For the three and nine months ended September 30, 2011, one customer accounted for 18% of our product sales.

We continue to monitor economic conditions, including volatility associated with international economies and the sovereign debt crisis in Europe, and the associated impacts on the financial markets and our business. The credit and economic conditions in Greece, Italy and Spain, among other members of the European Union, have deteriorated throughout 2011 and 2012. These conditions have resulted in, and may continue to result in, an increase in the average length of time it takes to collect our outstanding accounts receivable in these countries. 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. Our exposure to the sovereign debt crisis in Greece is limited, as we do not have a material amount of accounts receivable in Greece.

As of September 30, 2012, our gross accounts receivable in Italy and Spain were approximately $86,100. Approximately $25,300 of this amount has been outstanding for greater than one year, and we have recorded an allowance of approximately $2,500 related to these receivables as of September 30, 2012. During the three and nine months ended September 30, 2012, we have recorded expense of approximately $115 and $1,580 related to the expectation of delayed payment from these countries. Our net accounts receivable from these countries are summarized as follows:

	Total Accounts Receivable, net	Accounts Receivable, net > one year
Italy	$35,836	$6,805
Spain	$47,785	$17,130

We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. As of September 30, 2012, we have foreign exchange forward contracts with notional amounts totaling $945,320. These outstanding foreign exchange forward contracts had a net fair value of $7,871, of which an unrealized gain of $19,940 is included in other assets, offset by an unrealized loss of $12,069 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 September 30, 2012, 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. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, but substantially the full term of the financial instrument. Our Level 2 assets consist primarily of money market funds, commercial paper, U.S. corporate bonds, federal agency obligations 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.

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

Acquisitions and Contingent Consideration Obligations

In February 2012, we completed a business combination with Enobia. This acquisition required us to make upfront cash payments of approximately $623,876, which we have paid from our available cash and cash equivalents and proceeds from our new credit facility. In the second quarter 2012, as a result of structuring the Enobia business, we recorded income tax expense of $21,812 in our income statement. The structuring will require us to make a cash payment of approximately $50,000 in early 2013, and this amount is fully accrued on our balance sheet as of September 30, 2012.

The purchase agreements for the Enobia, Taligen and Orphatec acquisitions include contingent payments totaling up to $470,000, $367,000 and $42,000, respectively, if and when certain development and commercial milestones are achieved. Of these milestone amounts, $564,000 and $315,000 of the contingent payments relate to development and commercial milestones, respectively. We do not expect that any significant contingent payments will be made in the next 12 months and, accordingly, we do not expect these amounts to have an impact on our liquidity in the near-term. As future payments become probable, we will evaluate methods of funding payments, which could be made from available cash, cash generated from operations or proceeds from other financing.

Long-term Debt

In February 2012, we and our wholly-owned Swiss subsidiary, Alexion Pharma International Sàrl, entered into the 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. In connection with the acquisition of Enobia in February 2012, we borrowed $240,000 under the term loan facility and $80,000 under the revolving facility and we used our available cash for the remaining purchase price. During the second quarter ended June 30, 2012, we repaid the revolving facility in full. In addition to the required quarterly installment of $12,000, we also pre-paid $55,000 of the term loan facility during the third quarter of 2012, and we had $161,000 outstanding as of September 30, 2012. As of September 30, 2012, we had open letters of credit of $9,918, and our borrowing availability under the revolving facility was $190,082 at September 30, 2012. We expect that cash generated from operations will be sufficient to meet debt service obligations.

Contingent Liabilities

In October 2012, we entered into a settlement and non-exclusive license agreement with a third party. Under the terms of the agreement, we will make an upfront payment of approximately $38,000 in the fourth quarter of 2012 and will pay royalties on sales of Soliris in accordance with the terms of the agreement. As of September 30, 2012, our accrued royalty balance of $55,758 includes the upfront payment noted above and royalties owed to third parties.

We are currently involved in various claims and legal proceedings. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, we accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on our best estimates based on available information, and changes in the estimated amounts and timing of paying these potential liabilities could have a material impact on our liquidity.

Taxes

We do not record US tax expense on the undistributed earnings of our non-US subsidiaries as these earnings are intended to be permanently reinvested in the businesses offshore. We do not have any present or anticipated future need for cash held by our non-US subsidiaries, as cash generated in the US, as well as borrowings, are expected to be sufficient to meet future US liquidity needs. At September 30, 2012, approximately $91,000 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. In connection with the acquisition of Enobia, our foreign subsidiaries have bank debt which remains outstanding at September 30, 2012. Due to the liability position of our foreign subsidiaries, these subsidiaries

will repay the bank debt, as well as any outstanding intercompany debt, prior to having excess cash available which could be used to repatriate to our entities in the United States.

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

Cash Flows

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

	Nine months ended September 30,		
	2012	2011	$ Variance
Net cash provided by operating activities	$305,656	$179,297	$126,359
Net cash used in investing activities	(619,995)	(34,378)	(585,617)
Net cash provided by financing activities	678,882	26,197	652,685
Effect of exchange rate changes on cash	118	(107)	225
Net change in cash and cash equivalents	$364,661	$171,009	$193,652

The increase in cash and cash equivalents was primarily due to cash generated from operations, borrowings under our credit facility and stock option exercises, offset by cash used for the Enobia acquisition.

Operating Activities

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

- Our reported net income was $173,851 and $127,145 for the nine months ended September 30, 2012 and 2011, respectively. This amount included $53,377 of the gain related to the intellectual property settlement.
- Non-cash items included depreciation and amortization, impairment of intangible assets, change in fair value of contingent consideration, share-based compensation expense, deferred taxes, marketable securities premium amortization, unrealized foreign currency gains and losses, gains and losses on forward contracts, and currency translation adjustments, and were $140,653 and $70,691 for the nine months ended September 30, 2012 and 2011, respectively.
- Net cash outflow due to changes in operating assets and liabilities was $8,848 and $18,539 for the nine months ended September 30, 2012 and 2011, respectively. The $8,848 change in operating assets and liabilities primarily relates to:
- Increase in accounts receivable of $65,299 due to the increased number of patients treated with Soliris globally, as well as reimbursement and price approvals in additional territories.
- Increase in inventory of $3,467 related to increased production of inventory to support commercial growth.
- Increase in prepaid expenses and other assets of $17,065, primarily related to tax receivables and prepaid taxes.
- Increase of $59,945 in accounts payable and accrued expenses and other liabilities primarily related to increases in accrued income taxes and rebates, offset by a decrease in accrued royalties. The decrease in accrued royalties was related to the intellectual property settlement.
- Increase of $17,038 in deferred revenue due to increased shipments in advance of recognizing revenue.

Investing Activities

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

- Additions to property, plant and equipment were $14,257 and $15,241 for the nine months ended September 30, 2012 and 2011, respectively.
- Maturities of marketable securities of $87,100 for the nine months ended September 30, 2011.
- Payments of $605,735 and $105,886 related to the acquisitions of Enobia in the first quarter of 2012 and Taligen and Orphatec in the first quarter of 2011.

Financing Activities

Net cash flows from financing activities reflected proceeds from the exercise of stock options of $54,910 and $24,531 for the nine months ended September 30, 2012 and 2011, respectively. In addition, during the nine months ended September 30, 2012, we recognized proceeds of $462,212 in connection with the sale of 5,000 shares of our common stock.

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

In connection with the acquisition of Enobia in February 2012, we borrowed $240,000 under the term loan facility and $80,000 under the revolving facility, and we used our available cash for the remaining purchase price. During the second quarter of 2012, we repaid the revolving facility in full. In addition, during the nine months ended September 30, 2012, we made payments of $79,000 against the term loan facility. As of September 30, 2012, we had open letters of credit of $9,918, and our borrowing availability under the revolving facility was $190,082 at September 30, 2012.

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, 2011, in the section titled “Management's Discussion and Analysis of Financial Condition and Results of Operations” under the caption “Contractual Obligations.” In addition to the contingent consideration obligations associated with the Enobia, Taligen and Orphatec acquisitions, tax obligations and long-term debt (each described above), other significant contractual obligations are described below.

Revolving Credit Facility

On February 7, 2012, we and our wholly-owned Swiss subsidiary, Alexion Pharma International Sàrl entered into the 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 beginning on June 30, 2102 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 facility by $150,000.

We may elect that the loans under the Credit Agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.25% to 2.00% depending on our consolidated leverage ratio (as calculated in accordance with the Credit Agreement), or (ii) in the case of loans denominated in U.S. dollars, a Base Rate equal to the higher of the (A) Prime Rate then in effect, (B) Federal Funds Rate then in effect plus 0.50%, and (C) Eurodollar Rate then in effect plus 1.00%, plus in each case of (A), (B) or (C), 0.25% to 1.00% depending on our consolidated leverage ratio of our cash to liabilities (as calculated in accordance with the Credit Agreement). Interest is payable quarterly for Base Rate loans and, in the case of LIBOR-based loans, at the end of the applicable interest period, with the principal due on February 7, 2017, the maturity date.

Our obligations under the credit facilities are unconditionally guaranteed, jointly and severally, by certain of our existing domestic subsidiaries and are required to be guaranteed by certain of our future domestic subsidiaries. The obligations of Alexion Pharma International Sàrl under the credit facilities are unconditionally guaranteed, jointly and severally, by us, certain of our existing domestic subsidiaries, and certain of our foreign subsidiaries, and are required to be guaranteed by certain of our future subsidiaries. All obligations of each borrower under the credit facilities, and the guarantees of those obligations, are secured, subject to certain exceptions, by substantially all of each borrower's assets and the assets of certain guarantors, including the pledge of the equity interests of certain of our subsidiaries and real estate located in Smithfield, Rhode Island, but excluding intellectual property and assets of certain foreign subsidiaries.

The Credit Agreement requires us to comply with certain financial covenants on a quarterly basis. Further, the Credit Agreement includes negative covenants, subject to exceptions, restricting or limiting our ability and the ability of our subsidiaries to, among other things, incur additional indebtedness, grant liens, engage in certain investment, acquisition and disposition transactions, pay dividends, repurchase capital stock and enter into transactions with affiliates. The Credit Agreement also contains customary representations and warranties, affirmative covenants and events of default, including payment defaults, breach of representations and warranties, covenant defaults and cross defaults. If an event of default occurs, the interest rate would increase and the administrative agent would be entitled to take various actions, including the acceleration of amounts due under the loan.

Lonza Agreement

We have supply agreements with Lonza relating to the manufacture of eculizumab and asfotase alfa, which requires payments to Lonza at the inception of contract and upon the initiation and completion of product manufactured. On an ongoing basis, we evaluate our plans for future levels of manufacturing by Lonza, which depends upon our commercial requirements, the progress of our clinical development programs and the production levels of ARIMF. We have various agreements with Lonza, with remaining total commitments of approximately $190,000 through 2018. Such commitments may be canceled only in limited circumstances. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at ARIMF.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

(amounts in thousands, except per share data)

Interest Rate Risk

As of September 30, 2012, we held all of our cash and cash equivalents in bank accounts and money market funds, and we do not believe a change in interest rates would have a material impact on our statement of operations.

In February 2012, we entered into the Credit Agreement. Alexion may elect that the loans under the Credit Agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.25% to 2.00% depending on Alexion's consolidated leverage ratio (as calculated in accordance with the Credit Agreement), or (ii) in the case of borrowings in U.S. dollars, a Base Rate equal to the higher of the (A) Prime Rate then in effect, (B) Federal Funds Rate then in effect plus 0.50%, and (C) Eurodollar Rate then in effect plus 1%, plus in each case of (A), (B) or (C) 0.25% to 1.00% depending on Alexion's consolidated leverage ratio (as calculated in accordance with the agreement). We do not expect changes in interest rates related to the Credit Agreement to have a material effect on our financial statements. At September 30, 2012, we had approximately $161,000 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 $1,610.

Foreign Exchange Market Risk

As a result of our foreign operations, we face exposure to movements in foreign currency exchange rates, primarily the Euro, Japanese Yen and Swiss Franc against the U.S. dollar. The current exposures arise primarily from cash, accounts receivable, intercompany receivables and payables, and product sales denominated in foreign currencies. Both positive and negative impacts to our international product sales from movements in foreign currency exchange rates are partially mitigated by the natural, opposite impact that foreign currency exchange rates have on our international operating expenses. We have substantial operations based in Switzerland to support our business outside the U.S., 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) limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet, using contracts with durations of up to 30 days and 2) hedge a portion of our forecasted intercompany product sales, using contracts with durations of up to 36 months. The objectives of this program are to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. This program utilizes foreign exchange forward contracts intended to reduce, not eliminate, the impact of fluctuations in foreign currency rates.

As of September 30, 2012, we held foreign exchange forward contracts with notional amounts totaling $945,320. As of September 30, 2012, our outstanding foreign exchange forward contracts had a net fair value of $7,871.

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.

Since our foreign currency hedges are designed to offset gains and losses on our monetary assets and liabilities, we do not expect that a hypothetical 10% adverse fluctuation in exchange rates would result in a material change in the fair value of our foreign currency sensitive net assets, which include our monetary assets and liabilities and our foreign exchange forward contracts. The analysis above does not consider the impact that hypothetical changes in foreign currency exchange rates would have on future transactions such as anticipated sales.

Credit Risk

We continue to monitor economic conditions, including volatility associated with international economies and the sovereign debt crisis in Europe, and the associated impacts on the financial markets and our business. The credit and economic conditions in Greece, Italy and Spain, among other members of the European Union, have deteriorated throughout 2011 and 2012. These conditions have resulted in, and may continue to result in, an increase in the average length of time it takes to collect our outstanding accounts receivable in these countries. 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. Our exposure to the sovereign debt crisis in Greece is limited, as we do not have a material amount of accounts receivable in Greece.

As of September 30, 2012, our gross accounts receivable in Italy and Spain were approximately $86,100. Approximately $25,300 of this amount has been outstanding for greater than one year, and we have recorded an allowance of approximately $2,500 related to these receivables as of September 30, 2012. During the three and nine months ended September 30, 2012 , we have recorded expense of approximately $115 and $1,580, respectively, related to expectation of delayed payment from these countries. Our net accounts receivable from these countries are summarized as follows:

	Total Accounts Receivable, net	Accounts Receivable, net > one year
Italy	$35,836	$6,805
Spain	$47,785	$17,130

Item 4. CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act) as of September 30, 2012. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2012, 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 Securities and Exchange Commission's rules and forms.

There has been no change in our internal control over financial reporting that occurred during the quarter ended September 30, 2012 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.

As previously reported in our Current Report on Form 8-K filed on January 28, 2011, in January 2011, Novartis Vaccines & Diagnostics, Inc. (Novartis) filed a civil action against Alexion and other biopharmaceutical companies in the U.S. District Court for the District of Delaware. Novartis claims willful infringement by Alexion of a Novartis patent and seeks, among other things, monetary damages.

Item 1A. Risk Factors.

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

Risks Related to Our Lead Product Soliris

We depend heavily on the success of our lead product, Soliris. If we are unable to increase sales of Soliris, or obtain approval or commercialize Soliris in new territories for the treatment of PNH, aHUS or for additional indications, or if we are significantly delayed or limited in doing so, our business may be materially harmed.

Our ability to generate revenues will continue to depend on commercial success of Soliris in the United States, Europe, Japan and in a number of key markets in the rest of the world and whether physicians, patients and health care payers view Soliris as therapeutically effective and safe relative to cost. Since we launched Soliris in the United States in April 2007, essentially all of our revenue has been attributed to sales of Soliris, and we expect that Soliris product sales will continue to contribute to a significant percentage or almost all of our total revenue over the next several years.

In September and November 2011 we obtained marketing approval in the United States and the European Union, respectively, for Soliris for the treatment of a second indication, aHUS.

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, including certain countries in the European Union, 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 will also commence similar discussions with authorities to facilitate the commercialization of Soliris for the treatment of aHUS in certain other countries of the European Union. We cannot guarantee that we will be able to obtain reimbursement for Soliris or successfully commercialize Soliris in any additional countries, or that we will be able to maintain coverage or reimbursement at anticipated levels in any country in which we have already received marketing approval. As a result, sales in certain countries may be delayed or never occur, or may be subsequently reduced.

The commercial success of Soliris and our ability to generate and increase revenues will depend on several factors, including the following:

- receipt of marketing approvals for Soliris for the treatment of PNH in new territories and the maintenance of marketing approvals for the treatment of PNH in the United States, the European Union, Japan and other territories;
- receipt and maintenance of marketing approvals for Soliris for the treatment of aHUS in Japan and other territories and the maintenance of the marketing approval in the United States and the European Union;
- the number of patients with PNH and aHUS, and the number of those patients who are diagnosed with PNH and aHUS and identified to us;
- the number of patients with PNH and aHUS that may be treated with Soliris;
- successful continuation of commercial sales in the United States, Japan and in European countries where we are already selling Soliris for the treatment of PNH, and successful launch in countries where we have not yet obtained, or

only recently obtained, marketing approval or commenced sales;

- successfully launching commercial sales of Soliris for the treatment of aHUS in the United States and Europe, and in countries where we have not yet obtained marketing approval;
- ability to obtain sufficient coverage or reimbursement by third-party payers and our ability to maintain coverage or reimbursement at anticipated levels;
- acceptance of Soliris and maintenance of safety and efficacy in the medical community;
- establishment and maintenance of commercial manufacturing capabilities ourselves or through third-party manufacturers; and
- our ability to develop, register and commercialize Soliris for indications other than PNH, including aHUS.

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

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

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

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

We may not be able to sell Soliris on a profitable basis or our profitability may be reduced if we are required to sell our product at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. Soliris is significantly more expensive than traditional drug treatments and almost all patients require some form of third party coverage to afford its cost. Our future revenues and profitability will be adversely affected if we cannot depend on governmental, private third-party payers and other third-party payers, such as Medicare and Medicaid in the United States or country specific governmental organizations, to defray the cost of Soliris to the patient. 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 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, countries in the European Union may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may from time to time approve a specific price 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. Some countries have or 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, European countries, and elsewhere, there have been, and we expect there will continue to be, efforts to control and reduce health care costs. Government and other third-party payers are challenging the prices charged for health care products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs. For example, during 2010 the German government adopted legislation to increase mandatory discounts on pharmaceutical products and impose a temporary freeze on pharmaceutical pricing, including Soliris. A significant reduction in the amount of reimbursement or pricing for Soliris in one or more countries may have a material adverse effect on our business. See additional discussion below under the headings “Government initiatives that affect coverage and reimbursement of drug products could adversely affect our business” and “The credit and financial market conditions may aggravate certain risks affecting our business.” In addition, certain countries establish pricing and reimbursement amounts by reference to the price of the same or similar products in other countries. If coverage or the level of reimbursement is limited in one or more countries, we may be unable to obtain or maintain anticipated pricing or reimbursement in current or new territories.

Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Third-party payers may be especially likely to impose these obstacles to coverage for higher-priced drugs such as Soliris.

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

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

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

We cannot be certain that Soliris will gain or maintain market acceptance in a particular country among physicians, patients, health care payers, and others. Although we have received regulatory approval for Soliris in certain territories, including the United States, Japan and Europe, such approvals do not guarantee future revenue. We cannot predict whether physicians, other health care providers, government agencies or private insurers will determine or continue to accept that Soliris is safe and therapeutically effective relative to its cost. Medical doctors' willingness to prescribe, and patients' willingness to accept, Soliris depends on many factors, including prevalence and severity of adverse side effects in both clinical trials and commercial use, effectiveness of our marketing strategy and the pricing of Soliris, publicity concerning Soliris, our other product candidates or competing products, our ability to obtain and maintain third-party coverage or reimbursement, and availability of alternative treatments, including bone marrow transplant as an alternative treatment for PNH. The likelihood of medical doctors to prescribe Soliris for patients with aHUS may also depend on how quickly Soliris can be delivered to the hospital or clinic and our distribution methods may not be sufficient to satisfy this need. If Soliris fails to achieve or maintain market acceptance among the medical

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

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

We cannot guarantee that we will be able to maintain our regulatory approvals for Soliris. If we do not maintain our regulatory approvals for Soliris, the value of our company and our results of operations will be materially harmed. We and our current and future partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by the FDA, other federal and state agencies, and governmental authorities in other territories. These regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, finishing, vialing, 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 Program (REMS) program, approved by the FDA in 2010. The REMS program requires mandatory physician certification in the United States. Each physician must certify that the physician is aware of the potential risks associated with the administration of Soliris and that the physician will inform each patient of these risks using educational material approved by the FDA.

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

Failure to comply with the laws and requirements, including statutes and regulations, administered by the FDA, the EMA, the MHLW or other agencies, could result in:

- administrative and judicial sanctions, including, warning letters;
- fines and other civil penalties;
- withdrawal of a previously granted approval for Soliris;
- interruption of production;
- operating restrictions;
- delays in approving or refusal to approve Soliris or a facility that manufactures Soliris;
- product recall or seizure;
- injunctions; and
- criminal prosecution.

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

damaging product liability claims.

The testing, manufacturing, marketing and sale of drugs for use in humans exposes us to product liability risks. Side effects and other problems from using Soliris could (1) lessen the frequency with which physicians decide to prescribe Soliris, (2) encourage physicians to stop prescribing Soliris to their patients who previously had been prescribed Soliris, (3) cause

serious adverse events and give rise to product liability claims against us, and (4) result in our need to withdraw or recall Soliris from the marketplace. Some of these risks are unknown at this time.

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

Escherichia 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 thrombotic microangiopathy (TMA). After missing a dose or discontinuing Soliris, blood clots may form in small blood vessels throughout the body, causing a reduction in platelet count. The reduction in platelet count may lead to numerous complications, including changes in mental status, seizures, angina, thrombosis, renal failure or even death. In our aHUS clinical studies, such TMA complications were observed in some patients who missed a dose.

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

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

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

Regulatory agencies may require additional information or data with respect to our submissions for Soliris, including the marketing applications submitted to the EMA for the treatment of patients with aHUS. We may have to conduct additional lengthy clinical testing and other costly and time-consuming procedures to satisfy foreign regulatory agencies. Even with approval of Soliris in certain countries, the regulatory agencies in other countries may not agree with our interpretations of our clinical trial data for Soliris and may decide that our results are not adequate to support approval for marketing of Soliris. In those circumstances, we would not be able to obtain regulatory approval in such country on a timely basis, if ever. Even if approval is granted in such country, the approval may require limitations on the indicated uses for which the drug may be marketed. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. We must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. We were required to conduct clinical studies with Soliris in patients with PNH in Japan prior to obtaining marketing approval in that country and Japanese authorities could require additional studies in Japan for Soliris for the treatment of patients with aHUS. We are also conducting prospective clinical trials in adult and pediatric patients to confirm the benefit of Soliris for the treatment of aHUS. Commercialization of Soliris for the treatment of PNH, aHUS or any other indication could be delayed, limited or may not occur in territories where we seek marketing approval if the applicable regulatory agency requires additional information or data.

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

Commercial quantities of Soliris are manufactured by us at Alexion's Rhode Island Manufacturing Facility (ARIMF) and by Lonza. Manufacturing processes must comply with applicable regulations and manufacturing practices, as well

as our own quality standards. In particular, the manufacture of Soliris is heavily regulated by governmental authorities around the world, including the FDA, EMA and MHLW. If we or our third-party providers, including our product vialers, packagers and labelers, fail to comply fully with such regulations then there could be a government-enforced shutdown of production facilities or production lines, which in turn could lead to product shortages.

The manufacture of Soliris is difficult. Manufacture of a biologic requires a multi-step controlled process and even minor problems or deviations could result in defects or failures. We cannot be certain that we, Lonza or our other third party

providers will be able to perform uninterrupted supply chain services. The failure to manufacture appropriate supplies of Soliris, on a timely basis, or at all, may prevent or interrupt the commercialization of Soliris. If we, Lonza or our other third party providers were unable to manufacture Soliris for any period, or if we, Lonza or our other third party providers do not obtain approval of the respective facility by the applicable regulatory agencies, we may incur substantial loss of sales. If we are forced to find an alternative supplier or other third party providers for Soliris, in addition to loss of sales, we may also incur significant costs and experience significant delay in establishing a new arrangement.

We are authorized to sell product that is manufactured in our facility in the United States, the European Union, Japan and certain other territories. However, we will not be capable of manufacturing Soliris at ARIMF for commercial sale in certain other territories until such time as we have received the required regulatory approval for our facility, if ever. We will continue to depend entirely on one company, Lonza, to manufacture Soliris for commercial sale in such other territories until that time.

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

We depend on a very limited number of third party providers for other services with respect to our clinical and commercial requirements, including product finishing, packaging, vialing and labeling. We have changed or added third party vialers in the past in order to best ensure uninterrupted supply, and may do so in the future. We currently rely on two third party vialers to support our commercial requirements in the US and Europe, and a single third party vialer to support requirements in Japan. No guarantee can be made that any third party vialer 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, 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. 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.

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

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

For the three months ended September 30, 2012, our single largest customer accounted for 21% of our global Soliris net product sales, and our three largest customers accounted for approximately 41% of our global net product sales. As of September 30, 2012, our single largest customer accounted for 19% of the global accounts receivable balance. We expect such customer concentration to continue for the foreseeable future. We typically sell Soliris to third party distributors, such as specialty pharmacies, who in turn sell to patient health care providers. We do not promote Soliris to these distributors, and they do not set or determine demand for Soliris. Our ability to successfully commercialize Soliris will depend, in part, on the extent to which we are able to provide adequate distribution of Soliris to patients. Although a number of specialty distributors and specialty pharmacies, which supply physician office clinics, hospital outpatient clinics, infusion clinics, home health care providers, and governmental organizations, distribute Soliris, they generally carry a very limited inventory and may be reluctant to distribute Soliris in the future if demand for the product does not increase. Further, it is possible that our distributors could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to distribute smaller volume products such as Soliris,

or cause higher product distribution costs, lower margins or the need to find alternative methods of distributing our product. Although we believe we can find alternative distributors on a relatively short notice, our revenue during that period of time may suffer and we may incur additional costs to replace a distributor. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us or any failure to pay for the products we have shipped to them could materially and adversely affect our results of operations and financial condition.

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

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

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

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

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws 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; reporting to pricing services inflated average wholesale prices 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 Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program.

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

significant expenses defending our position and have to divert significant management resources from other matters. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the

narrowness of the safe harbors and because government scrutiny in this area is high, it is possible that some of our business activities could come under that scrutiny.

In recent years, several states and localities, including California, the District of Columbia, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Additionally, as part of the Patient Protection and Affordable Care Act, the federal government has enacted the Physician Payment Sunshine provisions. Beginning in 2013, the Sunshine provisions require manufacturers to publicly report gifts and payments made to physicians and teaching hospitals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

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

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

All of our product candidates except Soliris are in early stages of development, and we do not expect our other product candidates to be commercially available for several years, if at all. Similarly, Soliris has not been approved for any indication other than for the treatment of patients with PNH in the United States, the European Union, Japan and other territories, and for patients with aHUS in the United States and the European Union. We do not know when or if our product candidates, including asfotase alfa and Soliris for other indications, will be approved. Our product candidates are subject to strict regulation by regulatory authorities in the United States and in other countries. We cannot market any product candidate until we have completed all necessary preclinical studies and clinical trials and have obtained the necessary regulatory approvals. We do not know whether regulatory agencies will grant approval for any of our product candidates. Even if we complete preclinical studies and clinical trials successfully, we may not be able to obtain regulatory approvals or we may not receive approvals to make claims about our products that we believe to be necessary to effectively market our products. Data obtained from preclinical studies and clinical trials are subject to varying interpretations that could delay, limit or prevent regulatory approval, and failure to comply with regulatory requirements or inadequate manufacturing processes are examples of other problems that could prevent approval. In addition, we may encounter delays or rejections due to additional government regulation from future legislation, administrative action or changes in the FDA policy. Even if the FDA approves a product, the approval will be limited to those indications covered in the approval.

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

Completion of preclinical studies or clinical trials does not guarantee advancement to the next phase of development.

Completion of preclinical studies or clinical trials does not guarantee that we will initiate additional studies or trials for our product candidates, including asfotase alfa, that if further studies or trials are initiated what the scope and phase of the trial will be or that they will be completed, or that if these further studies or trials are completed, that the design or results will provide a sufficient basis to apply for or receive regulatory approvals or to commercialize products. Results of clinical trials could be inconclusive, requiring additional or repeat trials. If the design or results achieved in our clinical trials are insufficient to proceed to further trials or to regulatory approval of our product candidates, including asfotase alfa, our company could be materially adversely affected. Failure of a clinical trial to achieve its pre-specified primary endpoint generally increases the likelihood that additional studies or trials will be required if we determine to continue development of the product candidate, reduces the likelihood of timely development of and regulatory approval to market the product candidate, and may decrease the chances for successfully achieving the primary endpoint in scientifically similar indications.

There are many reasons why drug testing could be delayed or terminated.

For human trials, patients must be recruited and each product candidate must be tested at various doses and formulations for each clinical indication. In addition, to ensure safety and effectiveness, the effect of drugs often must be studied over a long period of time, especially for the chronic diseases that we are studying. Many of our programs focus on diseases with small patient populations and insufficient patient enrollment in our clinical trials could delay or cause us to abandon a product development program. We may decide to abandon development of a product candidate, including asfotase alfa, 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:

- slow patient enrollment, including, for example, due to the rarity of the disease being studied;
- 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;
- the 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 manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner; and
- failure to obtain the necessary regulatory approvals for the product candidate or the approvals for the facilities in which such product candidate is manufactured.

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

The preclinical development, clinical trials, manufacturing, marketing and labeling of pharmaceuticals are all subject to extensive regulation by numerous governmental authorities and agencies in the United States and other countries. We must obtain regulatory approval for each of our product candidates, including 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. 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 that result in excessive costs, this may prevent us from continuing to develop our product candidates, including asfotase alfa. 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;
- limitation on the indicated uses for which a product may be marketed;
- unforeseen safety issues or side effects; and
- governmental or regulatory delays and changes in regulatory requirements and guidelines.

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

Physicians may elect not to recommend our drugs even if they receive marketing approval for a variety of reasons, including the timing of the market introduction of competitive drugs; lower demonstrated clinical safety and efficacy compared to other drugs; perceived lack of cost-effectiveness; lack of availability of reimbursement from third-party payers; convenience and ease of administration; prevalence and severity of adverse side effects; other potential advantages of alternative treatment methods; and ineffective marketing and distribution support. Sales of pharmaceutical products depend in significant part on the coverage and reimbursement policies of government programs, including Medicare and Medicaid in the United States and similar programs in other countries, and other third-party payers. These health insurance programs may restrict coverage of some products by using payer

formularies under which only selected drugs are covered, variable co-payments that make drugs

that are not preferred by the payer more expensive for patients, and by using utilization management controls, such as requirements for prior authorization or failure on another type of treatment. Payers may especially impose these obstacles to coverage for higher-priced drugs, and consequently our drug candidates may be subject to payer-driven restrictions. In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, countries in the European Union 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 member state may approve a specific price or level of reimbursement for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. The reimbursement or budget identified by a government or non-government payer for Soliris in a new indication, if obtained, may be adversely affected by the reimbursement or budget for Soliris in previously approved indications and/or adversely affect the reimbursement or budget for Soliris in such previously approved indication by that payer.

Inability to contract with third party manufacturers and other third party providers on commercially reasonable terms, or failure or delay by us or our third party manufacturers or other third party providers to provide services with respect to our drug products, including asfotase alfa if approved, in the volumes and quality required, would have a material adverse effect on our business.

Clinical quantities of eculizumab are manufactured by us at ARIMF and by Lonza. Clinical quantities of our other product candidates are manufactured by us at ARIMF or by a third party. We also depend on a very limited number of third party providers for other services with respect to our clinical and commercial requirements, including product finishing, packaging, vialing and labeling. We have changed or added third party vialers in the past in order to best ensure uninterrupted supply, and may do so in the future. No guarantee can be made that regulators will approve additional third party vialers in a timely manner or at all, or that any third party vialer will be able to perform such services for sufficient product volumes for any country or territory. Manufacture of our drug products, including asfotase alfa, is highly technical, and only a small number of companies have the ability and capacity to manufacture our drug products for our development and commercialization needs. Due to the highly technical requirements of manufacturing our drug products and the strict quality and control specifications, we and our third party providers may be unable to manufacture or supply our drug products despite our and their efforts. In addition, we cannot be certain that any third party will be able or willing to honor the terms of its agreement, including any obligations to manufacture the drug products in accordance with regulatory requirements and to our quality specifications and volume requirements. Further, we have limited experience manufacturing the drug candidates that we acquired from Enobia, Taligen and Orphatec, such as asfotase alfa, ALXN1102 and cPMP. We cannot guarantee that we or any third party provider will be able to manufacture or supply such drug candidates, or that we or a third party provider will be able to manufacture or supply sufficient quantities to satisfy our requirements.

Manufacture of drug products, including the need to develop and utilize manufacturing processes that consistently produce our drug products to their required quality specifications, is highly regulated by the FDA and other domestic and foreign authorities. Regulatory authorities must approve the facilities in which our products are manufactured vialed, packaged and labeled prior to granting marketing approval for any product candidate. Such facilities are also subject to ongoing inspections, and minor changes in manufacturing or other related processes may require additional regulatory approvals. We cannot assure you that we or our third party providers will successfully comply with all requirements and regulations, which failure could have a material adverse effect on our business.

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

in the applicable countries or regions, and we will continue to be subject to ongoing regulatory inspections thereafter. We, and our third party providers, may experience higher failure rates than in the past if and when we attempt to increase production volume. If we experience interruptions in the manufacture or supply of our products, our drug development and commercialization efforts will be delayed. If any of our outside third party providers stops manufacturing or supplying our products or reduces the amount manufactured or supplied, or is otherwise unable to provide our required amounts at our required quality, we may need to find other alternatives, which is likely to be expensive and time consuming, and also may result in reduced revenue during this period. Even if we are able to find alternatives they may ultimately be insufficient for our needs. As a result, our ability to conduct testing and drug trials and our plans for commercialization could

be materially adversely affected. Submission of products and new development programs for regulatory approval, as well as our plans for commercialization, would be delayed or suspended. Our competitive position and our prospects for achieving or maintaining profitability could be materially and adversely affected.

Due to the nature of the current market for third-party commercial manufacturing, many arrangements require substantial penalty payments by the customer for failure to use the manufacturing capacity for which it contracted. Penalty payments under these agreements typically decrease over the life of the agreement, and may be substantial initially and de minimis or non-existent in the final period. The payment of a substantial penalty could harm our financial condition.

Risks Related to Intellectual Property

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

In order to protect our drugs and technology more effectively, we need to obtain and maintain patents covering the drugs and technologies we develop. We have and may in the future obtain patents or the right to practice patents through ownership or license. Our patent applications may not result in the issue of patents in the United States or other countries. Our patents may not afford adequate protection for our products. Third parties may challenge our patents. If any of our patents are narrowed, invalidated or become unenforceable, competitors may develop and market products similar to ours that do not conflict with or infringe our patents rights, which could have a material adverse effect on our financial condition. We may also finance and collaborate in research conducted by government organizations, hospitals, universities or other educational or research institutions. Such research partners may be unwilling to grant us exclusive rights to technology or products developed through such collaborations. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties. Soliris and our drug candidates are expensive and time-consuming to test and develop. Even if we obtain and maintain patents, our business may be significantly harmed if the patents are not broad enough to protect our drugs from copycat products.

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

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

Parts of our technology, techniques and proprietary compounds and potential drug candidates, including those which are or may be in-licensed, may be found to infringe patents owned by or granted to others. On January 26, 2011, Novartis Vaccines & Diagnostics, Inc. (Novartis) filed a civil action against us and other biopharmaceuticals companies claiming willful infringement by us of its patent. If it is finally determined that we infringe the Novartis patent, we may be required to pay royalties to Novartis on sales of Soliris regarding certain manufacturing technology. Although we do not believe that the manufacture of Soliris infringes a valid patent claim owned by Novartis, we cannot guarantee that we will be successful in defending against such action. In addition to Novartis, other 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. We are aware of broad patents owned by others relating to the manufacture, use and sale of recombinant humanized antibodies, recombinant human antibodies, and recombinant human single chain antibodies. Soliris and many of our product candidates are genetically engineered antibodies, including recombinant humanized antibodies, recombinant human antibodies, or recombinant human single chain antibodies. In addition to the actions described above, we have received and may receive notices from the owners of some of these broad patents claiming that their patents may be infringed by the development, manufacture or sale of Soliris or some of our drug candidates. We are also aware of other 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.

Risks Related to Our Operations

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

Until the quarter ended June 30, 2008, we had never been profitable since we were incorporated in January 1992. We have maintained profitability on a quarterly basis since the quarter ended June 30, 2008 and on an annual basis beginning with the year ended December 31, 2008. We believe that we formulate our annual operating budgets with reasonable assumptions and targets, however we cannot guarantee that we will be able to generate sufficient revenues or control expenses to achieve our financial goals, including continued profitability. Even if we do achieve profitability in any subsequent quarters, we may not be able to sustain or increase profitability on a quarterly or annual basis. You should not consider our revenue growth in recent periods as indicative of our future performance. Our revenue in future periods could decline. We may make errors in predicting and reacting to relevant business trends or our business may be subject to factors beyond our control, which could harm our operations. Since we began our business, we have focused on research and development of product candidates. We launched Soliris for sale for the treatment of patients with PNH in the United States and Europe during 2007. We obtained marketing approval from the FDA and the E.C. for Soliris for the treatment of patients with aHUS in September and November 2011, respectively, and have not obtained marketing approval for aHUS in any other country or territory. We cannot guarantee that we will be successful in marketing and selling Soliris on a continued basis in countries or regions where we have obtained marketing approval, including the United States, Europe and Japan, and we do not know when we will have Soliris available for sale in territories where we have applied or will apply for marketing approval, if ever.

We incurred significant debt to finance the acquisition of Enobia and we will have substantial expenses as we continue our research and development efforts, integrate the programs we acquired from Enobia, Taligen and Orphatec, continue to conduct clinical trials, including the clinical trial initiated during the third quarter of 2011 to investigate eculizumab as a treatment for patients with STEC-HUS, 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, Europe and Japan and other territories, our ability to obtain regulatory, pricing, coverage, and reimbursement approvals of Soliris in additional countries and regions and for aHUS and other indications, our ability to successfully market Soliris in additional countries and regions, our ability to successfully manufacture and commercialize our drug candidates and our ability to successfully bring our other product candidates, including product candidates we acquired from Enobia, Taligen and Orphatec, 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 which entitles us to exclusivity for a total of seven years in the United States and for ten years in Europe and Japan. However, if a competitive product that is the same as Soliris, as defined under the applicable regulations, is shown to be clinically superior to Soliris in the treatment of the

stated disease, 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. These and other companies, many of which have significantly greater resources than us, may develop, manufacture, and market better or cheaper drugs than Soliris or our product candidates. They may establish themselves in the marketplace before us for Soliris for other indications

or for any of our other product candidates. Other pharmaceutical companies also compete with us to attract academic research institutions as drug development partners, including for licensing these institutions' proprietary technology. If our competitors successfully enter into such arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may not be able to find equivalent opportunities elsewhere.

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

In February 2012 we acquired Enobia Pharma Corp and made an upfront payment of approximately $624 million. We used a substantial portion of our cash on hand and incurred $320,000 of debt under the terms of a senior secured credit facility to finance the acquisition. In addition, the definitive agreements for each of the Enobia, Taligen and Orphatec acquisitions include contingent payments totaling $470,000 , $367,000 and $42,000, respectively, if and when certain development and commercial milestones are achieved. In May 2012 Alexion issued 5 million shares of its common stock in a public offering resulting in net proceeds of approximately $462,000. We believe that revenues and collections from sales of Soliris along with our existing cash and cash equivalents will provide sufficient capital to satisfy our debt service obligations and the contingent consideration required by the acquisitions, and to fund our operations and product development for at least twelve months. We may need to raise additional capital before or after that time to complete or continue the development or commercialization of our products and product candidates or for other purposes. We are currently selling or preparing for the commercialization of Soliris in the United States, Europe, Japan, and several other territories, evaluating and preparing regulatory submissions for Soliris in several countries, and conducting, preparing or evaluating several clinical trials. Funding needs may shift between projects and potentially accelerate and increase as we continue launch and commercialization activities throughout the world and as we initiate or continue clinical trials for our product candidates.

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

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

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

otherwise retain for ourselves. Any of these actions would harm our business.

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

We are highly dependent upon the efforts of our senior management and scientific personnel, particularly Dr. Leonard Bell, M.D., our Chief Executive Officer and a member of our Board of Directors, and Stephen P. Squinto, Ph.D., our Executive Vice President and Head of Research and Development. There is intense competition in the biopharmaceutical industry for qualified scientific and technical personnel. Since our business is science-oriented and specialized, we need to continue to attract and retain such people. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. We have employment agreements with Dr. Bell and Dr. Squinto. None of our key personnel is nearing retirement age or to our knowledge, planning to retire. To our knowledge, there is no tension between any of our key personnel and the Board of Directors. If we are unable to retain and recruit highly qualified personnel, our ability to execute our business plan will be materially and adversely affected.

In particular, we highly value the services of Dr. Bell, our Chief Executive Officer. The loss of his services could materially and adversely affect our ability to achieve our objectives.

We are significantly leveraged.

In February 2012 we and our wholly-owned Swiss subsidiary, Alexion Pharma International Sàrl, entered into a credit agreement (Credit Agreement) with a syndication of lenders. The Credit Agreement provides for a $240,000 senior secured term loan facility and a $200,000 senior secured revolving credit facility, which includes up to a $60,000 sublimit for letters of credit and a $10,000 sublimit for swingline loans. Our obligations under the credit facility are unconditionally guaranteed, jointly and severally, by certain of our existing domestic subsidiaries and are required to be guaranteed by certain of our future domestic subsidiaries. The obligations of Alexion Pharma International under the credit facilities are unconditionally guaranteed, jointly and severally, by us, certain of our existing domestic subsidiaries, and certain of our foreign subsidiaries, and are required to be guaranteed by certain of our future subsidiaries. All obligations of each borrower under the credit facilities, and the guarantees of those obligations, are secured, subject to certain exceptions, by substantially all of each borrower's assets and the assets of certain guarantors, including the pledge of the equity interests of certain of our subsidiaries and real estate located in Smithfield, Rhode Island, but excluding intellectual property and assets of certain foreign subsidiaries. We may elect that the loans under the credit facilities bear interest at a rate per annum equal to (i) LIBOR plus 1.25% to 2.00% depending on our consolidated leverage ratio (as calculated in accordance with the Credit Agreement), or (ii) in the case of borrowings in U.S. dollars, a Base Rate equal to the higher of the (A) Prime Rate then in effect, (B) Federal Funds Rate then in effect plus 0.50%, and (C) Eurodollar Rate then in effect plus 1.00%, plus in each case of (A), (B) or (C), 0.25% to 1.00% depending on our consolidated leverage ratio (as calculated in accordance with the Credit Agreement).

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

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

Our ability to meet our debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

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, the handling and disposal of non-hazardous and hazardous wastes, such as medical and biological wastes, and emissions and discharges into the environment, such as air, soils and water sources. Failure to comply with such laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We also are subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs of remediating its property or locations

to which wastes were sent from its facilities, without regard to whether the owner or operator knew of, or necessarily caused, the contamination. Such obligations and liabilities, which to date have not been material, could have a material impact on our business and financial condition.

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

Our business strategy includes expanding our products and capabilities. In 2011, we acquired Taligen and certain assets of Orphatec. In February 2012 we acquired Enobia. We may seek additional acquisitions or in-licensing of businesses or products to expand our products and capabilities. Acquisitions of new businesses or products, including the Enobia, Taligen and Orphatec acquisitions, and in-licensing of new products involve numerous risks, including:

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

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

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

Our ability to use net operating loss carry forwards to reduce future tax payments may be limited if there is a change in ownership of Alexion, or if taxable income does not reach sufficient levels.

As of December 31, 2011, we had approximately $464,900 of U.S. federal net operating loss carryforwards (NOL's), available to reduce taxable income in future years. Included in our U.S. federal net operating losses is approximately $36,500 associated with the acquisition of Taligen. A portion of these NOL's are currently subject to an annual limitation under section 382 of the Internal Revenue Code of 1986, as amended. We believe it is more likely than not that we will use the majority of net operating losses. However, the ability to use net operating loss carryforwards will be dependent on our ability to generate taxable income. The net operating loss carryforwards may expire before we generate sufficient taxable income.

Our ability to utilize the NOL's may be further limited if we undergo an ownership change, as defined in section 382. This ownership change could be triggered by substantial changes in the ownership of our outstanding stock, which are generally outside of our control. An ownership change would exist if the stockholders, or group of stockholders, who own or have owned, directly or indirectly, 5% or more of the value of our stock, or are otherwise treated as 5% stockholders under section 382 and the regulations promulgated there under, increase their aggregate percentage ownership of our stock by more than 50 percentage points over the lowest percentage of our stock owned by these stockholders at any time during the testing period, which is generally the three-year period preceding the potential ownership change. In the event of an ownership change, section 382 imposes an annual limitation on the amount of

post-ownership change taxable income a corporation may offset with pre-ownership change NOL's. The limitation imposed by section 382 for any post-change year would be determined by multiplying the value of our stock immediately before the ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Any unused annual limitation may be carried over to later years, and the limitation

may under certain circumstances be increased by built-in gains which may be present with respect to assets held by us at the time of the ownership change that are recognized in the five-year period after the ownership change. Our use of NOL's arising after the date of an ownership change would not be affected.

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

As a company with international operations, we are subject to income taxes, as well as non-income based taxes, in both the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities. Although we believe our estimates are reasonable, the ultimate outcome with respect to the taxes we owe may differ from the amounts recorded in our financial statements. If the Internal Revenue Service, or other taxing authority, disagrees with the positions taken by our company, we could have additional tax liability, and this could have a material impact on our results of operations and financial position. In addition, the United States government and other governments are considering and may adopt tax reform measures that significantly increase our worldwide tax liabilities which could materially harm our business, financial condition and results of operations.

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

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

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

Our business and marketing methods are also subject to regulation by the governments of the countries in which we operate. The United States Foreign Corrupt Practices Act (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 US dollar. We are exposed to fluctuations in foreign currency exchange rates in the normal course of our business. The exposures result from portions of our revenues, as well as the related receivables, and expenses that are denominated in currencies other than the US dollar, primarily the Euro, Japanese Yen and Swiss Franc. We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. We enter into foreign exchange forward contracts, with durations of up to 36 months, to hedge exposures resulting from portions of our forecasted intercompany revenues that are denominated in currencies other than the U.S. dollar. The purpose of the hedges of intercompany revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. Further, we

enter into foreign exchange forward contracts, with durations of approximately 30 days,

designed to limit the balance sheet exposure of monetary assets and liabilities. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results. Gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. While we attempt to hedge certain currency risks, currency fluctuations between the U.S. dollar and the currencies in which we do business have, in the past, caused foreign currency transaction gains and losses and have also impacted the amounts of revenues and expenses calculated in U.S. dollars and will likely do so in the future. Likewise, past currency fluctuations have at times resulted in foreign currency transaction gains, and there can be no assurance that these gains can be reproduced. See also Footnote 9, Derivative Instruments and Hedging Activities, in the Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q.

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

Sales of Soliris are dependent, in large part, on reimbursement from government health administration organizations and private and governmental third-party payers, and also co-payments from individual patients in certain situations. As a result of adverse credit and financial market conditions, and the overall financial climate, these governmental organizations and payers, and/or individuals, may reduce or delay initiation of treatment, may be unable to satisfy their reimbursement obligations, may delay payment or may seek to reduce reimbursement for Soliris in the future, which could have a material adverse effect on our business and results of operations. For example, in July 2011, we received non-interest bearing bonds issued by the Greek government that mature in 2012 and 2013 for payment on receivables from 2008 and 2009 as part of the Greek government's plan repayment of its debt to international pharmaceutical companies. We sold the associated bonds in July 2011 and recorded expense of approximately $4,100 through December 31, 2011 related to the reduction of value of the Greek bonds and other delays impacting the book value of our accounts receivable in other countries. Soliris is approved for the treatment of patients with PNH and aHUS in the United States and the European Union 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 international economies, associated impacts on the financial markets and our business, and the sovereign debt crisis in Europe. The credit and economic conditions in Greece, Italy and Spain, among other members of the European Union have deteriorated throughout 2011 and into 2012. These conditions have resulted in, and may continue to result in, an increase in the average length of time it takes to collect our outstanding accounts receivable in these countries. We have recorded an allowance related to receivables in Greece, Italy and Spain that have been outstanding for greater than one year as of September 30, 2012.

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

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

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

Governments in countries where we operate have adopted or have shown significant interest in pursuing legislative initiatives to reduce costs of health care, such as the Affordable Care Act adopted in the United States in March 2010. 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 governments of Germany and Spain each approved increases to mandatory rebates on the sales of

pharmaceutical products. The pricing and reimbursement environment for Soliris may become more challenging due to, among other reasons, changes in government policies or new legislation, or the impact of total Soliris reimbursement to any one payer. In many cases, these government initiatives, even if enacted into law, are subject to future rulemaking by regulatory agencies. Although we have evaluated these government initiatives and the impact on our business, we cannot know with certainty whether any such law, rule or regulation will adversely affect coverage and reimbursement of Soliris, or to what extent, until such laws, rules and regulations are promulgated, implemented and enforced. The announcement or adoption of regulatory or legislative proposals could delay or

prevent our entry into new markets, affect our reimbursement or sales in the markets where we are already selling Soliris and materially harm our business, financial condition and results of operations.

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

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

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

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

Risks Related to Our Common Stock

If the trading price of our common stock continues to fluctuate in a wide range, our stockholders will suffer considerable 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, and market conditions for biopharmaceutical stocks in general could have a significant impact on the future trading prices of our common stock. In particular, the trading price of the common stock of many biopharmaceutical companies, including ours, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of the companies whose stocks were affected. This is due to several factors, including general market conditions, sales of Soliris, the announcement of the results of our clinical trials or product development and the results of our efforts to obtain regulatory approval for our products. While we cannot predict our future performance, if our stock price continues to fluctuate in a wide range, an investment in our common stock may result in considerable uncertainty for an investor.

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

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

Our corporate charter and by-law provisions and stockholder rights plan may discourage certain types of transactions involving an actual or potential change of control that might be beneficial to us or our stockholders. Our bylaws provide that special meetings of our stockholders may be called only by the Chairman of the Board, the President, the Secretary, or a majority of the Board of Directors, or upon the written request of stockholders who together own of record 50% of the outstanding stock of all classes entitled to vote at such meeting. Our bylaws also specify that the authorized number of directors may be changed only by resolution of the board of directors. Our charter does not include a provision for cumulative voting for directors, which may have enabled a minority stockholder holding a

sufficient percentage of a class of shares to elect one or more directors. Under our charter, our board of directors has the authority, without further action by stockholders, to designate up to 5,000,000 shares of preferred stock in one or more series. The rights of the holders of common stock will be

subject to, and may be adversely affected by, the rights of the holders of any class or series of preferred stock that may be issued in the future.

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

Item 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 September 30, 2012 formatted in eXtensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets at September 30, 2012 and December 31, 2011 , (ii) the Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2012 and 2011, (iii) the Condensed Consolidated Statements of Cash Flows for the nine months ended September 31, 2012 and 2011 and (iv) Notes To Condensed Consolidated Financial Statements.

SIGNATURES

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

ALEXION PHARMACEUTICALS, INC.

By: /s/ Leonard Bell
Leonard Bell, M.D.
Date: October 29, 2012 Chief Executive Officer, Secretary and Treasurer (principal executive officer)

By: /s/ Vikas Sinha
Vikas Sinha, M.B.A., C.A.
Date: October 29, 2012 Senior Vice President and Chief Financial Officer (principal financial officer)