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

FORM 10-Q

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended September 30, 2010

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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ 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	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

Common Stock, $0.0001 par value	**90,490,697**
Class	**Outstanding at October 26, 2010**

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ALEXION PHARMACEUTICALS, INC.

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ALEXION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

(in thousands, except per share amounts)	September 30, 2010	December 31, 2009
Assets		
Current Assets:		
Cash and cash equivalents	$ 209,956	$ 157,172
Marketable securities	88,598	19,048
Trade accounts receivable, net	154,088	113,731
Inventories	60,412	40,885
Deferred tax assets	19,714	16,726
Prepaid expenses and other current assets	25,469	25,894
Total current assets	558,237	373,456
Property, plant and equipment, net	162,111	164,691
Intangible assets, net	25,239	28,589
Goodwill	19,954	19,954
Deferred tax assets	164,446	194,308
Other assets	12,270	5,403
Total assets	$ 942,257	$ 786,401
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 13,322	$ 11,530
Accrued expenses	88,199	66,915
Deferred revenue	4,166	1,652
Current portion of capital lease obligations	939	422
Other current liabilities	11,037	4,743
Total current liabilities	117,663	85,262
Capital lease obligations, less current portion	306	503
Convertible notes	3,718	9,918
Deferred tax liabilities	217	204
Other liabilities	8,537	2,158
Total liabilities	130,441	98,045
Commitments and contingencies (Note 13)		
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; 90,905 and 89,097 shares issued at September 30, 2010 and December 31, 2009, respectively	5	5
Additional paid-in capital	1,149,470	1,093,933
Treasury stock, at cost	(2,676)	(2,676)
Accumulated other comprehensive loss	(4,599)	(1,942)
Accumulated deficit	(330,384)	(400,964)
Total stockholders' equity	811,816	688,356
Total liabilities and stockholders' equity	$ 942,257	$ 786,401

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

ALEXION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

(in thousands, except per share amounts)	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Net product sales	$141,569	$102,628	$384,982	$276,151
Cost of sales	16,495	11,895	44,215	32,167
Operating expenses:				
Research and development	25,153	21,323	71,217	58,700
Selling, general and administrative	57,208	41,523	163,941	120,880
Total operating expenses	82,361	62,846	235,158	179,580
Operating income	42,713	27,887	105,609	64,404
Other income and expense:				
Investment income	483	125	1,069	612
Interest expense	(162)	(80)	(530)	(522)
Foreign currency loss	(427)	(250)	(1,384)	(379)
Debt exchange expense	—	—	—	(3,395)
Income before income taxes	42,607	27,682	104,764	60,720
Income tax provision	14,734	951	34,184	2,681
Net income	$ 27,873	$ 26,731	$ 70,580	$ 58,039
Earnings per common share				
Basic	$ 0.31	$ 0.31	$ 0.79	$ 0.69
Diluted	$ 0.30	$ 0.29	$ 0.76	$ 0.65
Shares used in computing earnings per common share				
Basic	89,490	87,447	89,003	84,464
Diluted	93,021	90,946	92,580	90,246

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

ALEXION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

(in thousands)	Nine months ended September 30, 2010	2009
Cash flows from operating activities:		
Net income	$ 70,580	$ 58,039
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	11,864	8,935
Share-based compensation expense	24,733	21,853
Non-cash debt exchange expense	—	3,395
Deferred taxes	27,168	—
Marketable securities premium amortization	758	—
Unrealized foreign currency gain	(1,712)	(3,057)
Unrealized loss on forward contracts	8,869	1,673
Loss on disposal of property, plant and equipment	76	108
Changes in operating assets and liabilities:		
Accounts receivable	(42,159)	(30,886)
Inventories	(14,218)	9,809
Prepaid expenses and other assets	(3,534)	(6,335)
Accounts payable and accrued expenses	24,899	15,820
Deferred revenue	2,573	2,044
Net cash provided by operating activities	109,897	81,398
Cash flows from investing activities:		
Purchases of marketable securities	(82,545)	—
Proceeds from maturity or sale of marketable securities	12,155	—
Purchases of property, plant and equipment	(8,928)	(26,105)
Purchase of technology rights	(20)	(27,740)
(Increase) decrease in restricted cash	(2)	132
Net cash used in investing activities	(79,340)	(53,713)
Cash flows from financing activities:		
Payments on capital leases	(379)	(221)
Payments on mortgage loan	—	(24,000)
Excess tax benefit from stock options	577	—
Net proceeds from the exercise of stock options	22,819	22,533
Net cash provided by (used in) financing activities	23,017	(1,688)
Effect of exchange rate changes on cash	(790)	1,286
Net change in cash and cash equivalents	52,784	27,283
Cash and cash equivalents at beginning of period	157,172	138,012
Cash and cash equivalents at end of period	$209,956	$165,295

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

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)
(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 those in the therapeutic areas of hematology, nephrology including transplant rejection, neurology, ophthalmology and cancer. Our marketed product Soliris® (eculizumab) is the first and only therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH, an ultra-rare and life-threatening blood disorder. We were incorporated in 1992 and began commercial sale of Soliris in 2007.

2. Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. These accounting principles were applied on a basis consistent with those of the consolidated financial statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2009. In our opinion, the accompanying unaudited consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of our financial statements for interim periods in accordance with accounting principles generally accepted in the United States. The December 31, 2009 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. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2009 included in our Annual Report on Form 10-K. The results of operations for the three and nine months ended September 30, 2010 are not necessarily indicative of the results to be expected for the full year.

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

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

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

3. Revenue and Accounts Receivable

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

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)
(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.

In addition to sales in countries where Soliris is commercially available, we have also recorded revenue on sales for individual patients through named-patient programs. The relevant authorities or institutions in those countries have agreed to reimburse for product sold on a named-patient basis where Soliris has not received final approval for commercial sales.

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

In March 2010, United States government healthcare legislation, which contains several provisions that impact rebates payable, was enacted. The provisions in the legislation related to rebates payable include an increase in the minimum Medicaid rebate percentages, which is also extended as a discount to 340B institutions, and an extension of the Medicaid rebate to managed care organizations that dispense drugs to Medicaid recipients. We have recorded estimated rebates payable according to the new legislation. If the provisions of this legislation change, we may 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 enter into foreign exchange forward contracts to hedge exposures resulting from portions of our forecasted intercompany revenues that are denominated in currencies other than the U.S. dollar. These hedges are designated as cash flow hedges upon inception. We record the effective portion of these cash flow hedges to revenue in the period in which the derivative contract is settled.

Accounts Receivable

Our product sales to government-owned or supported customers in certain European countries, including Greece, are subject to delays in payments due to government funding and reimbursement practices. Because these customers are government-owned or supported, we may also be impacted by declines in sovereign credit ratings or sovereign defaults in these countries. During the second quarter of 2010, the Greek government announced a plan for repayment of its debt to international pharmaceutical companies. This plan calls for the majority of pharmaceutical industry receivables from 2007 to 2009 to be settled in non-interest bearing bonds issued by the Greek government, with maturity dates ranging from 1 to 4 years.

For non-interest bearing receivables with an estimated payment beyond one year, we discount the accounts receivable to present value, with a corresponding adjustment to revenue.

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)
(in thousands, except per share amounts)

A significant further decline in sovereign credit ratings or a default in Greece, or in other countries, may decrease the likelihood that we will collect these accounts receivable or may increase the length of time until these receivables are collected, which could result in a negative impact to our operating results.

4. Inventories

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

The components of inventory are as follows:

	September 30, 2010	December 31, 2009
Raw materials	$ 2,912	$ 2,678
Work-in-process	33,510	6,900
Finished goods	23,990	31,307
	$ 60,412	$ 40,885

5. Comprehensive Income

The following table summarizes components of our comprehensive income:

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Net income	$ 27,873	$26,731	$70,580	$ 58,039
Unrealized losses on hedge contracts, net of tax	(24,027)	(5,525)	(550)	(14,039)
Net unrealized gain on available for sale securities, net of tax	151	—	24	—
Foreign currency translation adjustment	1,197	296	(299)	455
Comprehensive income	$ 5,194	$21,502	$69,755	$ 44,455

6. Debt

In January 2010, we amended and restated our existing credit agreement, the Amended Credit Agreement, to, among other things, increase the revolving credit facility by $25,000. The Amended Credit Agreement provides for a $50,000 facility through January 22, 2013, with up to a $20,000 sublimit for letters of credit that can be used for working capital requirements and other general corporate purposes. With the consent of the lenders and the administrative agent and subject to satisfaction of certain conditions, we may increase the facility to $75,000. The loan is collateralized by substantially all of Alexion Pharmaceuticals, Inc.’s assets, including the pledge of the equity interests of certain direct subsidiaries and the real estate owned by Alexion Manufacturing LLC, its wholly owned subsidiary, but excluding intellectual property and assets of foreign subsidiaries.

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)
(in thousands, except per share amounts)

We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 2.50% to 3.00% depending on the ratio of our cash to liabilities (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect, (B) Federal Funds Rate then in effect plus 0.50%, and (C) Eurodollar Rate then in effect plus 1.00%, plus 0.50% to 1.00% depending on the ratio of our cash to liabilities (as calculated in accordance with the agreement). Interest is payable quarterly for Base Rate loans and, in the case of LIBOR-based loans, at the end of the applicable interest period, with the principal due on January 22, 2013, the maturity date.

The Amended Credit Agreement requires us to comply with certain financial covenants on a quarterly basis. 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. 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. As of September 30, 2010, we had no outstanding amounts under the revolving credit facility other than letters of credit, and approximately $43,000 was available for withdrawal.

In the first quarter of 2010, certain holders of our 1.375% Convertible Senior Notes due February 2012, or the 1.375% Notes, exercised conversion rights with respect to an aggregate principal amount of $1,000 resulting in the issuance of 63,582 shares of our common stock. In the second quarter of 2010, certain holders of our 1.375% Notes exercised conversion rights with respect to an aggregate principal amount of $5,200 resulting in the issuance of 330,629 shares of our common stock. As of September 30, 2010, $3,718 of the 1.375% Notes remains outstanding, and the fair value, based on quoted market prices, was estimated at $15,141.

7. Earnings Per Common Share

Basic earnings per common share (EPS) are computed by dividing net income by the weighted-average number of shares of common stock outstanding. For purposes of calculating diluted EPS, net income is adjusted for the after-tax amount of interest and deferred financing costs associated with our convertible debt, and the denominator reflects the potential dilution that could occur if stock options, unvested restricted stock 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.

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)
(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, 2010 and 2009:

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Net income used for basic calculation	$27,873	$26,731	$70,580	$58,039
Weighted-average effect of dilutive securities:				
Interest expense and debt financing cost amortization, net of tax, related to our 1.375% convertible senior notes	11	11	63	287
Net income used for diluted calculation	27,884	26,742	70,643	58,326
Shares used in computing earnings per common share—basic	89,490	87,447	89,003	84,464
Weighted-average effect of dilutive securities:				
Shares issuable upon the assumed conversion of our 1.375% convertible senior notes	237	631	432	3,073
Stock awards	3,294	2,868	3,145	2,709
Dilutive potential common shares	3,531	3,499	3,577	5,782
Shares used in computing earnings per common share—diluted	93,021	90,946	92,580	90,246
Earnings per common share:				
Basic	$ 0.31	$ 0.31	$ 0.79	$ 0.69
Diluted	$ 0.30	$ 0.29	$ 0.76	$ 0.65

The following table represents the potentially dilutive shares excluded from the calculation of EPS for the three and nine months ended September 30, 2010 and 2009 because their effect is anti-dilutive:

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Potentially dilutive securities:				
Options to purchase common stock	1,461	2,024	1,412	2,442
Unvested restricted stock	2	19	4	28
	1,463	2,043	1,416	2,470

8. Derivative Instruments and Hedging Activities

We operate internationally and, in the normal course of business, are exposed to fluctuations in foreign currency exchange rates. The exposures result from portions of our revenues, as well as the related receivables, and expenses that are denominated in currencies other than the U.S. dollar, primarily the Euro, Japanese Yen, 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 forward contracts, with durations of up to 36 months, to hedge exposures resulting from portions of our forecasted intercompany revenues that are denominated in currencies other than the U.S. dollar. The purpose of the hedges of intercompany revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted intercompany revenues. These hedges are designated as cash flow hedges upon contract inception. As of September 30, 2010, we have open contracts with notional amounts totaling $134,379 that qualified for hedge accounting.

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)
(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, 2010 and 2009, are as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Loss recognized in OCI, net of tax	$(24,027)	$(5,525)	$ (550)	$(14,039)
Gain reclassified from OCI to net product sales (Effective portion)	$ 4,512	$ 444	$7,023	$ 6,940
Gain (loss) reclassified from OCI to other income (Ineffective portion)	$ (716)	$ 270	$ 103	$ 482

Assuming no change in foreign exchange rates from market rates at September 30, 2010, $2,034 of the gain recognized in other comprehensive income is expected to be reclassified to revenue over the next twelve months.

We enter into foreign exchange forward contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities of our foreign subsidiaries. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results. These derivative instruments do not qualify for hedge accounting 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, 2010, the notional settlement amount of foreign exchange contracts relating to monetary assets and liabilities was $63,835.

We recognized a gain (loss) of $3,511 and $(2,096), in other income and expense, for the three months ended September 30, 2010 and 2009, respectively, and $13,464 and $(5,045), for the nine months ended September 30, 2010 and 2009, respectively, associated with foreign exchange contracts not designated as hedging instruments under the guidance. These amounts were largely offset by gains or losses in monetary assets and liabilities.

The following table summarizes the Company's fair value of outstanding derivatives at September 30, 2010:

	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	$8,213	Other current liabilities	$ 5,320
Foreign exchange forward contracts	Other non-current assets	640	Other non-current liabilities	3,234
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	192	Other current liabilities	5,717
Total fair value of derivative instruments		**$9,045**		**$14,271**

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)
(in thousands, except per share amounts)

9. Share-Based Compensation

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

	September 30,		September 30,	
	2010	2009	2010	2009
Research and development	$2,029	$2,108	$ 6,139	$ 6,163
Selling, general and administrative	6,060	4,871	17,739	15,690
Total share-based compensation expense	$8,089	$6,979	$23,878	$21,853

For the three and nine months ended September 30, 2010, $290 and $855, respectively, of share-based compensation expense was recognized in cost of sales that was previously capitalized into inventory. The corresponding amounts recognized in 2009 are not material to the results of operations.

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

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Share-based compensation expense capitalized to inventory	$ 741	$ 435	$2,087	$1,004
Share-based compensation expense capitalized to fixed assets	$ —	$ 202	$ —	$ 854

10. Fair Value Measurement

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

The following table presents information about our assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2010, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)
(in thousands, except per share amounts)

Balance Sheet Classification	Type of Instrument	Fair Value Measurement at September 30, 2010			
		Total	Level 1	Level 2	Level 3
Cash equivalents	Money market funds	$ 121,842	$ —	$ 121,842	$ —
Marketable securities	Federal agency obligations	$ 10,016	$ —	$ 10,016	$ —
Marketable securities	U.S. Corporate bonds	$ 78,582	$ —	$ 78,582	$ —
Other current assets	Foreign exchange forward contracts	$ 8,405	$ —	$ 8,405	$ —
Other assets	Foreign exchange forward contracts	$ 640	$ —	$ 640	$ —
Other current liabilities	Foreign exchange forward contracts	$ 11,037	$ —	$ 11,037	$ —
Other liabilities	Foreign exchange forward contracts	$ 3,234	$ —	$ 3,234	$ —

Valuation Techniques

Items classified as Level 2 within the valuation hierarchy, consisting of an institutional money market fund held at a multinational financial institution and corporate and federal agency bonds, are valued based upon pricing of securities with similar investment characteristics and holdings. Our derivative assets and liabilities include foreign exchange derivatives that are measured at fair value using observable market inputs such as forward rates, interest rates, our own credit risk and our counterparties' credit risks. Based on these inputs, the derivative assets and liabilities are classified within Level 2 of the valuation hierarchy.

As of September 30, 2010, 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.

11. Income Taxes

We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax basis of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. We provide a valuation allowance when it is more likely than not that deferred tax assets will not be realized.

In the fourth quarter of 2009, we reversed the valuation allowance recorded against a substantial portion of our deferred tax assets in the United States. We also reversed the valuation allowance recorded against certain non-U.S. deferred tax assets in the second quarter of 2010 where realization of those assets is now more likely than not. At the end of the third quarter of 2010, we continue to maintain a valuation allowance against certain other deferred tax assets where the realization is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized.

ALEXION PHARMACEUTICALS, INC.
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(unaudited)
(in thousands, except per share amounts)

The following table provides a comparative summary of our provision for income taxes and effective tax rate for the three and nine months ended September 30, 2010 and 2009, respectively:

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Provision for income taxes	$14,734	$951	$34,184	$2,681
Effective tax rate	34.6%	3.4%	32.6%	4.4%

Because the valuation allowance on a substantial portion of our U.S. deferred tax assets was reversed at the end of 2009, the tax provision for periods ending December 31, 2009 and prior included a benefit from the utilization of U.S. net operating losses. The tax provision against our U.S. earnings for periods after December 31, 2009 does not include this benefit.

The tax provision for the three and nine months ended September 30, 2010 is principally attributable to the U.S. federal, state and foreign income taxes on our profitable operations. 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.

12. Employee Benefit Plans

Defined Contribution Plan

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

- $1.00 for each dollar contributed up to the first 3 percent of an individual’s base salary and incentive cash bonus; and
- $0.50 for each dollar contributed of the next 2 percent of such compensation.

For the three months ended September 30, 2010 and 2009, we recorded matching contributions of approximately $410 and $371, respectively. For the nine months ended September 30, 2010 and 2009, we recorded matching contributions of approximately $1,466 and $1,221, respectively.

Defined Benefit Plan

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

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)
(in thousands, except per share amounts)

The components of net periodic benefit cost are as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Service cost	$ 414	$ 95	$ 1,539	$ 273
Interest cost	103	25	188	73
Expected return on plan assets	(69)	(24)	(175)	(69)
Amortization	13	3	25	9
Employee contribution	(160)	(28)	(423)	(83)
Total net periodic benefit cost	$ 301	$ 71	$ 1,154	$ 203

13. Commitments and Contingencies

Royalties

Our cost of sales for the three and nine months ended September 30, 2010 and 2009 includes royalties to third parties related to the sale of Soliris. As of September 30, 2010 and December 31, 2009, we have recorded $43,675 and $29,177, respectively, in accrued expenses for royalties.

A portion of the accrued royalty balance relates to known contractual obligations which are paid to third parties on a regular basis. In addition to known obligations, we also make estimates of our royalty obligations based on our assessment of estimated royalties potentially owed to other third parties. This remaining estimated amount represents a substantial portion of the accrued royalty balance. The estimates of amounts potentially owed to other third parties 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, which could result in a material adverse adjustment to our operating results.

ALEXION PHARMACEUTICALS, INC.
(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 indication and any expanded uses, timing and effect of sales of Soliris in various markets worldwide, level of coverage and reimbursement for Soliris, pricing, level of future Soliris sales and collections, costs, expenses and capital requirements, cash outflows, cash from operations, status of reimbursement, price approval and funding processes in various countries worldwide, progress in developing commercial infrastructure and interest about Soliris 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, status of our ongoing clinical trials, commencement dates for new clinical trials, clinical trial results, evaluation of our clinical trial results by regulatory agencies, prospects for regulatory approval, need for additional research and testing, the uncertainties involved in the drug development process and manufacturing, our future research and development activities, assessment of competitors and potential competitors, the outcome of challenges and opposition proceedings to our intellectual property, estimates of the capacity of manufacturing and other facilities to support Soliris and our product candidates, potential costs resulting from product liability or other third party claims, the sufficiency of our existing capital resources and projected cash needs, assessment of impact of recent accounting pronouncements, declines in sovereign credit ratings or sovereign defaults in countries where we commercialize our products, delay of collection or reduction in reimbursement due to adverse economic conditions, the short and long term effects of government healthcare measures, and the effect of shifting foreign exchange rates. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this report under the section entitled "Risk Factors". Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in other reports or documents we file from time to time with the Securities and Exchange Commission.

Business

Overview

Alexion Pharmaceuticals, Inc. 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 those in the therapeutic areas of hematology, nephrology including transplant rejection, neurology, ophthalmology and cancer. Our marketed product Soliris® (eculizumab) is the first and only therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH, an ultra-rare and life-threatening blood disorder. We were incorporated in 1992 and began commercial sale of Soliris in 2007.

Soliris is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation associated with chronic disorders in the therapeutic areas of hematology, nephrology including transplant rejection, neurology and ophthalmology. 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 an ultra-rare, debilitating and life-threatening, acquired genetic deficiency blood disorder defined by uncontrolled complement activation leading to

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).

Soliris was approved by the U.S. Food and Drug Administration (FDA), and the European Commission (E.C.) in 2007 and by Japan's Ministry of Health, Labour and Welfare (MHLW) in 2010. Additionally, Soliris was granted orphan drug designation for the treatment of PNH in the United States, Europe, Japan and several other territories.

In 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.

Clinical

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

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

Product	Development Area	Indication	Development Stage
Soliris	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Commercial
		PNH Registry	Phase IV
		Cold agglutinin disease*	Phase II
	Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)	Phase II
		MPGN II (Dense Deposit Disease)*	Phase II
		Presensitized Renal Transplant*	Phase II
		Kidney Transplant for Catastrophic Antiphospholipid Syndrome*	Phase II
		ABO Incompatible Renal Transplant*	Phase II
	Neurology	Myasthenia Gravis	Phase II
		Neuromyelitis Optica*	Phase II
		Multifocal Motor Neuropathy*	Phase II
	Ophthalmology	Dry Age-Related Macular Degeneration (AMD)*	Phase II
Samalizumab	Oncology	Chronic Lymphocytic Leukemia	Phase I
		Multiple Myeloma	Phase I

* Investigator Initiated Trial

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(in thousands, except per share amounts)

We are currently focusing our development efforts in two therapeutic areas: hematology and nephrology. We are also continuing to advance our pipeline programs in neurology, ophthalmology and cancer.

Hematology: PNH

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

Hematology: CAD

Also within our hematology therapeutic area, an investigator-initiated Phase II study will soon begin dosing patients with eculizumab for the treatment of Cold Agglutinin Disease, or CAD. CAD is a severe, ultra-rare complement-mediated autoimmune disease characterized by the presence of high concentrations of circulating complement-activating antibodies directed against red blood cells. As observed with PNH patients, CAD patients also suffer from the clinical consequences of severe hemolysis.

Nephrology: aHUS

In 2009, the FDA and E.C. granted eculizumab orphan drug designation for the treatment of patients with the ultra-rare and life-threatening disorder aHUS. In patients with aHUS, deficiency of naturally occurring complement inhibitors causes uncontrolled complement activation which leads to thrombotic microangiopathy (TMA), the formation of blood clots in small blood vessels throughout the body causing a reduction in platelet count (thrombocytopenia) and life-threatening damage to the kidney, brain, heart and other vital organs. In April 2010, we completed enrollment of two (each with adolescent and adult patients) multi-national, multi-center clinical trials evaluating eculizumab for the treatment of adolescent and adult aHUS patients with evidence of thrombotic microangiopathy (clotting in small blood vessels). Approximately 35 patients are being dosed in these studies. The studies include patients who had received plasma therapy chronically and others who were resistant or intolerant to plasma therapy. In October 2010, scientific abstracts were published of interim results from these two trials which indicated that the primary and key secondary endpoints were positive, and that updated and further results were expected to be presented at the 2010 American Society of Nephrology scientific meetings. Following the closing of enrollment in these two clinical studies, we have commenced a new Phase II, open-label trial in adult aHUS patients and, separately, we have also commenced a pediatric aHUS study.

Nephrology: MPGN II

Further, in our nephrology therapeutic area we are aware that independent investigators have commenced studies to evaluate eculizumab in patients with MPGN II, or dense deposit disease, another ultra-rare and severe kidney disease in which uncontrolled complement activation can evolve into chronic renal failure, requiring dialysis and renal transplantation.

Nephrology: Transplant

We are aware that independent investigators are continuing to enroll patients in clinical trials to evaluate eculizumab in presensitized renal transplant patients at elevated risk for acute humoral rejection, or AHR, as well as transplant patients with catastrophic antiphospholipid syndrome. We are also aware that an independent investigator

has begun enrolling patients in a clinical trial to evaluate eculizumab in kidney transplant patients sensitized to their donor kidney due to an ABO blood group mismatch between donor and recipient. We are developing protocols to initiate multi-national, multi-site controlled clinical trials of eculizumab in presensitized renal transplant patients at elevated risk for acute humoral rejection and are further considering expansion of development efforts to include investigation of eculizumab as a treatment for patients undergoing transplantation of other organs.

Neurology

The FDA authorized our Investigational New Drug Application, or IND, for studying the safety and efficacy of eculizumab in treating patients with myasthenia gravis, a rare autoimmune syndrome characterized by complement activation leading to the failure of 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: neuromyelitis optica and multifocal motor neuropathy.

Ophthalmology

We are aware of an independent investigator who continues to enroll patients in a study evaluating the safety and efficacy of eculizumab as a treatment for the dry form of age-related macular degeneration. Age-related macular degeneration is a medical condition usually affecting older adults in which uncontrolled complement activation results in a loss of vision in the center of the visual field (the macula) and complement-mediated damage to the retina. It occurs in both “dry” and “wet” (involving new blood vessel formation) forms. It is a major cause of visual impairment in older adults.

Oncology

Enrollment is now completed in our Phase I dose-escalation clinical study of samalizumab, our anti-CD200 antibody, in patients with treatment refractory chronic lymphocytic leukemia or multiple myeloma. The trial has enrolled approximately 25 patients.

Manufacturing

We currently rely on two facilities, our own facility in Rhode Island and a third party manufacturer, for commercial and clinical quantities of Soliris, as well as for clinical quantities of product candidates. 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 December 2009 and August 2010, the E.C. and FDA, respectively, approved our Rhode Island manufacturing facility for the production of Soliris.

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 provided 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 pay Lonza a royalty on sales of Soliris manufactured at our Rhode Island facility.

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, 2009. Under accounting principles

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generally accepted in the United States, we are required to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingent assets and liabilities in our financial statements. Actual results could differ from those estimates.

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

- Revenue recognition
- Royalties
- Inventories
- Research and development expenses
- Share-based compensation
- 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, 2009. 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

The following table summarizes product revenue for the three and nine months ended September 30, 2010 and 2009:

	Three months ended September 30,		$	Nine months ended September 30,		$
	2010	2009	Variance	2010	2009	Variance
Net product sales	$141,569	$102,628	$38,941	$384,982	$276,151	$108,831

The increase in revenue for the three and nine months ended September 30, 2010, as compared to the same period in 2009, was primarily due to an increased number of patients treated with Soliris globally. The increase in treated patients was due to additional patients and physicians requesting Soliris therapy, as well as reimbursement and price approvals in additional territories, including approvals in Japan which impacted sales in the third quarter of 2010. The increase in revenues was offset by the negative impact of approximately $3,300 and $10,300 for the three and nine months ended September 30, 2010 due to changes in foreign currency exchange rates (inclusive of hedging activity), primarily the Euro and British Pound, versus the three and nine months ended September 30, 2009.

Cost of Sales

Cost of sales was $16,495 and $11,895 for the three months ended September 30, 2010 and 2009, respectively and $44,215 and $32,167, for the nine months ended September 30, 2010 and 2009, respectively. Cost of sales as a percentage of net product revenue was 11.7% and 11.6% for the three months ended September 30, 2010 and 2009 and 11.5% and 11.6% for the nine months ended September 30, 2010 and 2009, respectively. Cost of sales includes manufacturing costs, as well as actual and estimated royalty expenses associated with sales of Soliris.

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(in thousands, except per share amounts)

The estimates of our royalty obligations are based on our assessment of estimated royalties potentially owed to other third parties. The estimates of amounts potentially owed to third parties 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, which could result in a material adverse adjustment to our operating results.

Research and Development Expense

Our research and development expense includes personnel, facility and external costs associated with the research and development of our product candidates, as well as product development costs.

We group our research and development expenses into two major categories: external direct expenses and all other R&D expenses.

External direct expenses are comprised of costs paid to outside parties for clinical development, product development and discovery research. Clinical development costs are comprised of costs to conduct and manage clinical trials related to eculizumab and other product candidates. Product development costs are those incurred in performing duties related to manufacturing development and regulatory functions. Discovery research costs are incurred in conducting laboratory studies and performing preclinical research for other uses of eculizumab and other product candidates. Clinical development costs have been accumulated and allocated to each of our programs, while product development and discovery research costs have not been allocated.

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

The following table provides information regarding research and development expenses:

	Three months ended September 30,		$	Nine months ended September 30,		$
	2010	2009	Variance	2010	2009	Variance
Clinical development	$ 6,914	$ 6,520	$ 394	$19,260	$16,467	$ 2,793
Product development	2,963	1,640	1,323	6,632	5,142	1,490
Discovery research	810	458	352	1,695	1,092	603
Total external direct expenses	**10,687**	**8,618**	**2,069**	**27,587**	**22,701**	**4,886**
Payroll and benefits	11,987	10,603	1,384	36,216	29,581	6,635
Operating and occupancy	1,055	1,172	(117)	3,237	3,676	(439)
Depreciation and amortization	1,424	930	494	4,177	2,742	1,435
Total other R&D expenses	**14,466**	**12,705**	**1,761**	**43,630**	**35,999**	**7,631**
Research and development expense	**$25,153**	**$21,323**	**$ 3,830**	**$71,217**	**$58,700**	**$12,517**

For the three months ended September 30, 2010, the increase of $3,830 in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase of $1,384 in research and development payroll and benefit expense related primarily to global expansion of staff supporting our increasing number of clinical programs.

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(in thousands, except per share amounts)

- Increase of $1,323 in external product development expenses related primarily to increases in manufacturing development activities at our production facility in Smithfield, RI.

For the nine months ended September 30, 2010, the increase of $12,517 in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase of $6,635 in research and development payroll and benefit expense related primarily to global expansion of staff supporting our increasing number of clinical programs.
- Increase of $2,793 in external clinical development expenses related primarily to an expansion of studies of eculizumab for non-PNH indications, offset by decreases in spending on PNH programs (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,		$
	2010	2009	Variance	2010	2009	Variance
External direct expenses						
Eculizumab: PNH program	$1,892	$ 2,356	$ (464)	$ 4,655	$ 6,472	$(1,817)
Eculizumab: non-PNH programs	4,679	3,308	1,371	13,079	8,082	4,997
Samalizumab	261	292	(31)	975	876	99
Unallocated	82	564	(482)	551	1,037	(486)
	$6,914	**$ 6,520**	**$ 394**	**$19,260**	**$16,467**	**$ 2,793**

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

Selling, General and Administrative Expense

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

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

	Three months ended September 30,		$	Nine months ended September 30,		$
	2010	2009	Variance	2010	2009	Variance
Selling, general and administrative expense	$57,208	$41,523	$15,685	$163,941	$120,880	$43,061

ALEXION PHARMACEUTICALS, INC.
(in thousands, except per share amounts)

For the three months ended September 30, 2010, the increase of $15,685 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 $8,300. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of $4,000 related to our global commercial operations teams. This increase was also due to increases in payroll and benefits of $4,300 within our general and administrative functions to support our infrastructure growth as a global commercial entity.
- Increase in external selling, general and administrative expenses of $7,300 was due primarily to increases in marketing services of $3,600, occupancy and depreciation expenses of $1,200 relating to new and expanded office spaces in Europe, Japan, Canada, Australia and Latin America and travel costs of $1,000.

For the nine months ended September 30, 2010, the increase of $43,061 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase in salary, benefits and other labor expenses of $22,800. The increase was a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of $13,200 related to our global commercial operations teams. This increase was also due to increases in payroll and benefits of $9,600 within our general and administrative functions to support our infrastructure growth as a global commercial entity.
- Increase in external selling, general and administrative expenses of $20,300 was due primarily to increases in marketing services of $8,600, charitable contributions of $2,600, travel costs of $2,200, occupancy and depreciation expenses of $2,800 relating to new and expanded office spaces in Europe, Japan, Canada, Australia and Latin America and telecommunication/software costs of $900.

Other Income and Expense

We recognize investment income primarily from our portfolio of cash equivalents and marketable securities. Investment income was $483 and $125, for the three months ended, and $1,069 and $612, for the nine months ended, September 30, 2010 and 2009, respectively. The increases were due to higher cash equivalents and marketable securities balances during the three and nine months ended September 30, 2010, as compared to the same period in the prior year.

We incur interest on our convertible notes, revolving credit facility and capital lease obligations. Interest expense was $162 and $80, for the three months ended, and $530 and $522 for the nine months ended, September 30, 2010 and 2009, respectively. The increase in interest expense was due primarily to a reduction in capitalized interest associated with our manufacturing plant in Rhode Island, which was placed in service in the fourth quarter of 2009, and fees relating to our amended and restated credit facility, partially offset by the lower principal balance of our convertible notes as a result of the note conversions and exchanges during 2009 and 2010.

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 $427 and $250, for the three months ended, and $1,384 and $379, for the nine months ended, September 30, 2010 and 2009, 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 as part of our hedging programs.

We recorded $3,395 of non-cash debt exchange expense for the nine months ended September 30, 2009 relating to the exchange of 5,644 shares for $87,304 principal amount of our 1.375% Convertible Senior Notes. The expense was recorded based on the fair value of the additional shares provided to the note holders over the stated conversion rate.

ALEXION PHARMACEUTICALS, INC.
(in thousands, except per share amounts)

Income Taxes

During the three and nine months ended September 30, 2010, we recorded an income tax provision of $14,734 and $34,184, an effective rate of 34.6% and 32.6%, respectively, compared to the income tax provision of $951 and $2,681 an effective rate of 3.4% and 4.4%, for the three and nine months ended September 30, 2009. Because the valuation allowance on a substantial portion of our U.S. deferred tax assets was reversed at the end of 2009, the tax provision for periods ending December 31, 2009 and prior included a benefit from the utilization of U.S. net operating losses. The tax provision for periods after December 31, 2009 does not include this benefit.

The tax provision for the three and nine months ended September 30, 2010 is principally attributable to the U.S. federal, state and foreign income taxes on our profitable operations. 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.

In the fourth quarter of 2009, we reversed the valuation allowance recorded against a substantial portion of our deferred tax assets in the United States. We also reversed the valuation allowance recorded against certain non-U.S. deferred tax assets in the second quarter of 2010 where realization of those assets is now more likely than not. At the end of the third quarter of 2010, we continue to maintain a valuation allowance against certain other deferred tax assets where the realization is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized.

We expect that our normalized effective tax rate will range from between 32 and 33 percent for 2010. The U.S. federal research credit provision expired on December 31, 2009. While Congress may reinstate the research tax credit retroactive to the beginning of the year, we have not yet considered any tax benefit for the credit and we will continue to monitor the status of this provision. We would report any related tax benefit if and when the credit is reinstated.

Liquidity and Capital Resources

Cash, cash equivalents, marketable securities and working capital as of September 30, 2010 and December 31, 2009 were as follows:

Financial assets:

	September 30, 2010	December 31, 2009	$ Variance
Cash and cash equivalents	$ 209,956	$ 157,172	$ 52,784
Marketable securities	88,598	19,048	69,550
Cash, cash equivalents and marketable securities	$ 298,554	$ 176,220	$ 122,334

Select measures of liquidity and capital resources:

	September 30, 2010	December 31, 2009	$ Variance
Current assets	$ 558,237	$ 373,456	$ 184,781
Current liabilities	(117,663)	(85,262)	(32,401)
Working capital	$ 440,574	$ 288,194	$ 152,380
Current ratio	4.74	4.38	

Until required for use in the business, we invest our cash reserves in money market funds and high quality commercial, corporate and U.S. government and agency bonds in accordance with our investment policy. The stated objectives of our investment policy is to preserve capital, provide liquidity consistent with forecasted cash flow requirements, maintain appropriate diversification and generate returns relative to these investment objectives and prevailing market conditions.

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(in thousands, except per share amounts)

The increase in cash, cash equivalents and marketable securities was primarily attributable to the increase in product sales and the related cash generated from operations. The increase in working capital was primarily due to increases in our cash and cash equivalents, marketable securities, accounts receivable and inventory offset primarily by an increase in accrued expenses.

Financial instruments that potentially expose the Company to concentrations of credit risk are limited to cash equivalents, corporate bonds, accounts receivable and our foreign exchange derivative contracts. At September 30, 2010, one individual customer accounted for 26.7% of the accounts receivable balance. At September 30, 2009, one individual customer accounted for 17.8% of the accounts receivable balance.

For the three and nine months ended September 30, 2010, one customer accounted for 20.8% and 21.5% of our product sales, respectively. For the three and nine months ended September 30, 2009, one customer accounted for 18.9% and 19.6% of our product sales, respectively.

We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. As of September 30, 2010, we have foreign exchange forward contracts with notional amounts totaling $198,214. These outstanding foreign exchange forward contracts had a net fair value of $(5,226), of which an unrealized gain of $9,045 is included in other assets, offset by an unrealized loss of $14,271 included in other liabilities. The counterparties to these foreign exchange forward contracts are large multinational commercial banks, and we believe the risk of nonperformance is not material.

In January 2010, we amended and restated our existing credit agreement to, among other things, increase our revolving credit facility by $25,000. The Amended Credit Agreement provides for a $50,000 revolving credit facility, with up to a $20,000 sublimit for letters of credit that can be used for working capital requirements and other general corporate purposes. With the consent of the lenders and the administrative agent and subject to satisfaction of certain conditions, we may increase the facility to $75,000 in accordance with its terms.

As of September 30, 2010, our accrued royalty balance of $43,675 includes estimates of royalties potentially owed to other third parties. The estimates of amounts potentially owed to other third parties may be influenced by the outcome of future litigation or other claims, if any, the results of which are uncertain. An increase in estimated amounts owed or a requirement to pay these amounts on an accelerated basis may result in a material adverse effect on liquidity.

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

ALEXION PHARMACEUTICALS, INC.
(in thousands, except per share amounts)

Cash Flows

Change in cash and cash equivalents:

	Nine months ended September 30,		$
	2010	2009	Variance
Net cash provided by operating activities	$109,897	$ 81,398	$ 28,499
Net cash used in investing activities	(79,340)	(53,713)	(25,627)
Net cash provided by (used in) financing activities	23,017	(1,688)	24,705
Effect of exchange rate changes on cash	(790)	1,286	(2,076)
Net change in cash and cash equivalents	$ 52,784	$ 27,283	$ 25,501

Operating Activities

The increase in net cash and cash equivalents from September 30, 2009 is primarily due to the net income achieved in 2010 versus the net income achieved in the same period in 2009. The components of cash flows from operating activities, as reported in our Statement of Cash Flows, are as follows:

- Our reported net income, adjusted for non-cash items, including depreciation and amortization, share-based compensation expense, non-cash debt exchange expense, deferred taxes, unrealized foreign currency gain, and unrealized loss on foreign exchange forward contracts, was $142,336 and $90,946 for the nine months ended September 30, 2010 and 2009, respectively.
- Net cash outflow due to changes in operating assets and liabilities was $32,439 and $9,548 for the nine months ended September 30, 2010 and 2009, respectively. The $32,439 change in operating assets and liabilities primarily relates to increases in accounts receivable of $42,159 due to the increased number of patients treated with Soliris globally, as well as reimbursement and price approvals in additional territories. Additionally, the increase in inventory of $14,218 relates to increased production at our manufacturing facility in Rhode Island and resulting inventory buildup to support commercial growth. These increases were offset by an increase of $24,899 in accounts payable and accrued expenses, which consists primarily of accrued royalties, payroll and taxes.

Investing Activities

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

- Additions to property, plant and equipment were $8,928 and $26,105 for the nine months ended September 30, 2010 and 2009, respectively. The reduction in additions to property, plant and equipment was primarily as a result of the approval of our Rhode Island manufacturing facility by the E.C. in December 2009. Through the approval date, we capitalized costs associated with the construction and validation of our Rhode Island manufacturing facility, and we ceased capitalization of these costs beginning in January 2010.
- Purchases of marketable securities of $82,545 and sales of marketable securities of $12,155 for the nine months ended September 30, 2010.
- Payments of $25,000 and $2,500 related to the final payment for the PDL BioPharma patent settlement and Oklahoma Medical Research Foundation patent purchase agreement for the nine months ended September 30, 2009.

Financing Activities

Net cash flows from financing activities reflected proceeds from the exercise of stock options of $22,819 and $22,533 for the nine months ended September 30, 2010 and 2009, respectively. In 2009, cash from financing activities was reduced by a $24,000 prepayment on our mortgage loan.

ALEXION PHARMACEUTICALS, INC.
(in thousands, except per share amounts)

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, 2009, in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" under the caption "Contractual Obligations." There have been no material changes in our contractual obligations.

Significant borrowings and contractual obligations include the following:

Revolving Credit Facility

In January 2010, we entered into an amended and restated credit agreement, the Amended Credit Agreement, that provides for an available $50,000 revolving credit facility through January 22, 2013, with up to a $20,000 sublimit for letters of credit that can be used for working capital requirements and other general corporate purposes. With the consent of the lenders and the administrative agent and subject to satisfaction of certain conditions, we may increase the facility to $75,000. The loan is collateralized by substantially all of Alexion Pharmaceuticals, Inc.'s assets, including the pledge of the equity interests of certain direct subsidiaries and the real estate owned by Alexion Manufacturing LLC, its wholly owned subsidiary, but excluding intellectual property and assets of foreign subsidiaries.

We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 2.50% to 3.00% depending on the ratio of our cash to liabilities (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect, (B) Federal Funds Rate then in effect plus 0.50%, and (C) Eurodollar Rate then in effect plus 1.00%, plus 0.50% to 1.00% depending on the ratio of our cash to liabilities (as calculated in accordance with the agreement). Interest is payable quarterly for Base Rate loans and, in the case of LIBOR-based loans, at the end of the applicable interest period, with the principal due on January 22, 2013, the maturity date.

The Amended Credit Agreement requires us to comply with certain financial covenants on a quarterly basis. 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.

As of September 30, 2010, we had no outstanding amounts under the revolving credit facility other than letters of credit, and approximately $43,000 was available for withdrawal.

Convertible Notes

As of September 30, 2010, we had outstanding $3,718 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. However, no principal payments are due until February 2012, except under certain circumstances such as liquidation, merger or business combination. The Notes do not contain covenants related to our financial performance.

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.

ALEXION PHARMACEUTICALS, INC.
(in thousands, except per share amounts)

In the first quarter of 2010, certain holders of the 1.375% Notes exercised conversion rights with respect to an aggregate principal amount of $1,000 resulting in the issuance of 63,582 shares of our common stock. In the second quarter of 2010, certain holders of the 1.375% Notes exercised conversion rights with respect to an aggregate principal amount of $5,200 resulting in the issuance of 330,629 shares of our common stock.

As of September 30, 2010, $3,718 principal amount of the 1.375% Notes is outstanding, and the fair value, based on quoted market prices, was estimated at $15,141. The $15,591 decrease in fair value from December 31, 2009 is primarily attributable to the exchange of $6,200 principal amount of the notes for 394,211 shares of common stock during the first half of 2010.

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. On an ongoing basis, we evaluate our plans for future levels of manufacturing by Lonza, which depends upon our commercial requirements, the progress of our clinical development programs and the production levels of our Smithfield, Rhode Island manufacturing 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.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

As of September 30, 2010, we held all of our cash and cash equivalents in bank accounts and money market funds, which are not subject to significant interest rate risk.

As of September 30, 2010, we held $88,598 in marketable securities with maturity dates of less than one year. These financial instruments are subject to interest rate risk and will decline in value if interest rates increase. However, we expect to hold time-based investments, such as corporate bonds, through maturity.

Our outstanding long-term liabilities as of September 30, 2010 included our $3,718 principal amount of 1.375% 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.

In January 2010, we entered into a $50,000 amended and restated revolving credit facility, the Amended Credit Agreement. We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 2.50% to 3.00% depending on the ratio of our cash to liabilities (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect, (B) Federal Funds Rate then in effect plus 0.50%, and (C) Eurodollar Rate then in effect plus 1%, plus 0.50% to 1.00% depending on the ratio of our cash to liabilities (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 Currency Exchange Rate Risk

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

currency exchange rates have on our international operating expenses. We have substantial operations based in Switzerland to support our business outside the U.S. and Canada, and accordingly, our expenses are impacted by fluctuations in the value of the Swiss Franc against the U.S. dollar.

We currently have a derivative program in place to achieve two goals: 1) limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet and 2) hedge a portion of our forecasted intercompany product sales, using contracts with duration of up to 36 months, to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted intercompany revenues. Both programs utilize foreign exchange forward contracts intended to reduce, not eliminate, the impact of fluctuations in foreign currency rates.

As of September 30, 2010, we held foreign exchange forward contracts with notional amounts totaling $198,214. As of September 30, 2010, our outstanding foreign exchange forward contracts had a net fair value of $(5,226).

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

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

Credit Risk

Our product sales to government-owned or supported customers in certain European countries, including Greece, are subject to delays in payments due to government funding and reimbursement practices. Because these customers are government-owned or supported, we may also be impacted by declines in sovereign credit ratings or sovereign defaults in these countries. During the second quarter of 2010, the Greek government announced a plan for repayment of its debt to international pharmaceutical companies. This plan calls for the majority of pharmaceutical industry receivables from 2007 to 2009 to be settled in non-interest bearing bonds issued by the Greek government, with maturity dates ranging from 1 to 4 years.

For non-interest bearing receivables with an estimated payment beyond one year, we discount the accounts receivable to present value, with a corresponding adjustment to revenue.

A significant further decline in sovereign credit ratings or a default in Greece, or in other countries, may decrease the likelihood that we will collect these accounts receivable or may increase the length of time until these receivables are collected, which could result in a negative impact to our operating results.

Item 4. Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of September 30, 2010. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2010, our disclosure controls and procedures were effective to provide reasonable assurance that information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure, and ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms.

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(in thousands, except per share amounts)

There has been no change in our internal control over financial reporting that occurred during the quarter ended September 30, 2010 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

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 2007 and in Japan in 2010, for the treatment of PNH. If we are unable to increase sales of Soliris in the United States, Europe and Japan, or commercialize Soliris in additional countries, or for additional indications, or if we are significantly delayed or limited in doing so, our business may be materially harmed.

Our ability to generate revenues will depend on commercial success of Soliris in the United States, Europe and throughout the rest of the world and whether physicians, patients and healthcare payors 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, Japan and in European countries where we are already selling Soliris, and successful launch in countries where we have not yet obtained, or only recently obtained, marketing approval or commenced sales;
- ability to obtain and maintain sufficient coverage or reimbursement by third-party payors;
- acceptance of Soliris in the medical community;
- receipt and maintenance of marketing approvals from the United States and foreign regulatory authorities;
- establishment and maintenance of commercial manufacturing capabilities ourselves or through third-party manufacturers; and
- our ability to develop, register and commercialize Soliris for one or more indications in addition to PNH.

We dedicate significant resources to the worldwide expansion of the commercialization of Soliris for the treatment of PNH. We have established sales and marketing capabilities, and are commercializing Soliris in many countries throughout the world. In certain countries, particularly Canada, Australia and certain countries in the European Union, we continue discussions with appropriate authorities to finalize operational, reimbursement, price approval and funding processes so that we may, upon conclusion of such discussions, commence commercial sales in those countries. We have submitted applications for marketing authorization of Soliris for the treatment of PNH in additional territories. We cannot guarantee that any marketing application that we file will be approved in all countries where we seek authorization to sell Soliris, or even if approved, that we will be able to obtain reimbursement for Soliris or that we will be able to successfully commercialize Soliris in any additional countries. 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, Europe and Japan 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 may be materially harmed and we may need to significantly curtail operations.

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

We may not be able to sell Soliris on a profitable basis or our profitability may be reduced if we are required to sell our product at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. Soliris is significantly more expensive than traditional drug treatments and almost all patients require some form of third party coverage to afford its cost. Our future revenues and profitability will be adversely affected if we cannot depend on governmental, private third-party payors and other third-party payors, 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, determine to provide a lower level of coverage and reimbursement than anticipated, or reduce previously approved levels of coverage and reimbursement, including in the form of higher mandatory rebates, then our pricing or reimbursement for Soliris may be affected and our product sales, results of operations or financial condition could be harmed.

In certain countries where we are seeking or may seek to commercialize Soliris, 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 payors, including private insurance and governmental payors. 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 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, or we could decide to sell Soliris at a lower than anticipated price in such countries, and our revenues may be adversely affected as a result.

Changes in pricing or the amount of reimbursement in countries where we currently commercialize Soliris may also reduce our profitability and worsen our financial condition. In the United States, European countries, and elsewhere, there have been, and we expect there will continue to be, efforts to control and reduce healthcare costs. Government and other third-party payors are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs. For example, the German government recently adopted legislation to increase mandatory discounts on pharmaceutical products and impose a temporary freeze on pharmaceutical pricing, including Soliris. A significant reduction in the amount of

reimbursement or pricing for Soliris in one or more countries may have a material adverse effect on our business. See additional discussion below under the headings “Government initiatives that affect coverage and reimbursement of drug products could adversely affect our business” and “The credit and financial market conditions may aggravate certain risks affecting our business.” In addition, certain countries establish pricing and reimbursement amounts by reference to the price of the same or similar products in other countries. If coverage or the level of reimbursement is limited in one or more countries, we may be unable to obtain or maintain anticipated pricing or reimbursement in current or new territories.

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

Even in countries where patients have access to insurance, their insurance co-payment amounts or annual or lifetime caps on reimbursements may represent a barrier to obtaining or continuing Soliris. In the United States, we have financially supported non-profit organizations, such as the PNH Fund of the National Organization for Rare Disorders, or NORD, which assist patients in accessing treatment for PNH, including Soliris. Such organizations assist patients whose insurance coverage leaves them with prohibitive co-payment amounts or other expensive financial obligations. NORD’s, and other similar organizations’, 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 in the United States and elsewhere. We are not able to predict the financial impact of the support we may provide for these and other charitable purposes; however, substantial support could have a material adverse effect on our profitability in the future.

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

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

We cannot be certain that Soliris will gain or maintain market acceptance in a particular country among physicians, patients, healthcare payors, and others. Although we have received regulatory approval for Soliris in certain territories, including the United States, Japan and Europe, such approvals do not guarantee future revenue. We cannot predict whether physicians, other healthcare providers, government agencies or private insurers will determine that Soliris is safe and therapeutically effective relative to its cost. Medical doctors’ willingness to prescribe, and patients’ willingness to accept, Soliris depends on many factors, including prevalence and severity of adverse side effects in both clinical trials and commercial use, effectiveness of our marketing strategy and the pricing of Soliris, publicity concerning Soliris, our other product candidates or competing products, our ability to obtain and maintain third-party coverage or reimbursement, and availability of alternative treatments, including bone marrow transplant as an alternative treatment for PNH. If Soliris fails to achieve or maintain market acceptance among the medical community or patients in a particular country, we may not be able to market and sell it successfully in such country, which would limit our ability to generate revenue and could harm our overall business.

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

We cannot guarantee that we will be able to maintain our regulatory approvals for Soliris. If we do not maintain our regulatory approvals for Soliris, the value of our company and our results of operations will be materially harmed. We and our current and future partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by the Food and Drug Administration, or FDA, other federal and state agencies, and governmental authorities in other territories. These regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, risk mitigation, adverse event reporting requirements, and export of biologics. For example, the risk management program established in 2007 upon the FDA's approval of Soliris for the treatment of PNH was replaced with a Risk Evaluation and Mitigation Strategy Program, or REMS program, approved by the FDA in 2010. The REMS program requires mandatory physician certification in the United States. Each physician must certify that the physician is aware of the potential risks associated with the administration of Soliris and that the physician will inform each patient of these risks using educational material approved by the FDA.

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

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

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

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

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

been prescribed Soliris, (3) cause serious adverse events and give rise to product liability claims against us, and (4) result in our need to withdraw or recall Soliris from the marketplace. Some of these risks are unknown at this time.

We tested Soliris in only a small number of patients. As more patients begin to use Soliris, new risks and side effects may be discovered, the rate of known risks or side effects may increase, and risks previously viewed as less significant could be determined to be significant. Previously unknown risks and adverse effects of Soliris may also be discovered in connection with unapproved, 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 applicable 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 independent investigators are doing 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.

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 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 patients who are prescribed Soliris in most countries 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 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.

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

Governments in countries where we seek to commercialize Soliris regulate the distribution of drugs and the facilities where such drugs are manufactured, and obtaining their approvals can be lengthy, expensive and highly uncertain. The approval process varies from country to country, and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. In certain jurisdictions, we are required to finalize operational, reimbursement, price approval and funding processes prior to marketing our products, even in countries where marketing approval has been obtained. 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 the United States, the European Union, Japan and other territories. We may not receive regulatory approval for Soliris in any other territories 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 in certain countries, the regulatory agencies in other countries may not agree with our interpretations of our clinical trial data for Soliris and may decide that our results are not adequate to support approval for marketing of Soliris. In those circumstances, we would not be able to obtain regulatory approval in such country on a timely basis, if ever. Even if approval is granted in such country, the approval may require limitations on the indicated uses for which the drug may be marketed. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. We must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. For example, we were required to conduct clinical studies with Soliris in patients with PNH in Japan prior to obtaining marketing approval in that country.

Our commercialization of Soliris may be stopped, delayed or made less profitable if we or any other supply vendor fails to provide sufficient quantities of Soliris. Commercial quantities of Soliris can only be manufactured at two facilities, including our own facility in Rhode Island. We are currently entirely dependent on a single third party to manufacture commercial quantities of Soliris for sale in Japan.

Commercial quantities of Soliris are manufactured by us at our Rhode Island manufacturing facility and by Lonza Sales AG, or Lonza. Manufacturing processes must comply with applicable regulations and manufacturing practices, as well as our own quality standards. In particular, the manufacture of Soliris is heavily regulated by governmental authorities around the world, including the FDA, EMA and MHLW. If we or our third-party suppliers fail to comply fully with such regulations then there could be a government-enforced shutdown of production facilities or production lines, which in turn could lead to product shortages.

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

Until December 2009, only Lonza was capable of manufacturing commercial quantities of Soliris. The E.C. and the FDA approved the use of our Rhode Island manufacturing facility for the production of Soliris in December 2009 and August 2010, respectively. We are authorized to sell product that is manufactured in our facility in the United States, the European Union and certain other territories. However, we will not be capable of manufacturing Soliris for commercial sale in Japan or other territories until such time as we have received the required regulatory approval for our manufacturing facility in Rhode Island, if ever. We will continue to depend entirely on one company, Lonza, to manufacture Soliris for commercial sale in Japan and such other territories until that time.

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, EMA, MHLW 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 or incur penalties for failure to deliver product, make us postpone or cancel clinical trials, or cause our products to be recalled or withdrawn.

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 specialty pharmacies and specialty 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, 2010, our single largest customer, AmerisourceBergen, accounted for 20.8% of our Soliris net product sales, and our three largest customers accounted for approximately 34.5% of our net product sales. As of September 30, 2010, our single largest customer, AmerisourceBergen, accounted for 26.7% 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 for the treatment of PNH ourselves in the United States, Europe, Japan and several other territories, but have only limited experience thus far with marketing, sales or distribution of drug products. We have established commercial capabilities in the United States, Europe and Japan. If we are unable to establish and/or expand our capabilities to sell, market and distribute Soliris for the treatment of PNH or, if approved by the necessary regulatory agencies, other future indications, either through our own capabilities or by entering into agreements with others, or to maintain such capabilities in countries where we have already commenced commercial sales, we will not be able to successfully sell Soliris. In that event, we will not be able to generate significant revenues. We cannot guarantee that we will be able to establish and maintain our own capabilities or enter into and maintain any marketing or distribution agreements with third-party providers on acceptable terms, if at all. Even if we hire the qualified sales and marketing personnel we need to support our objectives, or enter into marketing and distribution agreements with third parties on acceptable terms, we may not do so in an efficient manner or on a timely basis. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell Soliris. Establishing and maintaining sales, marketing and distribution capabilities are expensive and time-consuming. Our expenses associated with building up and maintaining the sales force and distribution capabilities around the world may be 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 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 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 payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors and because government scrutiny in this area is high, it is possible that some of our business activities could come under that scrutiny.

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

Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candidates, 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, including 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 know when or if Soliris will be approved in other indications. 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 further studies or trials are initiated what the scope and phase of the trial will be or that they will be completed, or that if these further studies or trials are completed, that the design or results will provide a sufficient basis to apply for or receive regulatory approvals or to commercialize products. Results of clinical trials could be inconclusive, requiring additional or repeat trials. If the design or results achieved in our clinical trials are insufficient to proceed to further trials or to regulatory approval of our product candidates, our company could be materially adversely affected. Failure of a clinical trial to achieve its pre-specified primary endpoint generally increases the likelihood that additional studies or trials will be required if we determine to continue development of the product candidate, reduces the likelihood of timely development of and regulatory approval to market the product candidate, and may decrease the chances for successfully achieving the primary endpoint in scientifically similar indications.

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

For human trials, patients must be recruited and each product candidate must be tested at various doses and formulations for each clinical indication. In addition, to ensure safety and effectiveness, the effect of drugs often must be studied over a long period of time, especially for the chronic diseases that we are studying. 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;
- disruption of operations at the clinical trial sites;
- adverse medical events or side effects in treated patients;
- the failure of patients taking the placebo to continue to participate in our clinical trials;
- insufficient clinical trial data to support effectiveness of the product candidates;
- lack of effectiveness or safety of the product candidate being tested;
- lack of sufficient funds;
- inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner; and
- failure to obtain the necessary regulatory approvals for the product candidate or the approvals for the facilities in which such product candidate is manufactured.

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

The preclinical development, clinical trials, manufacturing, marketing and labeling of pharmaceuticals are all subject to extensive regulation by numerous governmental authorities and agencies in the United States and other countries. We must obtain regulatory approval for each of our product candidates 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 payors.

Physicians may elect not to recommend our drugs even if they receive marketing approval for a variety of reasons, including the timing of the market introduction of competitive drugs; lower demonstrated clinical safety and efficacy compared to other drugs; perceived lack of cost-effectiveness; lack of availability of reimbursement from third-party payors; convenience and ease of administration; prevalence and severity of adverse side effects; other potential advantages of alternative treatment methods; and ineffective marketing and distribution support. Sales of pharmaceutical products depend in significant part on the coverage and reimbursement policies of government programs, including Medicare and Medicaid in the United States and similar programs in other countries, and other third-party payors. 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 our drug candidates 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 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 or our third-party manufacturers or other third party providers to provide services with respect to our drug products in the volumes and quality required, would have a material adverse effect on our business.

Clinical quantities of eculizumab are manufactured by us in our Rhode Island facility and by Lonza. Clinical quantities of samalizumab 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. Due to the highly technical requirements of manufacturing our drug products, we and our third-party collaborators may be unable to manufacture our drug products despite our and their efforts. In addition, we cannot be certain that any third party will be able or willing to honor the terms of its agreement, including any obligations to manufacture the drug products in accordance with regulatory requirements and to our quality specifications and volume requirements.

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 could have a material adverse effect on our business.

We currently have limited experience in manufacturing drug products in volumes that would be necessary to support commercial sales, and we can provide no assurance that we will be able to do so successfully. We acquired a commercial-scale manufacturing plant in Smithfield, Rhode Island in July 2006. The E.C. and the FDA have approved the use of our facility for the production of Soliris, and we are authorized to sell Soliris manufactured in our facility in the United States, the European Union and certain other territories. The plant is not currently approved by the MHLW or other regulatory agencies to manufacture Soliris and we will not be capable of manufacturing Soliris for commercial sale in Japan on our own until such time as we have received MHLW approval of our manufacturing facility, if ever. Until December 2009, we have depended on a single third party for commercial supply of Soliris, and we are still entirely dependent on this third party for commercial quantities of Soliris for sale in Japan. We have limited experience in developing commercial-scale manufacturing. We can provide no assurance that we will be able to manufacture our drug products at our Rhode Island plant under conditions required by the FDA or foreign regulatory agencies on a timely basis, if at all. Our plant in Rhode Island is subject to approval by other national and regional regulatory agencies before we can begin sales of Soliris or other drug products manufactured in this facility in the applicable countries or regions, and we will continue to be subject to ongoing regulatory inspections thereafter.

We, and our 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 may need to find other alternatives, which is likely to be expensive and time consuming, and also may result in reduced revenue during this period. Even if we are able to find alternatives they may ultimately be insufficient for our needs. As a result, our ability to conduct testing and drug trials and our plans for commercialization could be materially adversely affected. Submission of products and new development programs for regulatory approval, as well as our plans for commercialization, would be delayed or suspended. Our competitive position and our prospects for achieving or maintaining profitability could be materially and adversely affected.

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

Risks Related to Intellectual Property

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

In order to protect our drugs and technology more effectively, we need to obtain and maintain patents covering the drugs and technologies we develop. We have and may in the future obtain patents or the right to practice patents through ownership or license. Our patent applications may not result in the issue of patents in the United States or other countries. Our patents may not afford adequate protection for our products. Third parties may challenge our patents. For example, a third party filed an opposition with the European Patent Office to our European Patent 0758904, which covers Soliris. The opposition argues that essential claims in our European Patent 0758904 should be narrowed or invalidated. If any of our patents are narrowed, invalidated or become unenforceable, including European Patent 0758904, competitors may develop and market products similar to ours that do not conflict with or infringe our patents rights, which could have a material adverse effect on our financial condition. Soliris and our drug candidates are expensive and time-consuming to test and develop. Even if we obtain and maintain patents, our business may be significantly harmed if the patents are not broad enough to protect our drugs from copycat products.

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

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

Parts of our technology, techniques and proprietary compounds and potential drug candidates, including those which are or may be in-licensed, may be found to infringe patents owned by or granted to others. We previously reported that 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 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 tested or are testing various modifications that we believe should not infringe the patents and which should permit commercialization of our product candidates.

Any holder of these patents or other patents covering similar technology could sue us for damages and seek to prevent us from manufacturing, selling or developing our drugs. Legal disputes can be costly and time consuming to defend. If we cannot successfully defend against any future actions or conflicts, if they arise, we may incur substantial legal costs and may be liable for damages, be required to obtain costly licenses or need to stop

manufacturing, using or selling Soliris, which would adversely affect our business. A required license may be costly or may not be available on acceptable terms, if at all. A costly license, or inability to obtain a necessary license, could have a material adverse effect on our business.

There can be no assurance that we would prevail in a patent infringement action; that we would be able to obtain a license to any third-party patent on commercially reasonable terms or any terms at all; successfully develop non-infringing alternatives on a timely basis; or license alternative non-infringing technology, if any exists, on commercially reasonable terms. Any impediment to our ability to manufacture, use or sell approved forms of Soliris or our product candidates could have a material adverse effect on our business and prospects.

Risks Related to Our Operations

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

Until the quarter ended June 30, 2008, we had never been profitable since we started our company in January 1992. We have maintained profitability on a quarterly basis since the quarter ended June 30, 2008 and on an annual basis for the years ended December 31, 2009 and 2008. We believe that we formulate our annual operating budgets with reasonable assumptions and targets, however we cannot guarantee that we will be able to generate sufficient revenues or control expenses to achieve our financial goals, including continued profitability. Even if we do achieve profitability in any subsequent quarters, we may not be able to sustain or increase profitability on a quarterly or annual basis. You should not consider our revenue growth in recent periods as indicative of our future performance. Our revenue in future periods could decline. We may make errors in predicting and reacting to relevant business trends or our business may be subject to factors beyond control, which could harm our operations. Since we began our business, we have focused on research and development of product candidates. We launched Soliris for sale in the United States and Europe during 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, Europe and Japan, on a continued basis, and we do not know when we will have Soliris available for sale in territories where we have applied or will apply for marketing approval, if ever. We will have substantial expenses as we continue our research and development efforts, continue to conduct clinical trials, and continue to develop manufacturing, sales, marketing and distribution capabilities in the United States and abroad. The achievement of our financial goals, including the extent of our future profitability, depends on many factors, including our ability to successfully market Soliris in the United States, Europe and Japan and other territories, our ability to obtain regulatory, pricing, coverage, and reimbursement approvals of Soliris in additional countries and regions, our ability to successfully market Soliris in additional countries and regions, and our ability to successfully manufacture and commercialize our drug candidates.

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.

The FDA, E.C. and the MHLW granted orphan drug designation for Soliris in the treatment of PNH, which entitles us to exclusivity for a total of seven years in the United States and for ten years in Europe and Japan. However, if a competitive product that is the same as Soliris, as defined under the applicable regulations, is shown to be clinically superior to Soliris in the treatment of 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 us for Soliris for other indications or for any of our other product candidates. Other pharmaceutical companies also compete with us to attract academic research institutions as drug development partners, including for licensing these institutions' proprietary technology. If our competitors successfully enter into such arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may not be able to find equivalent opportunities elsewhere.

If we fail to 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, Japan, and several other territories, evaluating and preparing regulatory submissions for Soliris in several countries, and conducting, preparing or evaluating several clinical trials. Funding needs may shift between projects and potentially accelerate and increase as we continue launch and commercialization activities throughout the world and as we initiate or continue clinical trials for our product candidates.

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

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

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

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

We are 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 businesses 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;
- the potential loss of our key employees or key employees of the acquired companies; and
- failure of any acquired businesses or products or in-licensed products to achieve the scientific, medical, commercial or other results anticipated.

We compete with pharmaceutical companies that have significantly greater resources than we for many of the same acquisition and in-licensing opportunities. Such pharmaceutical companies may be less leveraged and have better access to capital resources that may preclude us from completing any acquisition or in-licensing. 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.

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, 2009, we have approximately $661.4 million of U.S. Federal net operating loss carryforwards, or NOL's, available to reduce taxable income in future years. A portion of these NOL's are currently subject to an annual limitation under section 382 of the Internal Revenue Code of 1986, as amended. We believe it is more likely than not that we will use the net operating losses. However, the ability to use net operating loss carryforwards will be dependent on our ability to generate taxable income. The net operating loss carryforwards may expire before we generate sufficient taxable income. NOL's totaling $3.8 million expired in the year ended December 31, 2007. No NOL's expired during the years ended December 31, 2009 and 2008.

Our ability to utilize the NOL's may be further limited if we undergo an ownership change, as defined in section 382. This ownership change could be triggered by substantial changes in the ownership of our outstanding stock, which are generally outside of our control. An ownership change would exist if the stockholders, or group of stockholders, who own or have owned, directly or indirectly, 5% or more of the value of our stock, or are otherwise treated as 5% stockholders under section 382 and the regulations promulgated there under, increase their aggregate percentage ownership of our stock by more than 50 percentage points over the lowest percentage of our stock owned by these stockholders at any time during the testing period, which is generally the three-year period preceding the potential ownership change. In the event of an ownership change, section 382 imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change NOL's. The limitation imposed by section 382 for any post-change year would be determined by multiplying the value of our stock immediately before the ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Any unused annual limitation may be carried over to later years, and the limitation may under certain circumstances be increased by built-in gains which may be present with respect to assets held by us at the time of the ownership change that are recognized in the five-year period after the ownership change. Our use of NOL's arising after the date of an ownership change would not be affected.

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

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

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

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

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

Our business and marketing methods are also subject to regulation by the governments of the countries in which we operate. The United States Foreign Corrupt Practices Act, 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, or anticipate that we will conduct, a substantial portion of our business in currencies other than the U.S. dollar, primarily the Euro, Japanese Yen, Swiss Franc and British Pound. 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 payors, 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. Payment defaults by a government payor could require us to expense previously recorded revenue as uncollectable, and might cause us to end or restrict sales to patients in that country. Further, the risk of payment default by a government payor could require us to revise our revenue recognition policies in regard to that payor, causing revenue to be recorded only on a cash basis, and we may be required to end or restrict sales to patients in that country.

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

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

In March 2010, the United States adopted the Affordable Care Act and governments in many foreign countries where we operate have adopted or have shown significant interest in pursuing legislative initiatives to reduce costs of healthcare. Any such government-adopted healthcare measures could adversely impact the pricing of Soliris or the amount of coverage and reimbursement available for Soliris from governmental agencies or other third-party payors. For example, the governments of Germany and Spain each approved increases to mandatory rebates on the sales of pharmaceutical products. The pricing and reimbursement environment for Soliris may become more challenging due to, among other reasons, changes in government policies or new legislation, or the impact of total Soliris reimbursement to any one payor. In many cases, these government initiatives, even if enacted into law, are subject to future rulemaking by regulatory agencies. Although we have evaluated these government initiatives and the impact on our business, we cannot know with certainty whether any such law, rule or regulation will adversely affect coverage and reimbursement of Soliris, or to what extent, until such laws, rules and regulations are promulgated, implemented and enforced. The announcement or adoption of regulatory or legislative proposals could delay or prevent our entry into new markets, affect our reimbursement or sales in the markets where we are already selling Soliris and materially harm our business, financial condition and results of operations.

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, 2008 and October 31, 2010, the closing sales price of our common stock fluctuated from a low of $25.49 per share to a high of $68.41 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 us or our stockholders. Our bylaws provide that special meetings of our stockholders may be called only by the Chairman of the Board, the President, the Secretary, or a majority of the Board of Directors, or upon the written request of stockholders who together own of record 50% of the outstanding stock of all classes entitled to vote at such meeting. Our bylaws also specify that the authorized number of directors may be changed only by resolution of the board of directors. Our 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.

Item 5. OTHER INFORMATION

None.

Item 6. EXHIBITS

(a) Exhibits

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, 2010.

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, 2010.

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, 2010.

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, 2010.

101 The following materials from the Alexion Pharmaceuticals, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2010 formatted in eXtensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Statements of Operations, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) related notes, tagged as blocks of text.

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 2, 2010

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

Date: November 2, 2010

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

Exhibit 31.1

I, Leonard Bell, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles:

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2010

/s/ Leonard Bell

Leonard Bell, M.D.
Chief Executive Officer

Exhibit 31.2

I, Vikas Sinha, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles:

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2010

/s/ Vikas Sinha

Vikas Sinha
Senior Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc. (the "Company") for the fiscal quarter ended September 30, 2010 as filed with the Securities and Exchange Commission (the "Report"), I, Leonard Bell M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 2, 2010

/s/ Leonard Bell

Leonard Bell, M.D.
Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc. (the "Company") for the fiscal quarter ended September 30, 2010 as filed with the Securities and Exchange Commission (the "Report"), I, Vikas Sinha, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 2, 2010

/s/ Vikas Sinha

Vikas Sinha
Senior Vice President and Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.