ALEXION PHARMACEUTICALS INC
Form 10-Q
November 05, 2009
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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, 2009

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 45 of Regulation S-T (§ 232.404 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 ¨ 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.:

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 Act) Yes ¨ No x

Common Stock, $0.0001 par value	88,566,016
Class	**Outstanding at November 2, 2009**

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ALEXION PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(in thousands, except per share amounts)	September 30, 2009	December 31, 2008
Assets		
Current Assets:		
Cash and cash equivalents	$ 165,295	$ 138,012
Restricted cash	487	
Trade accounts receivable, net	109,455	74,476
Inventories	40,999	49,821
Deferred tax assets	982	972
Prepaid expenses and other current assets	14,926	13,820
Total current assets	332,144	277,101
Property, plant and equipment, net	162,221	139,885
Intangible assets, net	29,247	32,325
Goodwill, net	19,954	19,954
Restricted cash	1,087	1,699
Deferred tax assets	5,012	3,397
Other assets	2,341	3,190
Total assets	$ 552,006	$ 477,551
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 15,117	$ 8,655
Accrued expenses	68,400	46,200
Deferred revenue	3,283	1,128
License payable		25,000
Deferred tax liabilities	651	639
Current debt obligations	20,000	2,500
Current portion of capital lease obligations	494	296
Total current liabilities	107,945	84,418
Capital lease obligations, less current portion	496	203
Mortgage loan, less current portion		44,000
Convertible notes	9,918	97,222
Deferred tax liabilities	924	906
Other liabilities	5,485	3,801
Total liabilities	124,768	230,550
Commitments and contingencies (Notes 4 and 5)		
Stockholders Equity:		
Preferred stock, $0.0001 par value; 5,000 shares authorized, no shares issued or outstanding		
Common stock, $0.0001 par value; 145,000 shares authorized; 88,550 and 81,418 shares issued at September 30, 2009 and December 31, 2008, respectively	5	5

Additional paid-in capital	1,078,638	941,439
Treasury stock, at cost, 96 and 57 shares, respectively	(2,676)	(1,260)
Accumulated other comprehensive income (loss)	(10,637)	2,947
Accumulated deficit	(638,092)	(696,130)
Total stockholders equity	427,238	247,001
Total liabilities and stockholders equity	$ 552,006	$ 477,551

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

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ALEXION PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(in thousands, except per share amounts)	Three months ended September 30, 2009	Three months ended September 30, 2008	Nine months ended September 30, 2009	Nine months ended September 30, 2008
Revenues:				
Net product sales	$ 102,628	$ 76,500	$ 276,151	$ 181,605
Contract research revenues				95
Total revenues	102,628	76,500	276,151	181,700
Cost of sales	11,895	8,948	32,167	21,554
Operating expenses:				
Research and development	21,323	14,874	58,700	47,306
Selling, general and administrative	41,523	32,064	120,880	94,754
Total operating expenses	62,846	46,938	179,580	142,060
Operating income	27,887	20,614	64,404	18,086
Other income and expense:				
Investment income	125	690	612	2,071
Interest expense	(80)	(634)	(522)	(1,975)
Foreign currency loss	(250)	(566)	(379)	(200)
Debt exchange expense			(3,395)	
Income before income taxes	27,682	20,104	60,720	17,982
Income tax provision	951	415	2,681	169
Net income	$ 26,731	$ 19,689	$ 58,039	$ 17,813
Net income per share				
Basic	$ 0.31	$ 0.26	$ 0.69	$ 0.24
Diluted	$ 0.29	$ 0.23	$ 0.65	$ 0.22
Shares used in computing net income per share				
Basic	87,447	76,658	84,464	75,794
Diluted	90,946	89,843	90,246	88,797

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

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ALEXION PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(in thousands)	Nine months ended September 30, 2009	2008
Cash flows from operating activities:		
Net income	$ 58,039	$ 17,813
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	8,935	5,529
Share-based compensation expense	21,853	17,881
Non-cash debt exchange expense	3,395	
Unrealized foreign currency gain	(3,057)	
Unrealized loss on forward contracts	1,673	
Loss on disposal of property, plant and equipment	108	44
Changes in operating assets and liabilities:		
Accounts receivable	(30,886)	(26,125)
Inventories	9,809	(15,980)
Prepaid expenses and other assets	(8,008)	(2,148)
Accounts payable and accrued expenses	17,493	22,879
Deferred revenue	2,044	2,456
Net cash flows from operating activities	81,398	22,349
Cash flows from investing activities:		
Proceeds from maturity or sale of marketable securities		8,733
Purchases of property, plant and equipment	(26,105)	(27,180)
Purchase of technology rights	(27,740)	(3,000)
Release of restricted cash	132	406
Net cash flows from investing activities	(53,713)	(21,041)
Cash flows from financing activities:		
Payments under capital lease obligations	(221)	(202)
Payments on mortgage loan	(24,000)	
Debt issuance costs		(312)
Net proceeds from exercise of employee stock options	22,533	28,018
Net cash flows from financing activities	(1,688)	27,504
Effect of exchange rate changes on cash	1,286	17
Net change in cash and cash equivalents	27,283	28,829
Cash and cash equivalents at beginning of period	138,012	95,321
Cash and cash equivalents at end of period	$ 165,295	$ 124,150

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

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ALEXION PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts)

1. Business

Alexion Pharmaceuticals, Inc. (Alexion or the Company) is a biopharmaceutical company engaged in the discovery, development and commercialization of biologic therapeutic products aimed at treating patients with severe and life-threatening disease states, including hematologic, kidney and neurologic diseases, transplant rejection, cancer and autoimmune disorders. Our marketed product Soliris® (eculizumab) is the first and only therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH. 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 of America 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 of America 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, 2008. In our opinion, the accompanying unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to state fairly our financial position as of September 30, 2009 and the results of our operations and cash flows for the three and nine months ended September 30, 2009 and 2008. The December 31, 2008 condensed consolidated balance sheet data was derived from audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States of America. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2008 included in our Annual Report on Form 10-K. The results of operations for the three and nine months ended September 30, 2009 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 in stockholders equity. Foreign currency transaction gains and losses are included in the results of operations in other income (expense).

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

We have reclassified certain amounts for the prior period to conform to the current year presentation.

We have evaluated subsequent events through November 4, 2009. No material subsequent events have occurred since September 30, 2009 that required recognition or disclosure in these financial statements.

3. Revenue

Our principal source of revenue is product sales. We have applied the following principles in recognizing revenue:

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 patients health-care provider, which is typically a hospital, physician s office, pharmacy or health care facility. Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in the Company s statements of operations and do not impact net product sales.

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(in thousands, except per share amounts)

In the United States, our customers are primarily specialty distributors and specialty pharmacies which supply physician office clinics, hospital outpatient clinics, infusion clinics or home health care providers. We also sell Soliris to government agencies. Outside the United States, our customers are primarily hospitals, hospital buying groups, pharmacies, other health care providers and distributors.

Because of the pricing of Soliris, the limited number of patients, the short period from sale of product to patient infusion and the lack of contractual return rights, Soliris customers generally carry limited inventory. We monitor inventory within our distribution channel to determine whether deferral of sales is required. To date, actual refunds and returns have been negligible.

We record estimated rebates payable under governmental programs, including Medicaid and programs in Europe, as a reduction of revenue at the time product sales are recorded. Our calculations related to these rebate accruals require estimates, including 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. Generally, the length of time between product sale and the processing and reporting of the rebates is three to six months. Upon reconciliation of government reporting to our sales records, we revise our estimates of rebates payable, which may have an impact on revenue in the period in which the adjustment is made.

We record distribution and other fees paid to our customers as a reduction of revenue. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

We record the effective portion of our cash flow hedges to revenue in the period in which the derivative contract is settled.

4. Royalties

Our cost of sales for the three and nine months ended September 30, 2009 and 2008 includes royalties to third parties related to the sale and commercial manufacture of Soliris. We estimate our royalty obligations based on existing contractual obligations and our assessment of estimated royalties owed to other third parties. These estimates may be influenced by the outcome of future litigation or other claims, if any, the results of which are uncertain. On a periodic basis and based on specific events such as the outcome of litigation or settlement of claims, we may reassess these estimates, resulting in adjustments to cost of sales.

5. Inventories

Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of inventory using the average cost method.

The following table summarizes the components of our inventories:

	September 30, 2009	December 31, 2008
Raw materials	$ 2,595	$ 3,805
Work-in-process	5,257	27,017
Finished goods	33,147	18,999
	$ 40,999	$ 49,821

We have recorded approximately $10,476 of pre-approval inventory within property, plant and equipment. We will reclassify amounts to inventory in the period in which we have obtained regulatory approval and such inventory can be available for commercial sale.

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(in thousands, except per share amounts)

Two third party contractors provide vialing services for Soliris. In July 2009, we became aware that one of the vialers is undergoing regulatory review by the European Medicines Evaluation Agency, or EMEA to address deficiencies at its facility. We do not believe that this situation, even if resolved adversely, will result in a constraint on our ability to satisfy demand for Soliris supply. We believe we hold sufficient Soliris inventory to satisfy patient needs for commercial and clinical Soliris for the foreseeable future. Further, our second vialer continues to produce Soliris on a routine basis, and we believe they have the capacity to meet our current and future commercial and clinical needs.

If the contractor under review is unable to release certain lots of product to us for sale, it may be necessary to dispose of the inventory. As previously disclosed, the contractor informed us that it is actively developing a plan to resume manufacturing, release and shipment of product. During the three months ended September 30, 2009, approximately $8,100 of inventory vialed by the contract manufacturer was released to us for sale, however, approximately $2,900 of inventory remains at risk of disposal or expiry if the situation is resolved adversely. We continue to evaluate the situation, and at this time we can not estimate whether and to what extent a loss on this inventory is probable.

6. Comprehensive Income

The following table summarizes components of our comprehensive income:

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Net income	$ 26,731	$ 19,689	$ 58,039	$ 17,813
Defined benefit pension plan activity				(245)
Unrealized gains (losses) on hedge contracts	(5,525)	6,861	(14,039)	6,861
Foreign currency translation adjustment	296	(294)	455	(1,649)
Comprehensive income	$ 21,502	$ 26,256	$ 44,455	$ 22,780

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts)

7. Exit Activities

In December 2006, we initiated an integration plan with our subsidiary, Alexion Antibody Technologies, Inc., or AAT, to consolidate certain functions and operations, including the termination of all AAT personnel, closure of AAT facilities, and impairment of equipment in that facility. These costs were recognized as liabilities during the year ended December 31, 2006. The following table summarizes the activity recorded during the nine months ended September 30, 2009 and 2008:

	Nine Months Ended September 30,	
	2009	2008
Accrual balance, beginning of period	$ 596	$ 763
Revision of estimate	54	
Payments and other settlements	(181)	(124)
Accrual balance, end of period	$ 469	$ 639

We remain obligated for lease payments through 2012. In September 2007, we signed a sub-lease for the AAT facility, which provides for sub-lease payments through the term of the lease, or 2012. The accrual for restructuring activities reflects the present value of lease obligations, reduced by estimated sub-lease income.

8. Debt

In April and May 2009, we issued an aggregate of 5,644 shares of our common stock in exchange for $87,304 principal amount of our 1.375% Convertible Senior Notes due 2012 owned by certain note holders. The issuance of the shares was made solely in exchange of the notes pursuant to an exemption from the registration requirements of the Securities Act of 1933, as amended, under Section 3(a)(9) of such Act. We did not receive any cash proceeds as a result of the exchange, and the notes were retired and cancelled. The note holders received shares from the exchange in excess of the amount that they would have received pursuant to their conversion rights under the notes. In the second quarter of 2009, we recorded a non-cash expense of $3,395 for the fair value of the additional shares over the stated conversion rate. As of September 30, 2009, $9,918 of the convertible notes remains outstanding, and the fair value, based on quoted market prices, was estimated at $27,901.

On June 30, 2009, we amended our mortgage loan agreement to permit the prepayment of the mortgage loan without penalty. The mortgage loan accrued interest at a rate of 9.12% per annum. Through September 30, 2009, we prepaid $24,000 of the principal balance of the mortgage loan, without penalty, resulting in an outstanding principal balance of $20,000. In October 2009, we prepaid in full the remaining $20,000 balance of the mortgage loan.

In the second quarter 2009, we determined that we were not in compliance with a negative covenant relating to investments in subsidiaries under our revolving credit facility. In July 2009, our lender waived non-compliance, and we amended the credit agreement to modify the negative covenant.

In September 2009, we amended the credit agreement to modify other financial, non-financial and negative covenants. The covenants were modified to address the Company s expanding operations since the credit agreement was originally executed in early 2008.

9. Earnings (Loss) Per Common Share

Basic earnings per share (EPS) are computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding. For purposes of calculating diluted EPS, net income (loss) 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 options, unvested restricted stock 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.

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(in thousands, except per share amounts)

The following table summarizes the calculation of basic and diluted EPS for the three and nine months ended September 30, 2009 and 2008:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net income	$ 26,731	$ 19,689	$ 58,039	$ 17,813
Effect of dilutive securities:				
Interest expense and debt fee amortization related to our 1.375% convertible senior notes	11	528	287	1,694
Net income diluted	26,742	20,217	58,326	19,507
Shares used in computing net income per common share basic	87,447	76,658	84,464	75,794
Effect of dilutive securities:				
Shares issuable upon the assumed conversion of our 1.375% convertible senior notes	631	9,538	3,073	9,538
Stock options	2,449	3,032	2,342	2,953
Unvested restricted stock	419	615	367	512
Dilutive potential common shares	3,499	13,185	5,782	13,003
Shares used in computing net income per common share diluted	90,946	89,843	90,246	88,797
Net income per share:				
Basic	$ 0.31	$ 0.26	$ 0.69	$ 0.24
Diluted	$ 0.29	$ 0.23	$ 0.65	$ 0.22

The following table represents the potentially dilutive shares excluded from the calculation of EPS for the three and nine months ended September 30, 2009 and 2008 because their effect is anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Options to purchase common stock	2,024	1,217	2,442	1,526
Unvested restricted stock	19	13	28	68
	2,043	1,230	2,470	1,594

10. Derivative Instruments and Hedging Activities

In March 2008, the Financial Accounting Standards Board (FASB) revised the authoritative guidance for disclosures about derivative instruments and hedging activities, which requires entities to provide enhanced disclosures about how and why the entity uses derivative instruments, how the instruments and related hedged items are accounted for and how the instruments and related hedged items affect the financial position, results of operations, and cash flows of the entity. The Company adopted the provisions of the guidance during the three month period ended March 31, 2009.

The authoritative guidance establishes accounting and reporting standards for derivative instruments and hedging activities and requires the Company to recognize these as either assets or liabilities on the balance sheet and measure them at fair value. The accounting for gains and losses resulting from changes in fair value is dependent on the use of the derivative and whether it is designated and qualifies for hedge accounting.

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(in thousands, except per share amounts)

All hedging activities are documented at the inception of the hedge and must meet the definition of highly effective in offsetting changes to future cash flows to be a qualifying hedge. The effectiveness of the qualifying hedge contract is assessed quarterly. We record the fair value of our hedges in other current assets and other current liabilities. Gains or losses resulting from changes in the fair value of qualifying hedges are recorded in other comprehensive income until the forecasted transaction occurs. When the forecasted transaction occurs, the effective amount is reclassified into revenue. Any ineffective portion of the gains or losses resulting from changes in fair value, if any, is reported in other income or other expense.

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

We enter into foreign exchange contracts, with durations of up to 18 months, 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. As of September 30, 2009, we have open contracts with notional amounts totaling $141,798 that qualified for hedge accounting.

We enter into foreign exchange contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities of our foreign subsidiaries. These derivative instruments do not qualify for hedge accounting under the guidance; however, gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. As of September 30, 2009, the notional settlement amount of forward foreign exchange contracts relating to monetary assets and liabilities was $57,214.

The following table summarizes the Company s fair value of outstanding derivatives at September 30, 2009:

	Asset Derivatives 2009		Liability Derivatives 2009	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange contracts	Other current assets	$ 5	Accrued expenses	$ 9,208
Derivatives not designated as hedging instruments:				
Foreign exchange contracts	Other current assets	306	Accrued expenses	1,497
Total Derivatives		**$ 311**		**$ 10,705**

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts)

The impact on other comprehensive income (OCI) and earnings from foreign exchange contracts that qualified as cash flow hedges, for the three and nine months ended September 30, 2009, are as follows:

Foreign Exchange Contracts	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009
Gain (loss) recognized in OCI	$ (5,525)	$ (14,039)
Gain (loss) reclassified from OCI to net product sales (Effective portion)	$ 444	$ 6,940
Gain (loss) reclassified from OCI to other income and expense (Ineffective portion)	$ 270	$ 482

Assuming no change in foreign currency rates from market rates at September 30, 2009, $8,848 of the loss recognized in other comprehensive income is expected to be reclassified to revenue over the next twelve months.

We recognized a gain(loss) of $(2,096) and $1,976, in other income(expense), for the three months ended September 30, 2009 and 2008, respectively, and $(5,045) and $1,862, for the nine months ended September 30, 2009 and 2008, 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.

11. Stock-Based Compensation

The following table summarizes the components of stock-based compensation expense in the consolidated statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Research and development	$ 2,108	$ 1,200	$ 6,163	$ 4,355
Selling, general and administrative	4,871	4,790	15,690	13,526
	$ 6,979	$ 5,990	$ 21,853	$ 17,881

The following table summarizes the stock-based compensation capitalized to inventory and fixed assets:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Stock-based compensation expense capitalized to inventory	$ 435	$ 312	$ 1,004	$ 839
Stock-based compensation expense capitalized to fixed assets	$ 202	$ 481	$ 854	$ 1,250

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts)

12. Fair Value Measurement

The table below presents information about our assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2009 and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

		Fair Value Measurement at September 30, 2009			
Balance Sheet Classification	**Type of Instrument**	**Total**	**Level 1**	**Level 2**	**Level 3**
Cash equivalents	Money market funds	$ 107,162	$	$ 107,162	$
Other assets	Foreign exchange contracts	$ 311	$	$ 311	$
Accrued expenses	Foreign exchange contracts	$ 10,705	$	$ 10,705	$

As of September 30, 2009, 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.

13. Income Taxes

Despite achieving profitability, we continue to maintain a full valuation allowance against substantially all U.S. and certain foreign deferred tax assets where realization of those assets remains uncertain. Accordingly, we have not reported any tax benefit relating to the remaining net operating loss carryforwards (NOLs) and income tax credit carryforwards that will be utilized in future periods in these jurisdictions.

We will continue to reassess the need for a valuation allowance on a quarterly basis. We would consider reversing a significant portion of the valuation reserve upon assessment of certain factors, including a demonstration of sustained profitability and the support of internal financial forecasts demonstrating the utilization of the NOLs prior to their expiration. If we determine that the reversal of the valuation reserves in these jurisdictions is appropriate, a substantial, one-time, non-cash, income tax benefit will be recognized in the period of the reversal. Such release of valuation allowance on our U.S. deferred tax assets could occur in whole, or part, in the near-term; however, the exact timing and the portion of the valuation allowance released are subject to change based on the level of profitability that we achieve, as well as our forecasted profitability. The total deferred tax asset balance subject to valuation allowance was approximately $268,000 at December 31, 2008.

During the three and nine months ended September 30, 2009, we recorded an income tax provision of $951 and $2,681, respectively, compared to an income tax provision of $415 and $169, for the three and nine months ended September 30, 2008. The tax provision for the three and nine months ended September 30, 2009 is principally attributable to entities in certain foreign jurisdictions that reported profitability during the period as well as U.S. federal alternative minimum tax and certain state income taxes. The tax provision for the three and nine months ended September 30, 2008 was principally attributable to entities in certain foreign jurisdictions who reported profitability during the period.

14. Employee Benefit Plans

Defined Contribution Plans

We have two qualified 401(k) plans covering all eligible U.S. employees. Under the plans, employees may contribute up to the statutory allowable amount for any calendar year. For the three months ended September 30, 2009 and 2008, we recorded matching contributions of approximately $371 and $322, respectively. For the nine months ended September 30, 2009 and 2008, we recorded matching contributions of approximately $1,221 and $1,055, respectively.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts)

Defined Benefit Plan

We maintain a defined benefit plan for employees in Switzerland. The assets of the funded plan are held independently of our assets in a legally distinct and independent collective trust fund which serves various unrelated employers. Annually, the plan is 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. For the three months ended September 30, 2009 and 2008, we recorded net periodic benefit costs of $71 and $39, respectively. For the nine months ended September 30, 2009 and 2008, we recorded net periodic benefit costs of $203 and $120 respectively.

15. Recently Issued Accounting Pronouncements

On July 1, 2009, the FASB issued The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles (the Codification). The Codification establishes the exclusive authoritative reference for U.S. GAAP for use in financial statements, except for SEC rules and interpretive releases, which are also authoritative GAAP for SEC registrants. The Codification will supersede all existing non-SEC accounting and reporting standards. We have included the references to the Codification, as appropriate, in these consolidated financial statements.

In May 2009, the FASB issued authoritative guidance for subsequent events, which establishes general standards of accounting for, and requires disclosure of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. We adopted the provisions of the guidance for the quarter ended June 30, 2009. The adoption of the guidance did not have a material effect on our consolidated financial statements.

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(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 future indications, timing and effect of sales of Soliris in various markets worldwide, level of future Soliris sales and collections, costs, expenses and capital requirements, cash outflows, cash from operations, impact of interest rate changes on our outstanding obligations, status of reimbursement, price approval and funding processes in various countries worldwide, progress in developing commercial infrastructure and interest about Soliris 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 around the world, sales and marketing plans, any changes in the current or anticipated market demand or medical need for Soliris, potential clinical trials of our product candidates for new indications, status of our ongoing clinical trials, commencement dates for new clinical trials, evaluation of our clinical trial results by regulatory agencies in other countries, prospects for regulatory approval in other countries, the need for additional research and testing, the uncertainties involved in the drug development process and manufacturing, our future research and development activities, assessment of competitors and potential competitors, estimates of the capacity and ability of Alexion and third parties to provide manufacturing, product finishing, vial filling, packaging and other services to support Soliris and our product candidates, assessment of our ability to satisfy customer demand for Soliris if the inventory held by our finished vial contractor is not released for sale, costs relating to the validation process at the Rhode Island facility, timing for submission of sBLA for commercial production of eculizumab at the Rhode Island facility, 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, potential for release of tax valuation allowances, and the effect of shifting currency exchange rates. Words such as anticipates, expects, intends, plans, believes, seeks, estimates, variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this report under the section entitled Risk Factors. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in other reports or documents we file from time to time with the Securities and Exchange Commission.

Business

Overview

We are a biopharmaceutical company engaged in the discovery, development and commercialization of biologic therapeutic products aimed at treating patients with severe and life-threatening disease states, including hematologic, kidney and neurologic diseases, transplant rejection, cancer and autoimmune disorders. Our marketed product Soliris® (eculizumab) is the first and only therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH.

Soliris is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation associated with chronic hematologic, kidney and neurological disorders, transplant rejection, and autoimmune disorders. Soliris is a humanized monoclonal antibody that generally blocks complement activity for one to two weeks after a single dose at the doses currently prescribed. The initial indication for which we received approval for Soliris is PNH. PNH is a rare, debilitating and life-threatening, acquired genetic deficiency blood disorder defined by the 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).

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In March 2007, the Food and Drug Administration, or FDA, granted marketing approval for Soliris. In the United States, Soliris is indicated for the treatment of all patients with PNH to reduce hemolysis. We began commercial sale of Soliris in the United States during April 2007.

In June 2007, the European Commission, or E.C., approved the use of Soliris for patients with PNH in the European Union, which also serves as the basis for approval in Iceland and Norway. Subsequently, we engaged with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country and have initiated commercialization in those countries where this process was completed.

We were granted marketing approval in Canada in January 2009 and Australia in February 2009 for the use of Soliris for patients with PNH.

In January 2009, the Ministry of Health, Labour and Welfare of Japan designated Soliris as an orphan drug. Among other things, this designation will provide us, if Soliris is approved for marketing and sale in Japan, with 10 years of market exclusivity for Soliris as a treatment for patients with PNH in Japan, subject to limited exceptions. In March 2009, we submitted a New Drug Application for Soliris as a treatment for PNH patients to Japan s Pharmaceuticals and Medical Devices Agency.

In April 2009 and August 2009, the FDA and E.C. granted Soliris Orphan Drug Designation for the treatment of patients with atypical Hemolytic Uremic Syndrome, or aHUS, an ultra-rare, inherited, and life-threatening complement-inhibitor deficiency disease that often progresses to end-stage kidney disease or failure. Alexion is currently enrolling patients in four clinical studies of Soliris as an investigational treatment for adolescent and adult patients with aHUS.

Clinical

We are focusing our research and development efforts on the use of eculizumab as a treatment for patients with other rare and severe complement-mediated conditions, including kidney diseases, transplant rejection and other severe chronic disorders. We are particularly focusing our development efforts in two lead development areas: nephrology and transplant.

Nephrology

We are currently engaged in four clinical studies to investigate the use of eculizumab as a treatment for patients with aHUS, a disease in which the lack of naturally occurring complement inhibitors can cause life-threatening kidney damage. We are also aware that an investigator-initiated trial of eculizumab is ongoing in patients with dense deposit disease, another ultra-rare and severe kidney disease that can evolve into chronic renal failure, requiring dialysis and renal transplantation.

Transplant

We are aware that independent investigators are evaluating eculizumab in kidney transplant patients at elevated risk of rejection and we are considering initiating controlled clinical trials. We are further considering expansion of development efforts to include investigation of eculizumab as a treatment for patients undergoing transplantation of other organs.

Other Eculizumab Development Programs

The FDA authorized our Investigational New Drug Application, or IND, for studying the safety and efficacy of eculizumab in treating myasthenia gravis, a rare autoimmune syndrome characterized by the failure of

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neuromuscular transmission, and we are currently enrolling patients in this trial. We are also aware that independent investigators are examining the role of eculizumab for the treatment of two additional neurological disorders: multifocal motor neuropathy and neuromyelitis optica. We are also considering clinical development of eculizumab for cold agglutinin disease, an ultra-rare auto-immune hemolytic anemia.

Oncology

The FDA authorized our IND to evaluate the activity of an antibody to the immune regulator CD200 in patients with chronic lymphocytic leukemia, or CLL, an incurable chronic cancer that results from expansion of B-lymphocytes. We continue dosing of CLL patients with anti-CD200, which commenced in the second quarter of 2008, and have begun to screen and enroll patients with multiple myeloma as we expand our anti-CD200 clinical program.

Manufacturing

We currently rely on a single third-party contract manufacturer for commercial quantities of Soliris. We obtain drug product to meet our requirements for clinical studies using both internal and third-party contract manufacturing capabilities. For both clinical and commercial requirements, we have contracted and expect to continue contracting for product finishing, vial filling and packaging through third parties.

In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island for the future commercial production of Soliris and development and manufacturing of future products. We submitted a supplemental BLA during the third quarter of 2009 for commercial production of eculizumab at this facility. The EMEA and FDA have commenced their inspections of our Rhode Island manufacturing facility. We also commenced the use of our Rhode Island facility for the production and purification of certain of our product candidates for clinical studies.

Our most significant agreement with a third party manufacturer is the large-scale product supply agreement with Lonza Sales AG, or Lonza, dated December 18, 2002, which has been amended from time to time. This agreement, the Lonza Agreement, relates to the manufacture of eculizumab. An amendment to the Lonza Agreement, dated June 8, 2007, provides for additional production and minimum quantity purchase commitments of Soliris of $30,000 to $35,000 from 2009 through 2013. Such commitments may be cancelled only in limited circumstances. If we terminate the Lonza Agreement without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we expect to pay Lonza a royalty on sales of Soliris manufactured at our Rhode Island facility.

Two third party contractors provide vialing services for Soliris. In July 2009, we became aware that one of the vialers is undergoing regulatory review by the EMEA to address deficiencies at its facility. We do not believe that this situation, even if resolved adversely, will result in a constraint on our ability to satisfy demand for Soliris supply. We believe we hold sufficient Soliris inventory to satisfy patient needs for commercial and clinical Soliris for the foreseeable future. Further, our second vialer continues to produce Soliris on a routine basis, and we believe they have the capacity to meet our current and future commercial and clinical needs.

If the contractor under review is unable to release certain lots of product to us for sale, it may be necessary to dispose of the inventory. The contractor has informed us that it is actively developing a plan to resume manufacturing, release and shipment of product. During the three months ended September 30, 2009, approximately $8,100 of inventory vialed by the contract manufacturer was released for sale, however, approximately $2,900 remains at risk of disposal or expiry if the situation is resolved adversely. We continue to evaluate the situation, and at this time we can not estimate whether and to what extent a loss on this inventory is probable.

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, 2008. Under accounting principles generally

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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. We base our assumptions, judgments and estimates on historical experience and various other factors that we believe to be reasonable under the circumstances. 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, so we consider these to be our critical accounting policies:

Revenue recognition

Royalties

Inventories

Research and development expenses

Stock-based compensation

Long-lived assets

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, 2008. We have reviewed our critical accounting policies as disclosed in our Form 10-K, and we have not noted any material changes.

Results of Operations

Revenues

Net product sales

The following table summarizes product revenue for the three and nine months ended September 30, 2009 and 2008:

	Three months ended September 30,		Increase / (Decrease)	Nine months ended September 30,		Increase / (Decrease)
	2009	2008	$ Change	2009	2008	

			$ Change			$ Change
Net product sales	$ 102,628	$ 76,500	$ 26,128	$ 276,151	$ 181,605	$ 94,546

The increase in revenue for the three and nine months ended September 30, 2009, as compared to the same period in 2008, was due to an increased number of patients treated with Soliris. The increase in treated patients was due to additional patients and physicians requesting Soliris therapy, as well as reimbursement and price approvals in additional countries.

Cost of sales

Cost of sales was $11,895 and $8,948, for the three months ended September 30, 2009 and 2008, respectively and $32,167 and $21,554, for the nine months ended September 30, 2009 and 2008, respectively. Cost of sales as a percentage of net product revenue was 11.6% and 11.7% for the three months ended September 30, 2009 and 2008 and 11.6% and 11.9% for the nine months ended September 30, 2009 and 2008, respectively. Cost of sales includes manufacturing costs, as well as royalty expenses associated with sales of Soliris.

On a periodic basis and based on events such as the outcome of litigation, we may reassess the estimates of royalties owed to certain third parties. Changes in these estimates could have a material impact on our cost of sales in future periods.

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Research and Development

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 pre- and post-approval manufacturing development and regulatory functions. 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 as well as 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,		
	2009	2008	$ Variance	2009	2008	$ Variance
Clinical development	$ 6,246	$ 3,982	$ 2,264	$ 16,676	$ 15,614	$ 1,062
Product development	2,667	1,668	999	7,316	5,347	1,969
Discovery research	497	359	138	1,233	923	310
Total external direct expenses	**9,410**	**6,009**	**3,401**	**25,225**	**21,884**	**3,341**
Payroll and benefits	9,807	6,844	2,963	27,051	19,761	7,290
Operating and occupancy	1,176	1,048	128	3,682	3,039	643
Depreciation and amortization	930	973	(43)	2,742	2,622	120
Total other R&D expenses	**11,913**	**8,865**	**3,048**	**33,475**	**25,422**	**8,053**
Research and development expense	**$ 21,323**	**$ 14,874**	**$ 6,449**	**$ 58,700**	**$ 47,306**	**$ 11,394**

For the three months ended September 30, 2009, the increase in research and development expense of $6,449, as compared to the same period in the prior year, was primarily related to the following:

Increase of $2,264 in external clinical development expenses related primarily to an increase in spending for the study of eculizumab for non-PNH indications (see table below).

Increase of $2,963 in research and development payroll and benefit expense related primarily to manufacturing and product development activities at our production facility in Smithfield RI and global expansion of staff supporting our expanding number of clinical programs.

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For the nine months ended September 30, 2009, the increase in research and development expense of $11,394, as compared to the same period in the prior year, was primarily related to the following:

Increase of $7,290 in research and development payroll and benefit expense related primarily to manufacturing and product development activities at our production facility in Smithfield RI and global expansion of staff supporting our expanding number of clinical programs.

Increase of $1,969 in external product development expenses related primarily to increases in manufacturing development activities at our production facility in Smithfield RI.

Increase of $1,062 in external clinical development expenses related primarily to an increase in spending for the study of eculizumab for non-PNH indications (see table below).

The following table summarizes external direct expenses related to our clinical development programs:

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
External direct expenses				
Eculizumab: PNH program	$ 2,197	$ 3,007	$ 6,193	$ 11,309
Eculizumab: non-PNH programs	3,665	200	7,536	1,165
CD200 program	292	146	876	495
Unallocated	92	629	2,071	2,645
	$ 6,246	**$ 3,982**	**$ 16,676**	**$ 15,614**

At this time, due to the risks inherent in the clinical trial process and given the early stages of our various product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our programs for potential commercialization. While we are focused on advancing each of our product development programs, our future R&D expenses will depend on the determinations we make as to the scientific and clinical success of each program, as well as ongoing assessments as to program s commercial potential. As such, we are unable to predict how we will allocate available resources among our product development programs in the future.

The successful development of our drug candidates is uncertain and subject to a number of risks. A large portion of our annual expenses relates to commercialization of Soliris and general and administrative costs. We may not have or be able to raise the necessary capital to support both the commercialization of Soliris as well as each of our development programs through and until commercialization. Further, 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, including the risk factors set forth under the headings, If we fail to obtain the capital necessary to fund our operations, we will be unable to continue the commercialization of Soliris or continue to complete our product development , None of our product candidates except for Soliris has received regulatory approvals , Completion of preclinical studies or clinical trials does not guarantee advancement to the next phase of development and There are many reasons why drug testing could be delayed or terminated .

Selling, General and Administrative Expenses

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.

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

	Three months ended September 30,		$	Nine months ended September 30,		$
	2009	2008	Variance	2009	2008	Variance
Selling, general and administrative expense	$ 41,523	$ 32,064	$ 9,459	$ 120,880	$ 94,754	$ 26,126

For the three months ended September 30, 2009, the increase of $9,459 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 $5,590. The increases in these costs were a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs related to our global commercial teams of $5,051. This increase was also due to increases in payroll and benefits of $539 within other operational groups to support our worldwide growth.

Increase in external selling, general and administrative expenses of $3,869 was due primarily to increases in marketing and consulting services of $1,632, travel costs of $427, occupancy and depreciation expenses of $877 relating to new and expanded office space in Europe, Japan, Canada and Australia and $242 for our patient assistance program.

For the nine months ended September 30, 2009, the increase of $26,126 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 $14,782. The increases in these costs were a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs related to our global commercial teams of $10,683. This increase was also due to increases in payroll and benefits of $4,099 within other operational groups to support our worldwide growth.

Increase in external selling, general and administrative expenses of $11,344 was due primarily to increases in marketing and consulting services of $4,702, travel costs of $1,753 and occupancy and depreciation expenses of $3,061 relating to new and expanded office space in Europe, Japan, Canada and Australia.

Other Income and Expense

We recognize investment income primarily from our portfolio of cash equivalents and short-term marketable securities. Investment income was $125 and $690, for the three months ended, and $612 and $2,071, for the nine months ended, September 30, 2009 and 2008, respectively. The decreases were due to lower interest rates during the three and nine months ended September 30, 2009, as compared to the same period in the prior year.

We incur interest on our convertible notes, mortgage loan, revolving credit facility and capital lease obligations. Our interest expense is net of capitalized interest related to the construction and validation of our Rhode Island manufacturing facility, of $865 and $1,208 for the three months ended, and $3,221 and $3,496 for the nine months ended, September 30, 2009 and 2008, respectively. Interest expense was $80 and $634, for the three months ended, and $522 and $1,975, for the nine months ended, September 30, 2009 and 2008, respectively. The decrease in

interest expense was due to the lower principal balance of our convertible notes as a result of the note conversion in October 2008 and exchange in April and May 2009, as well as prepayment of our mortgage loan during the three months ended September 30, 2009.

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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 $250 and $566, for the three months ended, and $379 and $200, for the nine months ended, September 30, 2009 and 2008, respectively. The loss recorded in these periods was primarily a result of the fluctuation in exchange rates on the portion of our monetary assets and liabilities that were not fully hedged.

Income Taxes

During the three and nine months ended September 30, 2009, we recorded an income tax provision of $951 and $2,681, respectively, compared to an income tax provision of $415 and $169, for the three and nine months ended September 30, 2008. The tax provision for the three and nine months ended September 30, 2009 is principally attributable to entities in certain foreign jurisdictions who reported profitability during the period as well as U.S. federal alternative minimum tax and certain state income taxes. The tax provision for the three and nine months ended September 30, 2008 was principally attributable to entities in certain foreign jurisdictions who reported profitability during the period.

The Company maintains a valuation allowance against certain U.S. and foreign deferred tax assets as realizability of those assets is uncertain. We will continue to reassess the need for a valuation allowance on a quarterly basis. We would consider reversing a significant portion of the valuation reserve upon assessment of certain factors, including a demonstration of sustained profitability and the support of internal financial forecasts demonstrating the utilization of the NOLs prior to their expiration.

We may release the valuation allowance on our U.S. deferred tax assets in the near-term; however, the exact timing and the portion of the valuation allowance released are subject to change based on the level of profitability that we achieve, as well as our forecasted profitability. If we determine that the reversal of the valuation reserves in these jurisdictions is appropriate, a substantial, one-time, non-cash, income tax benefit will be recognized in the period of the reversal, resulting in a significant increase in our reported net income during this period. The total deferred tax asset balance subject to valuation allowance was approximately $268,000 at December 31, 2008.

Because we expect our recorded tax rate to increase in subsequent periods following a significant release of the valuation allowance, our net income will be negatively affected in the period following the release, even though there is no impact on the amount of cash paid for income taxes due to our substantial domestic NOL carryforwards.

Net Income (Loss)

The Company recorded net income of $26,731 or $0.29 per diluted share and $19,689 or $0.23 per diluted share for the three months ended September 30, 2009 and 2008, respectively. The Company recorded net income of $58,039 or $0.65 per diluted share and $17,813 or $0.22 per diluted share for the nine months ended September 30, 2009 and 2008, respectively.

Liquidity and Capital Resources

As of September 30, 2009, our consolidated cash and cash equivalents totaled $165,295. The $27,283 increase from December 31, 2008 is primarily related to increased sales and the resulting collection of accounts receivable and proceeds from employee option exercises, offset by investments in our Smithfield, Rhode Island facility, repayment of our mortgage loan, payment of year-end accruals and $27,500 in final payments related to technology rights. Until required for use in the business, we invest our cash reserves in highly-rated money market funds and high quality commercial, corporate and U.S. Government notes in accordance with our investment policy. We do not have any investments in auction rate securities or collateralized debt obligations.

Financial instruments that potentially expose us to concentrations of credit risk are limited to cash equivalents, accounts receivable and our foreign exchange derivative contracts. Substantially all cash equivalents are currently held in a AAA rated

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institutional money market fund and highly rated corporate debt securities. At September 30, 2009, one individual customer accounted for 17.8% of the accounts receivable balance. At September 30, 2008, two individual customers accounted for 27.3% and 20.2% of the accounts receivable balance.

For the three and nine months ended September 30, 2009, one customer accounted for 18.9% and 19.6% of our product sales, respectively. For the three and nine months ended September 30, 2008, one customer accounted for 18.5% and 21.6% of our product sales, respectively.

At September 30, 2009, we have foreign currency forward contracts with notional amounts totaling $199,012. These outstanding foreign currency forward contracts had a net cumulative loss of $10,394. The counterparty to these forward contracts is a large multinational commercial bank, and we believe the risk of nonperformance is not material. However, we can not be assured that the financial institution will not be further impacted by the negative economic environment.

At September 30, 2009, our working capital was $224,199, compared to $192,683 at December 31, 2008. At September 30, 2009, our current ratio was 3.08, compared to 3.28 at December 31, 2008. The decrease in current ratio relates primarily to the reclassification of the $20,000 mortgage loan from noncurrent to current liabilities due to our intent to prepay the full amount in the next 12 months.

We anticipate that cash generated from operations and our existing available cash, as well as interest and investment income earned on available cash and marketable securities, should provide us adequate resources to fund our operating expenses and capital requirements as currently planned for at least the next twelve months.

Operating Activities

Net cash provided by operating activities was $81,398 and $22,349 for the nine months ended September 30, 2009 and 2008, respectively. The change is primarily due to the net income achieved in 2009 versus the net income achieved in the same period in 2008. The components of cash provided by operating activities for the nine months ended September 30, 2009 are as follows:

Our reported net income, adjusted for non-cash items, including depreciation and amortization, non-cash debt exchange expense, unrealized currency gain, unrealized hedge gains and stock compensation, of $90,946.

Net cash outflow due to changes in operating assets and liabilities of $9,548, primarily relates to increases in accounts receivable of $30,886 offset by a $17,493 increase in accounts payable and accrued expenses.

Investing Activities

Net cash used in investing activities was $53,713 and $21,041 for the nine months ended September 30, 2009 and 2008, respectively. For the nine months ended September 30, 2009, the net cash used for investing activities consisted of the following:

Additions to property, plant and equipment of $26,105, of which $19,607 was attributable to expenditures related to our Rhode Island manufacturing facility, with the remaining attributable to spending on information technology and facility capital costs.

Payments of $25,000 and $2,500 related to the final payment for the PDL settlement and OMRF patent purchase agreement, respectively.

In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island for the future commercial production of Soliris and development and manufacturing of future products. Since this date, we have incurred costs related to the construction of the plant to support full-scale commercial manufacturing. We have also capitalized costs related to validation activities, including engineering runs and pre-approval inventory necessary to obtain approval of the facility from government regulators for the production of a commercially approved drug. We will

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begin depreciating the fixed assets related to the facility when the assets are substantially complete and ready for their intended use, which would occur upon the regulatory approval of the plant for production of commercial quantities of eculizumab. The EMEA and FDA have commenced their inspections of our Rhode Island manufacturing facility.

Through September 30, 2009, we have capitalized $143,253 related to the facility, which includes all costs associated with construction, renovation and upgrades, engineering runs, pre-approval inventory production and capitalized interest. Through September 30, 2009, costs incurred in seeking regulatory approval, including engineering runs and pre-approval inventory production, was $66,084, and capitalized interest was $12,265. We expect to continue to incur costs related to the validation and approval process through the end of 2009 and possibly into 2010.

At such point that we receive regulatory approval, we would cease capitalizing costs into property, plant and equipment. We have recorded approximately $10,476 of pre-approval inventory within property, plant and equipment. We will reclassify amounts to inventory in the period in which we have obtained regulatory approval and such inventory can be available for commercial sale.

Financing Activities

Net cash provided by (used in) financing activities was $(1,688) and $27,504 for the nine months ended September 30, 2009 and 2008, respectively. These amounts consisted primarily of proceeds from the issuance of common stock related to the exercise of stock options. In 2009, this amount was offset by a $24,000 prepayment on mortgage loan.

Borrowings and Contractual Obligations

The disclosure of payments we have committed to make under our contractual obligations are summarized in Form 10-K for the twelve-months ended December 31, 2008, in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations under the caption Contractual Obligations. Other than the note exchanges and prepayment of our mortgage loan described below, there have been no material changes in our contractual obligations.

Significant borrowings and contractual obligations include the following:

Revolving Credit Facility

In February 2008, we entered into a Credit Agreement with a financial institution to provide for an available $25,000 revolving credit facility that can be used for working capital requirements and other general corporate purposes. The loan is collateralized by substantially all of Alexion Pharmaceuticals, Inc. s assets, including the pledge of the equity interests of certain direct subsidiaries, but excluding intellectual property, assets of foreign subsidiaries and assets related to our manufacturing facility in Smithfield, RI. The borrowing base is limited to the lesser of $25,000 or 80% of eligible domestic receivables. We had no outstanding borrowings under the revolving credit facility as of September 30, 2009 other than $5,000 in letters of credit.

We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.75% to 2.25% depending on Alexion s liquidity (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect and (B) the Federal Funds Rate then in effect plus 0.50%, plus an additional 0% to 0.25% depending on Alexion s liquidity. 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 28, 2011, the maturity date.

The revolving credit facility requires that we comply with quarterly financial covenants related to liquidity and profitability ratios, as well as minimum revenue requirements. Further, the 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, and enter into transactions with affiliates. The 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.

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(in thousands, except per share amounts)

In the second quarter 2009, we determined that we were not in compliance with a negative covenant related to investments in our subsidiaries and intercompany balances under our revolving credit facility. In July 2009, our lender waived noncompliance, and we amended the agreement to modify the negative covenant.

In September 2009, we amended the credit agreement to modify other financial, non-financial and negative covenants. The covenants were modified to address the Company s expanding operations since the credit agreement was originally executed in early 2008.

Convertible Notes

As of September 30, 2009, we held $9,918 principal amount of 1.375% Convertible Senior Notes due February 1, 2012, or the 1.375% Notes. We pay interest on these notes on a semi-annual basis on February 1 and August 1 of each year, beginning August 1, 2005. However, no principal payments are due until February 2012, except under certain circumstances such as liquidation, merger or business combination. The convertible notes payable do not contain covenants related to our financial performance.

In April and May 2009, we issued an aggregate of 5,644 shares of our common stock in exchange for $87,304 principal amount of our 1.375% Convertible Senior Notes due 2012 owned by certain note holders.

The 1.375% Notes are convertible into our common stock at an initial conversion rate of 63.5828 shares of common stock (equivalent to a conversion price of approximately $15.73 per share) per $1 principal amount of the 1.375% Notes, subject to adjustment, at any time prior to the close of business on the final maturity date of the notes. We do not have the right to redeem any of the 1.375% Notes prior to maturity.

As of September 30, 2009, the market value of the 1.375% Notes, based on quoted market prices, was estimated at $27,901. The $183,205 decrease in fair value from December 31, 2008 is primarily attributable to the exchange of $87,304 principal amount of the notes for 5,644 shares of common stock during the first half of 2009.

Mortgage Loan

At September 30, 2009 we had a mortgage loan for the purchase and construction of our manufacturing facility in Smithfield, Rhode Island. On June 30, 2009, we amended the mortgage loan agreement to permit the prepayment of the loan without penalty. Through September 30, 2009, we prepaid $24,000 of the principal balance of the mortgage loan, without penalty, resulting in an outstanding balance of $20,000. In October 2009, we prepaid in full the remaining $20,000 balance of the mortgage loan.

Lonza Agreement

We have a supply agreement with Lonza Sales AG relating to the manufacture of Soliris, which requires payments to Lonza at the inception of the contract and as product is manufactured. We are required to prepay certain amounts related to the production of Soliris, which are recorded in prepaid expenses. Once we take title to the inventory produced by Lonza, the amounts are reclassified into inventory. On an ongoing basis, we evaluate our plans to proceed with production of Soliris by Lonza, which depends upon our commercial requirements, the progress of our clinical development programs and the status of our Smithfield, Rhode Island manufacturing facility. Under an existing arrangement with Lonza, we expect to pay Lonza a royalty on net sales of Soliris manufactured at our Rhode Island facility.

We have agreed to purchase certain minimum quantities of product from Lonza under our existing arrangements. If we terminate the Lonza Agreement without cause, we will be required to pay for batches of product scheduled for manufacture under our arrangement.

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MRC Agreement

In March 1996, the Company entered into a license agreement with the Medical Research Council, or MRC, whereby MRC granted to the Company worldwide non-exclusive rights to certain patents related to the humanization and production of monoclonal antibodies. We pay MRC royalties on a quarterly basis with respect to sales of Soliris. The royalty is payable until the last to expire of the patents covered by the license agreement, which is expected to be in 2015. MRC may terminate the license if Alexion files for bankruptcy or becomes insolvent, or if Alexion fails to perform its obligations under the agreement and such failure is not remedied within three months after delivery of notice. Under the agreement, Alexion has agreed to (a) make royalty payments with respect to sales of licensed products, (b) promote the sale of Soliris of good marketable quality, and (c) use reasonable endeavors to meet market demand for licensed products.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

Interest Rate Market Risk

As of September 30, 2009, we held substantially all of our cash equivalents in money market funds with original maturity dates of three months or less.

Our outstanding long-term liabilities as of September 30, 2009 included our $9,918, 1.375% Convertible Senior Notes due February 1, 2012. As the notes bear interest at a fixed rate, our results of operations would not be impacted by interest rate changes. As of September 30, 2009, the market value of our $9,918 1.375% convertible senior notes due February 1, 2012, based on quoted market prices, was estimated at $27,901.

In February 2008, we entered into a revolving credit facility with a financial institution and may borrow up to $25,000. We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.75% to 2.25% depending on Alexion s liquidity (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect and (B) the Federal Funds Rate then in effect plus 0.50%, plus 0% to 0.25% depending on Alexion s liquidity (as calculated in accordance with the agreement). We do not expect changes in interest rates related to our revolving credit facility to have a material effect on our financial statements.

Foreign Exchange Market Risk

As a result of our foreign operations, we face exposure to movements in foreign currency exchange rates, primarily the Euro, British Pound, Swiss Franc and Japanese Yen. The current exposures arise primarily from cash, accounts receivable, intercompany receivables and payables, product sales and expenses 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 currently have two programs related to our foreign currency exposure, 1) a program to limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet and 2) a program to hedge a portion of our forecasted product sales to mitigate fluctuations in foreign exchange rates. Both programs utilize forward foreign exchange contracts intended to reduce, not eliminate, the impact of fluctuations in foreign currency rates.

As of September 30, 2009, we had foreign currency forward contracts with notional amounts totaling $199,012, of which $141,798 qualified for hedge accounting. As of September 30, 2009, our outstanding foreign currency forward contracts had a cumulative net loss of $10,394.

We do not use derivative financial instruments for speculative trading purposes. The counterparty to these forward contracts is a multinational commercial bank. We believe the risk of counterparty nonperformance is not material. However, we can not be assured that the financial institution will not be further impacted by the negative economic environment.

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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 change fluctuation in exchange rates would result in a material change in the fair value of our foreign currency sensitive assets, which include our monetary assets and liabilities and our 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.

Item 4. Controls and Procedures

As of September 30, 2009, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2009.

There have been no changes in our internal control over financial reporting in connection with the evaluation required under paragraph (d) of Rule 13a-15 under the Exchange Act that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1A. Risk Factors

You should carefully consider the following risk factors before you decide to invest in our Company 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, which was approved in the United States and in Europe in March 2007 and June 2007, respectively, for the treatment of PNH. If we are unable to increase sales of Soliris in the United States and Europe and commercialize Soliris in additional countries or if we are significantly delayed or limited in doing so, our business will be materially harmed.

Our ability to generate revenues will depend on commercial success of Soliris in the United States, Europe and throughout the rest of the world and whether physicians, patients and healthcare payers view Soliris as therapeutically effective and safe relative to cost. Since we launched Soliris in the United States in April 2007, almost 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.

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

- the number of patients with PNH who are diagnosed with the disease and identified to us;
- the number of patients with PNH that may be treated with Soliris;
- successful continuation of commercial sales in the United States and in European countries where we are already selling Soliris, and successful launch in countries where we have not yet obtained marketing approval or commenced sales;
- ability to obtain and maintain sufficient coverage or reimbursement by third-party payers;
- acceptance of Soliris in the medical community;
- ability to effectively market and distribute Soliris in the United States, Europe and the rest of the world;
- receipt and maintenance of marketing approvals from the United States and foreign regulatory authorities; and
- establishment and maintenance of commercial manufacturing capabilities ourselves or through third-party manufacturers.

We obtained marketing approval for Soliris in Europe in June 2007 however such approval did not automatically authorize us to commence commercial sales in every country in the European Union. We continue discussions with appropriate authorities in different countries in Europe

so that we may, upon conclusion of such discussions, commence commercial sales in those countries. We have submitted applications for marketing authorization in countries outside the European Union and have received approval in Canada in January 2009 and Australia in February 2009. We cannot guarantee that reimbursement and other discussions and processes will be concluded successfully or on a timely basis and, as a result, sales in certain countries may be delayed or never occur, or may be subsequently reduced. If we are not successful in increasing sales of Soliris in the United States and commercializing in the rest of the world, or are significantly delayed or limited in doing so, we may experience a surplus inventory, our business will be materially harmed and we may need to significantly curtail operations.

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Because the target patient population of Soliris for the treatment of PNH is small and has not been definitively determined, we must be able to successfully identify PNH patients and achieve a significant market share in order to achieve or maintain profitability.

The prevalence of PNH patients has not been definitively determined but can be estimated at approximately 8,000 10,000 total patients in North America and Western Europe. There can be no guarantee that any of our programs will be effective at identifying PNH patients and the number of PNH patients in the United States and Europe may turn out to be lower than expected or may not be otherwise amenable to treatment with Soliris, all of which would adversely affect our results of operations and our business.

If we are unable to obtain and maintain reimbursement for Soliris from government health administration authorities, private health insurers and other organizations, Soliris may be too costly for regular use and our ability to generate revenues would 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. If these entities refuse to provide coverage and reimbursement with respect to Soliris or determine to provide a lower level of coverage and reimbursement than anticipated, Soliris may be too costly for general use, and physicians may not prescribe it.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control and 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. Our results of operations may suffer if we are unable to successfully and timely conclude reimbursement, price approval or funding processes and begin to market Soliris in foreign countries or if coverage and reimbursement for Soliris in foreign countries is limited. If we discover 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 in such countries and our plans for geographic expansion of sales and our business may be adversely affected as a result.

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.

In addition to potential restrictions on coverage, the amount of reimbursement for 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, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs. See additional discussion below under the headings Healthcare reform measures could adversely affect our business and The current credit and financial market conditions may aggravate certain risks affecting our business.

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Even 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. In the United States, Alexion has financially supported the PNH Fund of the National Organization for Rare Disorders, or NORD, which, among other things, assists patients in accessing treatment for PNH, including Soliris. Organizations such as NORD assist patients whose insurance coverage leaves them with prohibitive co-payment amounts or other expensive financial obligations. NORD s ability to provide assistance to PNH 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.

In furtherance of our efforts to facilitate access to Soliris in the United States, we have created the Soliris OneSource Program, a treatment support service for patients with PNH and their healthcare providers. Alexion Nurse case managers provide education about PNH and Soliris and help facilitate solutions for reimbursement, coverage and access. Although case managers assist patients and healthcare providers in locating and accessing Soliris, we cannot guarantee a sufficient level of coverage, reimbursement or financial assistance.

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

We cannot be certain that Soliris will gain or maintain market acceptance on a country-by-country basis among physicians, patients, healthcare payers, and others. Although we have received regulatory approval for Soliris in the United States, Europe, Australia and Canada, such approvals do not guarantee future revenue. We cannot predict whether physicians, other healthcare providers, government agencies or private insurers will determine that our products are safe and therapeutically effective relative to cost. Medical doctors willingness to prescribe, and patients willingness to accept, our products depend 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 our products, publicity concerning our products or competing products, our ability to obtain and maintain third-party coverage or reimbursement, and availability of alternative treatments, including bone marrow transplants. If Soliris fails to achieve or maintain market acceptance on a country-by-country basis, we may not be able to market and sell it successfully in such countries, which would limit our ability to generate revenue and could harm our overall business.

If we or our 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 future partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by the Food and Drug Administration, or FDA, other federal and state agencies, and governmental authorities in other countries or group of countries. These regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, risk mitigation, adverse event reporting requirements, and export of biologics. As a condition of approval for marketing our product, governmental authorities may require us to conduct additional clinical trials. For example, in connection with the approval of Soliris in the United States, we have 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. The FDA can propose to withdraw approval if new clinical data or information shows that a product is not safe for use in an approved indication or determines that such studies are inadequate. We are required to report any serious and unexpected adverse experiences and certain quality problems with Soliris to the FDA, the European Medicines Evaluation Agency, or EMEA, and certain other health

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agencies. We, the FDA, the EMEA or another health agency may have to notify healthcare 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. 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 and subject to continued review and periodic inspections by the regulatory authorities. Each of the EMEA and the FDA commenced their inspections of our Rhode Island manufacturing facility however we cannot sell Soliris manufactured at this facility until receipt of approval from such agencies, which we may never receive. Any third party we would use to manufacture Soliris for sale must also be licensed by applicable regulatory authorities.

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

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

The discovery of previously unknown problems with a product, including Soliris, or the facility used to produce the product could result in a regulatory authority imposing restrictions on us, or could cause us to voluntarily adopt such restrictions, including withdrawal of Soliris from the market.

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 have tested Soliris in only a small number of patients. As more patients begin to use Soliris, new risks and side effects, or the rate of such risks or side effects, may be discovered, 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, or off-label, uses of Soliris. We do not promote, or in any way support or encourage the promotion of Soliris for off-label uses in violation of relevant law, but physicians are permitted to use products for off-label purposes and we are aware of such off-label uses of Soliris. In addition, we are studying and expect to continue to study Soliris in diseases other than PNH in controlled clinical settings, and expect independent investigators to do so as well. In the event of any new risks or adverse effects discovered as new patients are treated for PNH and as Soliris is studied in or used by patients for off-label 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.

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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. 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 may be 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 or 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 Neisseria bacteria. Serious cases of Neisseria infection can result in severe illness, including but not limited to brain damage, loss of limbs or parts of limbs, kidney failure, or death. PNH patients in our TRIUMPH and SHEPHERD trials all received vaccination against Neisseria bacteria prior to first administration of Soliris and all patients who are prescribed Soliris are required by prescribing guidelines to be vaccinated prior to receiving their first dose; however, vaccination does not eliminate all risk of becoming infected with Neisseria bacteria. Some patients treated with Soliris, who had been vaccinated, including patients who have participated in our trials of Soliris for the treatment of PNH and other diseases, have become infected with Neisseria bacteria, 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. 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 for PNH.

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Although we obtained regulatory approval of Soliris for PNH in the United States, Canada, Australia and Europe, we may be unable to obtain regulatory approval for Soliris in any other territory.

Governments in countries outside the United States and Europe also regulate drugs distributed in such countries and facilities in such countries where such drugs are manufactured, and obtaining their approvals can also 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. Soliris became commercially available in certain countries in Europe in the fourth quarter of 2007. We received regulatory approval for Soliris for treatment of patients with PNH in Canada in January 2009 and Australia in February 2009. We may not receive regulatory approval for Soliris outside the United States, Canada, Australia and Europe for at least the next several years, if ever.

Regulatory agencies may require additional information or data with respect to our submissions for Soliris for PNH. 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 by the FDA, Health Canada, Therapeutic Goods Administration in Australia, and the E.C., other regulatory agencies 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. For example, we were required to conduct clinical studies with Soliris in patients with PNH in Japan; however, there is no assurance that the Japanese regulatory agency will find these studies sufficient for registration of Soliris in Japan.

We are currently entirely dependent on a single third party to manufacture commercial quantities of Soliris and our commercialization of Soliris may be stopped, delayed or made less profitable if such third party, or any other supply vendor, fails to provide us with sufficient quantities of Soliris.

Only Lonza Sales AG, or Lonza, is currently capable of manufacturing commercial quantities of Soliris. We will not be capable of manufacturing Soliris for commercial sale, on our own, until such time as we have received the required regulatory approvals for our manufacturing facility in Rhode Island, if ever. Each of the EMEA and FDA have commenced their inspection of our Rhode Island manufacturing facility however we cannot sell Soliris manufactured at this facility until receipt of approval from such agencies. Therefore, we will continue to depend entirely on one company, Lonza, to manufacture Soliris for commercial sale until that time. We cannot be certain that Lonza will be able to perform uninterrupted supply chain services. The failure of Lonza to manufacture appropriate supplies of Soliris, on a timely basis, or at all, may prevent or interrupt the commercialization of Soliris. If Lonza were unable to perform its services for any period, we may incur substantial loss of sales until such time as we are capable of manufacturing a sufficient commercial quantity of Soliris at our manufacturing facility, if ever. If we are forced to find an alternative supplier for Soliris, in addition to loss of sales, we may also incur significant costs in establishing a new arrangement.

In addition to currently depending on a single manufacturer for commercial supply of Soliris, we also depend on a few outside vendors for other services with respect to our clinical and commercial requirements, including product finishing, packaging, vialing and labeling. We do not have control over any third-party manufacturer s, vialer s or other third party provider s compliance with the rules and regulations of the FDA, EMEA or any other applicable regulations or standards. Any difficulties or delays in our third party manufacturing and supply of Soliris and other product candidates, or any failure of our third party providers to maintain compliance with the applicable regulations and standards could increase our costs, constrain our ability to satisfy demand for Soliris from customers, cause us to lose revenue, make us postpone or cancel clinical trials, or cause our products to be recalled or withdrawn.

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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.

In the United States, we sell Soliris to distributors 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. For the three months ended September 30, 2009, our single largest customer accounted for 18.9% of our Soliris net product sales, and our three largest customers accounted for approximately 34.6% of our net product sales. As of September 30, 2009, one individual customer accounted for 17.8% of the accounts receivable balance. We expect such customer concentration to continue for the foreseeable future. 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 and through our subsidiaries in Europe, but have only limited experience thus far with marketing, sales or distribution of drug products. We have established commercial capabilities in the United States and in Europe. If we are unable to establish and/or expand the capabilities to sell, market and distribute Soliris, 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 in the United States and in Europe 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 disproportional 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

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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 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. We market Soliris for PNH and provide promotional materials and training programs to physicians regarding the use of Soliris for PNH. Although we believe our marketing, promotional 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, and 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. 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.

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

Including Eculizumab for Indications Other than PNH

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. If we are unable to obtain regulatory approvals to market one or more of our product candidates, or 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, and we do not expect approval for use of Soliris in other indications for several years, if at all. 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, that if the studies or trials are initiated what the scope and phase of the trial will be or that they will be completed, or that if the studies or trials are completed, that the results will provide a sufficient basis to proceed with further studies or trials or 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 results achieved in our clinical trials are insufficient to proceed to further trials or to regulatory approval of our product candidates, our company could be materially adversely affected. Failure of a preclinical study or 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. Unfavorable results or insufficient patient enrollment in our clinical trials could delay or cause us to abandon a product development program. We may decide to abandon development of a product candidate at any time, 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;

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- 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; or
- 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 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. 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 our drug 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; 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 programs in other countries, and other third-party payers. These health insurance programs may restrict coverage of some products by using payor formularies under which only selected drugs are covered, variable co-payments that make drugs that are not preferred by the payor more expensive for patients, and by using utilization management controls, such as requirements for prior authorization or failure on another type of treatment. Payors may especially impose these obstacles to coverage for higher-priced drugs, and consequently Soliris may be subject to payor-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

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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 payor for Soliris in an indication other than PNH, if obtained, may be adversely affected by the reimbursement or budget for Soliris in PNH and/or adversely affect the reimbursement or budget for Soliris in PNH by that payor.

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

Clinical quantities of eculizumab are manufactured by us in our Rhode Island facility and by Lonza. Clinical quantities of CD200 are manufactured solely by us in Rhode Island. Manufacture of our drug products is highly technical and only a small number of companies have the ability and capacity to manufacture our drug products for our development and commercialization needs. 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. Due to the highly technical requirements of manufacturing our drug products, our third-party collaborators and we may be unable to manufacture our drug products despite their and our efforts.

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 prior to granting marketing approval for any product candidate. Manufacturing facilities are also subject to ongoing inspections, and minor changes in manufacturing processes may require additional regulatory approvals. We cannot assure you that we or our third-party collaborators will successfully comply with all requirements and regulations, which failure would have a material adverse effect on our business.

We currently have no experience or capacity for 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 currently depend on a single manufacturer for commercial supply of Soliris. We acquired a commercial-scale manufacturing plant in Smithfield, Rhode Island in July 2006. However, that plant is not currently approved by the FDA or other regulatory agencies to manufacture Soliris. Each of the FDA and EMEA have commenced their inspections of the facility but we expect that it will be at least 2010 before product from the plant is approved for commercial sale in the United States and Europe, if ever. We have no experience in developing commercial-scale manufacturing similar to anticipated production in Smithfield, Rhode Island. We can provide no assurance that we will be able to manufacture our drug products at our Smithfield, Rhode Island plant under conditions required by the FDA or foreign regulatory agencies on a timely basis, if at all. Our plant in Smithfield, Rhode Island is subject to approval by national and regional regulatory agencies before we can begin sales of Soliris or other drug products manufactured in this facility in such country or region, and we will continue to be subject to ongoing regulatory inspections thereafter.

We, and our outside manufacturers, may experience higher manufacturing failure rates than in the past, if and when, we attempt to substantially increase production volume. If we experience interruptions in the manufacture of our products, our drug development and commercialization efforts will be delayed. If any of our outside manufacturers stops manufacturing our products or reduces the amount manufactured, or is otherwise unable to manufacture our required amounts at our required quality, we will need to find other alternatives, which is likely to be expensive and time consuming. 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 would 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 would be materially and adversely affected.

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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 would harm our financial condition.

Risks Related to Intellectual Property

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

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 suppliers, outside scientists and other drug companies. Collaboration presents 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.

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 may obtain patents or the right to practice patents through ownership or license. Soliris and our drug candidates are expensive and time-consuming to test and develop. Without patent protection, competitors may copy our methods, or the chemical structure or other aspects of our drugs. Even if we obtain and maintain patents, the patents may not be broad enough to protect our drugs from copycat products.

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

Parts of our technology, techniques and proprietary compounds and potential drug candidates, including those which are or may be in-licensed, may be found to infringe patents owned by or granted to others. We previously reported that three civil actions were filed against us relating to the commercialization of Soliris and the intellectual property rights of third parties. Each of these cases was resolved in 2008, however, additional third parties may claim that the manufacture, use or sale of Soliris or other drugs under development infringes patents owned or granted to such third parties. 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 either 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 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 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 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. 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.

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There can be no assurance that we would prevail in a patent infringement action; that we would be able to obtain a license to any third-party patent on commercially reasonable terms; 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 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 may not be able 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 started our company in January 1992. We may not be able to generate sufficient revenues to achieve continued profitability in any subsequent quarters. 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. Because we have only limited experience thus far with marketing, sales and distribution of Soliris, we have limited insight into the trends that may emerge and affect us. We may make errors in predicting and reacting to relevant business trends, which could harm our business. As of December 31, 2008, we had an accumulated deficit of approximately $696,000. Since we began our business, we have focused on research and development of product candidates. We launched Soliris for sale in the United States during April 2007 and began commercial sales in Europe during the fourth quarter of 2007. We cannot guarantee that we will be successful in marketing and selling Soliris in countries or regions where we have obtained marketing approval, including the United States and Europe, on a continued basis, and we do not know when we will have Soliris available for sale in other countries and regions, if ever. All of our other product candidates are still in the early stages of research and development. We will have substantial expenses as we continue our research and development efforts, continue to conduct clinical trials, and continue to develop manufacturing, sales, marketing and distribution capabilities in the United States and abroad. Our future profitability depends on our ability to successfully market Soliris in the United States and Europe, on receiving regulatory, pricing, coverage, and reimbursement approvals of Soliris in other countries and regions, our ability to successfully market Soliris in other countries and regions, and our ability to successfully manufacture and commercialize our drug candidates. The extent and the timing of our future losses and our profitability are highly uncertain.

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

Both the FDA and the EMEA, have granted orphan drug designation for Soliris in the treatment of PNH, which entitles us to exclusivity for seven years in the United States and for ten years in Europe. 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 PNH, 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. Other companies have publicly announced intentions to develop therapeutic human antibodies from libraries of human antibody genes or therapeutic human antibodies from mice that have been bred to include some human antibody genes. A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us. 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 Alexion 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.

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

We believe that revenues and collections from sales of Soliris along with our existing cash and cash equivalents will provide sufficient capital 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. We are currently selling or preparing for the commercialization of Soliris in the United States, Europe, Canada, Latin America and Asia-Pacific, 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, 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 and for eculizumab for other indications 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; and
- any new collaborative, licensing or other commercial relationships that we may establish.

We may not receive funding when we need it or funding may only be available on unfavorable terms. Financial markets in the U.S., 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 credit or equity markets in order to finance our operations in the United States or Europe, 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

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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 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 the handling and disposal of non-hazardous and hazardous wastes, including medical and biological wastes, and emissions and discharges into the environment, including 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, and we may seek acquisitions or in-licensing of business or products to do so. Acquisitions of new businesses or products 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; and
- the potential loss of our key employees or key employees of the acquired companies.

We compete with pharmaceutical companies that have significantly greater resources than us for many of the same acquisition and in-licensing opportunities. Such pharmaceutical companies that are less leveraged and have better access to capital resources may preclude us from completing any acquisition or in-licensing. Even if we are able to complete an acquisition or in-licensing, we cannot assure you that any

acquisition or in-licensing of new products will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or an acquired or in-licensed product. In addition, our future success 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 acquired businesses or companies work or be successful. 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.

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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, 2008, we have approximately $745,000 of U.S. Federal net operating loss carryforwards (NOLs) available to reduce taxable income in future years. A portion of these NOLs are currently subject to an annual limitation under section 382 of the Internal Revenue Code of 1986, as amended.

Our ability to utilize the NOLs 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 NOLs. 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 NOLs arising after the date of an ownership change would not be affected.

In addition, 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. NOLs totaling $3,800 expired in the year ended December 31, 2007. No NOLs expired during the year-ended December 31, 2008.

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 and materially harm our business, financial condition and results of operations.

Our international 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 international sales and operations to be limited or disrupted.

Over the past few years, we have significantly expanded our international 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;
- economic problems or political instability that disrupts foreign healthcare payment systems;
- difficulties or inability to obtain financing in international markets;

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ALEXION PHARMACEUTICALS, INC.

- 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 staffing, 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, or 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 a substantial portion of our business in currencies other than the U.S. dollar, primarily Euros. While we attempt to hedge certain currency risks, currency fluctuations between the U.S. dollar and the currencies in which we do business have caused foreign currency transaction gains and losses in the past 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.

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 the current credit and financial market conditions, and the overall financial climate, these governmental organizations and payors, 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.

Additionally, we rely upon third-parties for certain parts of our business, including Lonza, our sole manufacturer of Soliris, licensees, wholesale distributors of Soliris, contract clinical trial providers, contract manufacturers and other third-party suppliers and financial institutions. Because of the recent 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.

Healthcare reform measures could adversely affect our business.

The United States government and governments in foreign countries have shown significant interest in pursuing healthcare reform in order to reduce costs of healthcare. Any government-adopted reform measures could adversely impact the pricing of Soliris or the amount of reimbursement available for Soliris from governmental agencies or other third-party payors. The pricing and reimbursement environment for

Soliris may become more challenging due to, among other reasons, policies of the administration or new healthcare legislation passed by Congress, or other changes in policy in the United States or in foreign countries. While we cannot predict what, if any, legislative or regulatory proposals will be adopted, the announcement or adoption of such 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.

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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 and our convertible senior notes. 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. In particular, between January 1, 2007 and December 31, 2008, the closing sales price of our common stock fluctuated from a low of $17.89 per share to a high of $47.51 per share, as reported after giving effect to the forward two-for-one stock split effected on August 22, 2008. 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 Alexion or its 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 certificate 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 certificate of incorporation, 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.

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Item 5. OTHER INFORMATION

On November 2, 2009, Dr. Ruedi Waeger notified the Company of his decision not to stand for reelection as a Director in 2010. Dr. Waeger s current term is expected to end at the next shareholders meeting in May 2010.

Item 6. EXHIBITS

(a) Exhibits

10.1 Waiver and Second Amendment to Credit Agreement, dated as of July 23, 2009, between the Company and Bank of America, N.A.

10.2 Third Amendment to Credit Agreement, dated as of September 11, 2009, between the Company and Bank of America, N.A.

31.1 Certification by Leonard Bell, Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009.

31.2 Certification by Vikas Sinha, Senior Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009.

32.1 Certification by Leonard Bell, Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009.

32.2 Certification by Vikas Sinha, Senior Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ALEXION PHARMACEUTICALS, INC.

Date: November 5, 2009

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

Date: November 5, 2009

By: /s/ Vikas Sinha
Vikas Sinha
Senior Vice President and Chief Financial Officer
(principal financial officer)