ALEXION PHARMACEUTICALS INC
Form 10-Q
May 08, 2009
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the quarterly period ended March 31, 2009

OR

¨ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the transition period from _____ to _____

Commission file number: 0-27756

Alexion Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**13-3648318**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

352 Knotter Drive, Cheshire, Connecticut 06410

(Address of principal executive offices) (Zip Code)

203-272-2596

(Registrant s telephone number, including area code)

N/A

(Former name, former address, and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 45 of Regulation S-T (§ 232,404 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ¨ No ¨

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

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

Indicate by check mark whether the registrant is a shell company (as defined in rule 12b-2 of the Act)

Yes ¨ No x

Common Stock, $0.0001 par value	**82,072,694**
Class	**Outstanding at April 30, 2009**

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ALEXION PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(in thousands, except per share amounts)	March 31, 2009	December 31, 2008
Assets		
Current Assets:		
Cash and cash equivalents	$ 139,039	$ 138,012
Trade accounts receivable	79,991	74,476
Inventories	49,360	49,821
Deferred tax assets	969	972
Prepaid expenses and other current assets	17,007	13,820
Total current assets	286,366	277,101
Property, plant and equipment, net	144,833	139,885
Intangible assets, net	31,100	32,325
Goodwill, net	19,954	19,954
Restricted cash	1,770	1,699
Deferred tax assets	4,147	3,397
Other assets	3,472	3,190
Total assets	$ 491,642	$ 477,551
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 7,884	$ 8,655
Accrued expenses	44,407	46,200
Deferred revenue	1,898	1,128
License payable	12,500	25,000
Deferred tax liabilities	592	639
Current debt obligations	2,500	2,500
Current portion of capital lease obligations	303	296
Total current liabilities	70,084	84,418
Capital lease obligations, less current portion	125	203
Mortgage loan	44,000	44,000
Convertible notes	97,222	97,222
Deferred tax liabilities	906	906
Other liabilities	4,594	3,801
Total liabilities	216,931	230,550
Commitments and contingencies		
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; 82,286 and 81,532 shares issued at March 31, 2009 and December 31, 2008 respectively	5	5
Additional paid-in capital	955,226	941,439
Treasury stock, at cost, 87 shares and 57 shares	(2,331)	(1,260)
Accumulated other comprehensive loss	3,436	2,947
Accumulated deficit	(681,625)	(696,130)

Total stockholders equity	274,711	247,001
Total liabilities and stockholders equity	$ 491,642	$ 477,551

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

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ALEXION PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(in thousands, except per share amounts)	Three months ended March 31, 2009	2008
Revenues:		
Net product sales	$ 81,267	$ 45,546
Contract research revenues		95
Total revenues	81,267	45,641
Cost of sales	9,959	5,464
Operating expenses:		
Research and development	19,089	15,609
Selling, general and administrative	36,652	29,781
Total operating expenses	55,741	45,390
Operating income (loss)	15,567	(5,213)
Other income and expense:		
Investment income	303	767
Interest expense	(333)	(596)
Foreign currency gain (loss)	(393)	703
Income (loss) before income taxes	15,144	(4,339)
Income tax provision (benefit)	638	(90)
Net income (loss)	$ 14,506	$ (4,249)
Net income (loss) per share		
Basic	0.18	$ (0.06)
Diluted	0.16	$ (0.06)
Shares used in computing net income (loss) per share		
Basic	81,698	75,028
Diluted	90,645	75,028

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

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CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(in thousands)	Three months ended March 31, 2009	2008
Cash flows from operating activities:		
Net income (loss)	$ 14,506	$ (4,249)
Adjustments to reconcile net income (loss) to net cash flows from operating activities:		
Depreciation and amortization	3,024	1,289
Share-based compensation expense	7,926	5,884
Unrealized foreign currency loss	322	1,187
Unrealized loss on forward contracts	1,972	
Loss on disposal of property, plant and equipment	24	42
Changes in operating assets and liabilities:		
Accounts receivable	(6,448)	(7,029)
Inventories	727	78
Prepaid expenses and other assets	(5,575)	(5,099)
Accounts payable and accrued expenses	(1,315)	(4,219)
Deferred revenue	766	863
Net cash flows from operating activities	15,929	(11,253)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(6,406)	(7,950)
Purchase of technology rights	(12,500)	(3,489)
Release of (increase in) restricted cash	(67)	542
Net cash flows from investing activities	(18,973)	(2,157)
Cash flows from financing activities:		
Payments under capital lease obligations	(71)	(64)
Proceeds from revolving credit facility		18,000
Net proceeds from issuance of common stock	4,199	4,486
Net cash flows from financing activities	4,128	22,422
Effect of exchange rate changes on cash	(57)	521
Net change in cash and cash equivalents	1,027	9,533
Cash and cash equivalents at beginning of period	138,012	95,321
Cash and cash equivalents at end of period	$ 139,039	$ 104,854

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

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except share and per share amounts)

1. Business

Alexion Pharmaceuticals, Inc. (Alexion or the Company) is a biopharmaceutical company engaged in the discovery, development and delivery of biologic therapeutic products aimed at treating patients with severe and life-threatening disease states, including hematologic, kidney and neurologic diseases, transplant rejection, cancer and autoimmune disorders. Our marketed product Soliris® (eculizumab) is the first therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH. We were incorporated in 1992 and began commercial sale of Soliris in the United States and Europe in 2007.

2. Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. These accounting principles were applied on a basis consistent with those of the consolidated financial statements contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2008. In our opinion, the accompanying unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to state fairly our financial position as of March 31, 2009 and the results of our operations and cash flows for the three months ended March 31, 2009 and 2008. The December 31, 2008 condensed consolidated balance sheet data was derived from audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States of America. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2008 included in our Annual Report on Form 10-K. The results of operations for the three months ended March 31, 2009 are not necessarily indicative of the results to be expected for the full year.

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

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

3. Revenue

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

We recognize revenue from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured and we have no further performance obligations. Revenue is recorded upon receipt of the product by the patients health-care provider, which is typically a hospital, physician s office, pharmacy or health care facility. Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in the Company s statements of operations and do not impact net product sales.

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. In some cases, 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.

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(in thousands, except share and per share amounts)

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

We record estimated rebates payable under governmental programs, including Medicaid and programs in Europe, as a reduction of revenue at the time product sales are recorded. Our calculations related to these rebate accruals require estimates, including estimates of customer mix, to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period and record any necessary adjustments. Generally, the length of time between product sale and the processing and reporting of the rebates is three to nine months. Upon reconciliation of government reporting to our sales records, we revise our estimates of rebates payable, which may have an impact on revenue in the period in which the adjustment was made.

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

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

4. Royalties

Our cost of sales for the three months ended March 31, 2009 and 2008 includes royalties to third parties related to the sale and commercial manufacture of Soliris. We estimate our royalty obligations based on existing contractual obligations and our assessment of estimated royalties owed to other third parties. These estimates may be influenced by the outcome of litigation and other claims, the results of which are uncertain. On a periodic basis and based on specific events such as the outcome of litigation, we may reassess these estimates, resulting in adjustments to cost of sales.

In December 2008, we entered into a definitive license agreement with PDL BioPharma, Inc. on their Queen patent portfolio relating to the humanization of antibodies for $25,000. The initial payment of $12,500 was paid in January 2009, with a final payment of $12,500 due by June 30, 2009. No additional payments will be owed by Alexion to PDL under the Queen patents in respect of Soliris sales for any indication.

5. Inventories

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

The following table summarizes the components of our inventories:

	March 31, 2009	December 31, 2008
Raw materials	$ 3,875	$ 3,805
Work-in-process	24,609	27,017
Finished goods	20,876	18,999
	$ 49,360	$ 49,821

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(in thousands, except share and per share amounts)

6. Comprehensive Income (Loss)

The following table summarizes components of our comprehensive income (loss):

	Three months ended March 31,	
	2009	2008
Net income (loss)	$ 14,506	(4,249)
Defined benefit pension plan activity		(245)
Unrealized gains (losses) on hedge contracts	629	
Foreign currency translation adjustment	(140)	(24)
Comprehensive income (loss)	$ 14,995	$ (4,518)

7. Exit Activities

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

	Three Months Ended March 31,	
	2009	2008
Accrual balance, beginning of period	$ 596	$ 763
Revision of estimate	24	
Payments and other settlements	(66)	(43)
Accrual balance, end of period	$ 554	$ 720

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

8. Earnings (Loss) Per Common Share

Basic earnings per share (EPS) are computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding. For purposes of calculating diluted EPS, net income (loss) is adjusted for the after-tax amount of interest and deferred financing costs associated with the convertible debt, and the denominator reflects the potential dilution using the treasury stock method, that could occur, if options, convertible debt, or other contracts to issue common stock were exercised or converted into common stock.

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The following table summarizes the calculation of basic and diluted EPS for the three month periods ended March 31, 2009 and 2008:

	Three Months Ended March 31,	
	2009	2008
Net income (loss)	$ 14,506	$ (4,249)
Effect of dilutive securities:		
Interest expense and debt fee amortization, net of tax, related to our 1.375% convertible senior notes	250	
Net income (loss) diluted	14,756	(4,249)
Shares used in computing net income (loss) per common share basic	81,698	75,028
Effect of dilutive securities:		
Shares issuable upon the assumed conversion of our 1.375% convertible senior notes	6,182	
Stock options	2,360	
Unvested restricted stock	405	
Dilutive potential common shares	8,947	
Shares used in computing net income (loss) per common share diluted	90,645	75,028
Net income (loss) per share:		
Basic	$ 0.18	$ (0.06)
Diluted	$ 0.16	$ (0.06)

The following table represents the potentially dilutive shares excluded from the calculation of EPS for the three month period ended March 31, 2009 and 2008 because their effect is anti-dilutive:

	March 31,	
	2008	2008
Options to purchase common stock	2,238	2,814
Unvested restricted stock	314	365
Common stock issuable under convertible debt		9,537
	2,552	12,716

9. Derivative Instruments and Hedging Activities

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133 (SFAS 161). FAS 161 requires entities to provide enhanced disclosures about how and why the entity uses derivative instruments, how the instruments and related hedged are accounted for under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, (SFAS 133) and how the instruments and related hedged items affect the financial position, results of operations, and cash flows of the entity. We adopted SFAS 161 during the three month period ended March 31, 2009.

We follow the provisions of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and related interpretations (SFAS 133). SFAS No. 133 establishes accounting and reporting standards for derivative instruments and hedging activities and requires the Company to recognize these as either assets or liabilities on the balance sheet and measure them at fair value. The accounting for gains and losses resulting from changes in fair value is dependent on the use of the derivative and whether it is designated and qualifies for hedge accounting.

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All hedging activities are documented at the inception of the hedge and must meet the definition of highly effective in offsetting changes to future cash flows within the meaning of SFAS No. 133 to be a qualifying hedge. The effectiveness of the qualifying hedge contract is assessed quarterly to ensure compliance with SFAS 133. We record the fair value of our hedges in other current assets and other current liabilities. Gains or losses resulting from changes in the fair value of qualifying hedges are recorded in other comprehensive income until the forecasted transaction occurs. When the forecasted transaction occurs, this amount is reclassified into revenue. Any non-qualifying portion of the gains or losses resulting from changes in fair value, if any, is reported in other income or other expense.

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

We enter into foreign exchange contracts, with durations of up to 18 months, to hedge exposures resulting from portions of our forecasted intercompany revenues that are denominated in currencies other than the U.S. dollar. These hedges are designated as cash flow hedges upon inception. As of March 31, 2009, we have open contracts with notional amounts totaling $124,988 that qualified for hedge accounting.

We enter into foreign exchange contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities of our foreign subsidiaries. These derivative instruments do not qualify for hedge accounting under SFAS 133; however, gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. As of March 31, 2009, the notional settlement amount of forward foreign exchange contracts relating to monetary assets and liabilities was $36,649.

The following table summarizes the Company s fair value of outstanding derivatives at March 31, 2009:

	Asset Derivatives Balance Sheet Location		Liability Derivatives Balance Sheet Location	
Derivatives designated as hedging instruments:				
Foreign exchange contracts	Prepaid expenses and other current assets	$ 6,837	Accrued expenses	$ (1,273)
Derivatives not designated as hedging instruments:				
Foreign exchange contracts	Prepaid expenses and other current assets	76	Accrued expenses	(1,575)
Total Derivatives		**$ 6,913**		**$ (2,848)**

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The impact on other comprehensive income (OCI) and earnings from foreign exchange contracts that qualified as cash flow hedges was as follows:

	Foreign Exchange Contracts 2009
Gain (loss) recognized in OCI (Effective portion)	$ 5,564
Gain (loss) reclassified from OCI to net product sales (Effective portion)	3,848
Gain (loss) recognized in other income and expense (Ineffective portion)	165

Assuming no change in foreign currency rates, $5,242 of the gain recognized in other comprehensive income is expected to be reclassified to revenue over the next twelve months.

We recognized a gain of $471 and $108, in other income, for the three months ended March 31, 2009 and 2008, respectively, associated with the foreign exchange contracts not designated as hedging instruments under SFAS 133.

10. Stock-Based Compensation

The following table summarizes the components of stock-based compensation expense in the consolidated statements for operations for the three months ended March 31, 2009 and 2008:

	Three Months Ended March 31,	
	2009	2008
Research and development	$ 2,238	$ 1,624
Selling, general and administrative	5,688	4,260
	$ 7,926	$ 5,884

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

	Three Months Ended March 31,	
	2009	2008
Stock-based compensation expense capitalized to inventory	$ 266	$ 257
Stock-based compensation expense capitalized to fixed assets	$ 320	$ 368

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11. Fair Value Measurement

The table below presents information about our assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2009 and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

		Fair Value Measurement at March 31, 2009			
Balance Sheet Classification	**Type of Instrument**	**Total**	**Level 1**	**Level 2**	**Level 3**
Cash equivalents	Money market funds	$ 112,885	$	$ 112,885	$
Other assets	Foreign exchange contracts	$ 6,913	$	$ 6,913	$
Accrued expenses	Foreign exchange contracts	$ 2,848	$	$ 2,848	$

As of March 31, 2009, there has not been any impact to the fair value of our derivative liabilities due to our own credit risk. Similarly, there has not been any significant adverse impact to our derivative assets based on our evaluation of our counterparties credit risks.

12. Income Taxes

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

We will continue to reassess the need for a valuation allowance on a quarterly basis. We assess certain factors in determining the period that we would reverse the valuation allowance, including: (i) a demonstration of sustained profitability; and (ii) the support of internal financial forecasts demonstrating the utilization of the NOLs prior to their expiration. If we determine that it is more likely than not that the deferred tax asset are realizable and that the reversal of the valuation reserves in these jurisdictions is appropriate, a significant one-time benefit would be recognized against our income tax provision in the period that this determination is made.

The tax provision of $638 for the three months ended March 31, 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.

13. Employee Benefit Plans

Defined Contribution Plans

We have two qualified 401(k) plans covering all eligible U.S. employees. Under the plans, employees may contribute up to the statutory allowable amount for any calendar year. For the three months ended March 31, 2009 and 2008, we recorded matching contributions of approximately $506 and $439, respectively.

Defined Benefit Plan

We maintain defined benefit plans for employees in Switzerland. The assets of the funded plan are held independently of our assets in a legally distinct and independent collective trust fund which serves various unrelated employers. Annually, the plan is valued by independent actuaries using the projected unit credit method. The liabilities correspond to the projected benefit obligations of which the discounted net present value is calculated based on years of employment, expected salary increases, and pension adjustments. For the three months ended March 31, 2009 and 2008, we recorded net periodic benefit costs of $65 and $37, respectively.

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14. Subsequent Events

In April 2009, we issued an aggregate of 3,299,865 shares of our common stock in exchange for $51,042 principal amount of our 1.375% Convertible Senior Notes due 2012 owned by certain noteholders. The issuance of the shares was made solely in exchange of the notes pursuant to an exemption from the registration requirements of the Securities Act of 1933, as amended, under Section 3(a)(9) of such Act. We did not receive any cash proceeds as a result of the exchange, and the notes were retired and cancelled. The noteholders received shares from the exchange in excess of the amount that they would have received pursuant to their conversion rights under the notes. In the second quarter of 2009, the fair value of the additional shares over the stated conversion rate will be recorded as an expense of approximately $2,000. As of April 30, 2009, $46,180 of the convertible notes remains outstanding.

During the first quarter of 2009, we determined that we were not in compliance with certain financial covenants under our working capital revolving credit facility. We notified our lender and our lender agreed to waive noncompliance under the agreement. In May 2009, we amended our revolving credit facility to modify such covenants. Other than letters of credit, we had no outstanding balance as of December 31, 2008 and did not borrow under this facility during the first quarter of 2009.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Note Regarding Forward-Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management s beliefs and certain assumptions made by our management, and may include, but are not limited to, statements regarding the potential benefits and commercial potential of Soliris® (eculizumab), for its approved indications and any future indications, timing and effect of sales of Soliris in various markets worldwide, level of future Soliris sales and collections, costs, expenses and capital requirements, cash outflows, cash from operations, impact of interest rate changes on our outstanding obligations, status of reimbursement, price approval and funding processes in various countries worldwide, progress in developing commercial infrastructure and interest about Soliris in the patient, physician and payor communities, the safety and efficacy of Soliris and our product candidates, estimates of the potential markets and estimated commercialization dates for Soliris around the world, sales and marketing plans, any changes in the current or anticipated market demand or medical need for Soliris, status of our ongoing clinical trials, commencement dates for new clinical trials, clinical trial results, evaluation of our clinical trial results by regulatory agencies in other countries, prospects for regulatory approval in other countries, the need for additional research and testing, the uncertainties involved in the drug development process and manufacturing, our future research and development activities, assessment of competitors and potential competitors, estimates of the capacity of manufacturing and other facilities to support Soliris and our product candidates, costs relating to the validation proceed at the Rhode Island facility, timing for submission of sBLA for commercial production of eculizumab at the Rhode Island facility, potential costs resulting from product liability or other third party claims, the sufficiency of our existing capital resources and projected cash needs, assessment of impact of recent accounting pronouncements, and the effect of shifting currency exchange rates. Words such as anticipates, expects, intends, plans, believes, seeks, estimates, variations of such words and si expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this report under the section entitled Risk Factors. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in other reports or documents we file from time to time with the Securities and Exchange Commission.

Business

Overview

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

Soliris is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation associated with chronic hematologic, kidney and neurological disorders, transplant rejection, and autoimmune disorders. Soliris is a humanized monoclonal antibody that generally blocks complement activity for one to two weeks after a single dose at the doses currently prescribed. The initial indication for which we received approval for Soliris is PNH. PNH is a rare, debilitating and life-threatening, acquired genetic deficiency blood disorder defined by the destruction of red blood cells, or hemolysis. The chronic hemolysis in patients with PNH may be associated with life-threatening thromboses, recurrent pain, kidney disease, disabling fatigue, impaired quality of life, severe anemia, pulmonary hypertension, shortness of breath and intermittent episodes of dark-colored urine (hemoglobinuria).

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

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

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

In January 2009, the Ministry of Health, Labour and Welfare of Japan designated Soliris as an orphan drug. Among other things, this designation provides Soliris with 10 years of market exclusivity as a treatment for patients with PNH in Japan. In April 2009, we submitted a New Drug Application for Soliris as a treatment for PNH patients to Japan s Pharmaceuticals and Medical Devices Agency.

Clinical

We are also focusing our research efforts on the use of eculizumab as a treatment for patients with other rare and severe complement-mediated conditions, including chronic hemolytic and thrombotic disorders, kidney diseases, transplant rejection and chronic and debilitating neurological disorders. The FDA authorized our Investigational New Drug Application, or IND, for studying the safety and efficacy of eculizumab in treating myasthenia gravis, a rare autoimmune syndrome characterized by the failure of neuromuscular transmission, and we commenced clinical development in 2008. We are currently engaged in clinical programs to investigate the use of eculizumab as a treatment for patients with other complement-mediated disorders, including atypical hemolytic uremic syndrome, or aHUS, a disease in which the lack of naturally occurring complement inhibitors can cause life-threatening kidney damage. We are also considering clinical development of eculizumab for cold agglutinin disease, an ultra-rare auto-immune hemolytic anemia. The program for aHUS was initiated in January 2009. Also, we completed a phase I/II proof of concept study of IV eculizumab in allergic asthmatic patients in the fourth quarter of 2008.

We are aware that investigator-initiated trials of eculizumab have begun in patients with multifocal motor neuropathy, a severe autoimmune neurologic disorder and dense deposit disease, a severe kidney disease. We are also aware that independent investigators have commenced a study to evaluate eculizumab in high risk organ transplantation.

The FDA has also authorized our IND to evaluate the activity of an antibody to the immune regulator CD200 in patients with chronic lymphocytic leukemia, or CLL, an incurable chronic cancer that results from expansion of B-lymphocytes. We commenced dosing of initial CLL patients with anti-CD200 in the second quarter of 2008.

Manufacturing

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

In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island for the future commercial production of Soliris and manufacturing development and manufacturing of future products. We have completed production of eculizumab for process validation purposes and are in the process of compiling a supplemental BLA

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for commercial production of eculizumab at this facility. We expect to submit the supplemental BLA in 2009. We transferred our pilot manufacturing capabilities from New Haven, Connecticut to Smithfield, Rhode Island during 2007, and we have commenced the use of this facility for the production and purification of certain of our product candidates for clinical studies.

Our most significant agreement with a third party manufacturer is the Large-Scale Product Supply Agreement with Lonza Sales AG, or Lonza, dated December 18, 2002, which has been amended from time to time. This agreement, the Lonza Agreement, relates to the manufacture of eculizumab. We executed the latest amendment to the Lonza Agreement in June 2007 to provide 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 batches of product scheduled for manufacture under our arrangement.

Other Events

In April 2009, we issued an aggregate of 3,299,865 shares of our common stock in exchange for $51,042 principal amount of our 1.375% Convertible Senior Notes due 2012 owned by certain noteholders. The issuance of the shares was made solely in exchange of the notes pursuant to an exemption from the registration requirements of the Securities Act of 1933, as amended, under Section 3(a)(9) of such Act. We did not receive any cash proceeds as a result of the exchange, and the notes were retired and cancelled. The noteholders received shares from the exchange in excess of the amount that they would have received pursuant to their conversion rights under the notes. In the second quarter of 2009, the fair value of the additional shares over the stated conversion rate will be recorded as an expense of approximately $2,000. As of April 30, 2009, $46,180 of the convertible notes remains outstanding.

Critical Accounting Policies and the Use of Estimates

The significant accounting policies and basis of preparation of our consolidated financial statements are described in Note 1, Business Overview and Summary of Significant Accounting Policies of our financial statements included in our Form 10-K for the year ended December 31, 2008. Under accounting principles generally accepted in the United States, we are required to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingent assets and liabilities in our financial statements. We base our assumptions, judgments and estimates on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results could differ from those estimates.

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

- Revenue recognition
- Royalties
- Inventories
- Research and development expenses
- Stock-based compensation

Long-lived assets

Income taxes

For a complete discussion of these critical accounting policies, refer to Critical Accounting Policies and Use of Estimates within Item 7 - Management s Discussion and Analysis of Financial Condition and Results of Operations included within our Form 10-K for the year ended December 31, 2008. We have reviewed our critical accounting policies as disclosed in our Form 10-K, and have not noted any material changes.

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Results of Operations

Revenues

Net product sales

The following table summarizes product revenue for the three months ended March 31, 2009 and 2008:

	Three months ended March 31,		Increase / (Decrease)
	2009	2008	$ Change
Net product sales	$ 81,267	$ 45,546	$ 35,721

The increase in revenue for the three months ended March 31, 2009, as compared to the same period in 2008, was due to an increased number of patients treated with Soliris. The increase in treated patients was due to additional patients and physicians requesting Soliris therapy, as well as reimbursement and price approvals in additional countries.

Cost of sales

Cost of sales was $9,959 and $5,464, for the three months ended March 31, 2009 and 2008, respectively. Cost of sales as a percentage of net product revenue was 12.3% and 12.0% for the three month period ended March 31, 2009 and 2008, respectively. Cost of sales includes manufacturing costs, as well as royalty expenses associated with sales of Soliris.

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

Research and Development

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

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

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

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

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The following table provides information regarding research and development expenses:

	Three months ended March 31,		$	%
	2009	2008	Variance	Variance
Clinical development	$ 4,191	$ 4,140	$ 51	1.2%
Product development	3,464	2,524	940	37.2%
Discovery research	284	276	8	2.9%
Total external direct expenses	**7,939**	**6,940**	**999**	**14.4%**
Payroll and benefits	8,934	6,813	2,121	31.1%
Operating and occupancy	1,316	1,030	286	27.8%
Depreciation and amortization	900	826	74	9.0%
Total other R&D expenses	**11,150**	**8,669**	**2,481**	**28.6%**
Research and development expense	**$ 19,089**	**$ 15,609**	**$ 3,480**	**22.3%**

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

	Three months ended March 31,	
	2009	2008
External direct expenses		
Soliris: PNH program	$ 2,183	$ 3,478
Soliris: non-PNH programs	1,314	463
CD200 program	261	45
Other	433	154
	$ 4,191	**$ 4,140**

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

The successful development of our drug candidates is uncertain and subject to a number of risks. A large portion of our annual expenses relates to commercialization of Soliris and general and administrative costs. We may not have or be able to raise the necessary capital to support both the commercialization of Soliris as well as each of our development programs through and until commercialization. Further, we cannot guarantee that results of clinical trials will be favorable or sufficient to support regulatory approvals for our other programs. We could decide to abandon development or be required to spend considerable resources not otherwise contemplated. For additional discussion regarding the risks and uncertainties regarding our development programs, please refer to the Risk Factors in this Form 10-Q, including the risk factors set forth under the headings, If we fail to obtain the capital necessary to fund our operations, we will be unable to continue the commercialization of

Soliris or continue to complete our product development , None of our product candidates except for Soliris has received regulatory approvals , Completion of pre-clinical studies or clinical trials does not guarantee advancement to the next phase of development and There are many reasons why drug testing could be delayed or terminated .

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Research and development expenses were $19,089 and $15,609, for the three months ended March 31, 2009 and 2008, respectively. The increase in research and development expense of $3,480, as compared to the same period in the prior year, was primarily related to the following:

Increase of $2,121 in research and development payroll and benefit expense related to increases in manufacturing development of $1,660, primarily due to increased manufacturing development activities for our CD200 program, and an increase of approximately $339 in discovery research payroll and benefit expense.

Increase of $940 in non-labor product development related primarily due to increased manufacturing development activities for our CD200 program.

Selling, General and Administrative Expenses

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

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

	Three months ended March 31,		$	%
	2009	2008	Variance	Variance
Selling, general and administrative expense	$ 36,652	$ 29,781	$ 6,871	23.1%

The increase of $6,871 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 $4,483 including increased share-based compensation cost of $1,428. The increases in these costs were a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs related to our global commercial operations teams of $2,655. This increase was also due to increases in payroll and benefits of $1,828, within other operational groups to support our worldwide growth.

Increase in non-labor commercial operations of $2,936 was due primarily to increases in marketing and consulting services of $1,280, travel and entertainment of approximately $366, office lease expense of $290, and freight and distribution expenses of $280.

Decrease in non-labor administration of $898 was due primarily to a decrease in legal expenses of $857 related to the settlement of litigation during 2008.

Other Income and Expense

We recognize investment income primarily from our portfolio of cash equivalents and short-term marketable securities. Investment income was $303 and $767, for the three months ended March 31, 2009 and 2008, respectively. The decrease was due to lower interest rates during the three month periods ended March 31, 2009, as compared to the same period in the prior year.

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We incur interest on our convertible notes, mortgage debt, revolving credit facility, and other debt and capital lease obligations. Our interest expense is net of capitalized interest related to the construction of our Rhode Island manufacturing facility, which was $1,202 and $1,196 for the three months ended March 31, 2009 and 2008, respectively. Interest expense was $333 and $596, for the three months ended March 31, 2009 and 2008, respectively.

Foreign currency transaction gains and losses relate to changes in the fair value of monetary assets and liabilities of our foreign operations. The foreign currency transaction gains (losses) totaled $(393) and $703, for the three months ended March 31, 2009 and 2008, respectively. The loss in the three months ended March 31, 2009 was primarily a result of the fluctuation in exchange rates on the unhedged portion of our monetary assets and liabilities, primarily related to movements in the U.S. dollar compared to the Japanese Yen. The gain in the three months ended March 31, 2008 reflected a favorable impact of exchange rate movements of the Euro prior to initiation of our hedging program.

Income Taxes

During the three months ended March 31, 2009, we recorded an income tax provision of $638, compared to an income tax benefit of $90 for the three months ended March 31, 2008. The tax provision for the three months ended March 31, 2009 is principally attributable to entities in certain foreign jurisdictions who reported profitability during the period and to U.S. federal alternative minimum tax and certain state income taxes. The income tax benefit for the three months ended March 31, 2008 is attributable to the exchange of research tax credits for cash.

The Company maintains a valuation allowance against certain U.S. and foreign deferred tax assets as realizability of those assets is uncertain. We will continue to reassess the need for a valuation allowance on a quarterly basis. We assess certain factors in determining the period that we would reverse the valuation allowance, including: (i) a demonstration of sustained profitability; and (ii) the support of internal financial forecasts demonstrating the utilization of the NOLs prior to their expiration. If we determine that it is more likely than not that the deferred tax asset are realizable and that the reversal of the valuation reserves in these jurisdictions is appropriate, a significant one-time benefit would be recognized against our income tax provision in the period that this determination is made.

Net Income (Loss)

The Company recorded net income for the three month period ended March 31, 2009 of $14,506 or $0.16 per diluted share, versus a net loss of $4,249 or $0.06 per diluted share, respectively, for the corresponding period in 2008.

Liquidity and Capital Resources

As of March 31, 2009, our consolidated cash, restricted cash, cash equivalents and marketable securities totaled $140,809. The $1,098 increase from December 31, 2008 is primarily related to increased sales and the resulting collection of accounts receivable and proceeds from employee option exercises, offset by investments in our Smithfield, Rhode Island facility, the initial $12,500 payment for the PDL settlement and payment of year-end accruals. Until required for use in the business, we invest our cash reserves in highly-rated money market funds and high quality commercial, corporate and U.S. Government notes in accordance with our investment policy. We do not have any investments in auction rate securities or collateralized debt obligations.

Financial instruments that potentially expose the Company to concentrations of credit risk are limited to cash equivalents, accounts receivable and our foreign exchange derivative contracts. Substantially all cash equivalents are currently held in a single AAA rated institutional money market fund that participates in the U.S. Department of Treasury s Temporary Guarantee Program for money market funds. At March 31, 2009, two individual customers accounted for 20.8% and 11.3% of the accounts receivable balance. For the three months ended March 31, 2009, one customer account for 20.5% of our product sales. At March 31, 2008, three individual customers accounted for 33.2%, 16.9% and 12.5% of the accounts receivable balance. For the three months ended March 31, 2008, one customer accounted for 22.8% of our product sales.

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At March 31, 2009, we have foreign currency forward contracts with notional amounts totaling $161,637. These outstanding foreign currency forward contracts had a net fair value of $4,065. The counterparty to these forward contracts is a large multinational commercial bank, and we believe the risk of nonperformance is not material. However, we can not be assured that the financial institution will not be further impacted by the negative economic environment.

At March 31, 2009, our working capital was $216,282, compared to $192,683 at December 31, 2008. At March 31, 2009, our current ratio was 4.09, compared to 3.28 at December 31, 2008. The increase in current ratio relates primarily to the increase in accounts receivable and decreases in accounts payable, accrued expenses and license payable.

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

Operating Activities

Net cash provided by operating activities was $15,929 for the three months ended March 31, 2009, as compared to $11,253 used in operating activities for the three months ended March 31, 2008. The change is primarily due to the net income achieved in 2009 versus the net loss achieved in the same period in 2008. The components of cash provided by operating activities for the three months ended March 31, 2009 are as follows:

- Our reported net income, adjusted for non-cash items, including depreciation and amortization, unrealized currency gain, unrealized hedge gains, unrealized pension losses and stock compensation, of $27,774.

- Net cash outflow due to changes in operating assets and liabilities of $11,845, primarily increases in accounts receivable and prepaid expenses and other current assets of $6,448 and $5,575, respectively.

During 2009, we expect changes in cash from operations to be highly dependent on sales levels, and the related cash collections, from Soliris. In addition, we expect that cash outflows related to the changes in operating assets will continue to increase related to sales and resulting accounts receivable increases.

Investing Activities

Net cash used in investing activities was $18,973 and $2,157 for the three months ended March 31, 2009 and 2008, respectively. For the three months ended March 31, 2009, the net cash used for investing activities consisted of the following:

- Additions to property, plant and equipment of $6,406, of which $4,360 was attributable to expenditures related to validation of our Rhode Island manufacturing facility, with the remaining attributable to spending on information technology and facility capital costs

- Initial payment of $12,500 related to the PDL settlement. During the second quarter of 2009, we will pay the second and final payment of $12,500 for the PDL settlement.

In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island for the future commercial production of Soliris, for manufacturing development and for manufacturing of future products. Since this date, we have incurred costs related to the construction of the plant to support full-scale commercial manufacturing. We have also capitalized costs related to validation activities, including engineering runs, necessary to

obtain approval of the facility from government regulators for the production of a commercially approved drug. To date, these costs primarily include direct labor, materials, overhead and pre-validation inventory related to the facility. We will begin depreciating the fixed assets related to the facility when the assets are substantially complete and ready for their intended use, which would occur upon the regulatory approval of the plant for production of commercial quantities of eculizumab.

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Through March 31, 2009, we have capitalized $120,767 related to the facility, which includes all costs associated with construction, renovation and upgrades, engineering runs and capitalized interest. Through March 31, 2009, costs incurred in seeking regulatory approval, including engineering runs, was $45,617, and capitalized interest was $10,247. We expect to continue to incur costs related to the validation process through the end of the 2009. At such point that we receive regulatory approval, we would cease capitalizing costs into property, plant and equipment.

Financing Activities

Net cash provided by financing activities was $4,128 and $22,422 for the three months ended March 31, 2009 and 2008, respectively. The $4,128 consisted primarily of proceeds of $4,199 from the issuance of common stock related to the exercise of stock options.

Borrowings and Contractual Obligations

The disclosure of payments we have committed to make under our contractual obligations are summarized in Form 10-K for the twelve-month period ended December 31, 2008, in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations under the caption Contractual Obligations. There have been no material changes in our contractual obligations since December 31, 2008.

Significant borrowings and contractual obligations include the following:

Revolving Credit Facility

In February 2008, we entered into a Credit Agreement with Bank of America, N.A. to provide for an available $25,000 revolving credit facility that can be used for working capital requirements and other general corporate purposes. The loan is collateralized by substantially all of Alexion Pharmaceuticals, Inc. s assets, including the pledge of the equity interests of certain direct subsidiaries, but excluding intellectual property, assets of foreign subsidiaries and assets related to our manufacturing facility in Smithfield, RI. The borrowing base is limited to the lesser of $25,000 or 80% of eligible domestic receivables. At March 31, 2009, we had no outstanding borrowings under the revolving credit facility.

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

The revolving credit facility requires that we comply with quarterly financial covenants related to liquidity and profitability ratios, as well as minimum revenue requirements. Further, the agreement includes negative covenants, subject to exceptions, restricting or limiting our ability and the ability of our subsidiaries to, among other things, incur additional indebtedness, grant liens, engage in certain investment, acquisition and disposition transactions, and enter into transactions with affiliates. The agreement also contains customary representations and warranties, affirmative covenants and events of default, including payment defaults, breach of representations and warranties, covenant defaults and cross defaults. If an event of default occurs, the interest rate would increase and the administrative agent would be entitled to take various actions, including the acceleration of amounts due under the loan.

During the first quarter 2009, we determined that we were not in compliance with certain financial covenants under our working capital revolving credit facility. We notified our lender and our lender agreed to waive noncompliance under the agreement. In May 2009, we amended our revolving credit facility to modify such covenants, and a copy of the amendment is filed as an exhibit to this Quarterly Report on Form 10-Q. Other than letters of credit, we had no outstanding balance as of December 31, 2008 and did not borrow under this facility during the first quarter of 2009.

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OMRF Obligation

In February 2008, we agreed to purchase certain patents related to complement-inhibition technology from Oklahoma Medical Research Foundation, or OMRF. We agreed to pay a total of $10,000, plus interest, to OMRF for the rights to the patents. In addition to the initial payment of $3,000 paid in February 2008 and $4,500 in December 2008, we are required to make a final payment of $2,500 by July 2009. Interest accrues on the unpaid amount at the rate of 50% of the sum of the prime rate plus 1%, per annum. We recorded the $10,000 as an intangible asset which is amortized in proportion to product sales through December 2014, the expiration date of the acquired patents.

PDL Obligation

In December 2008, we entered into a definitive license agreement with PDL BioPharma, Inc. on their Queen patent portfolio relating to the humanization of antibodies for $25,000. The initial payment of $12,500 was paid in January 2009, with a final payment of $12,500 due by June 30, 2009. No additional payments will be owed by Alexion to PDL under the Queen patents in respect of Soliris sales for any indication.

Convertible Notes

As of April 30, 2009, we held $46,180 principal amount of 1.375% Convertible Senior Notes due February 1, 2012, or the 1.375% Notes. We pay interest on these notes on a semi-annual basis on February 1 and August 1 of each year, beginning August 1, 2005. However, no principal payments are due until February 2012, except under certain circumstances such as liquidation, merger or business combination. The convertible notes payable do not contain covenants related to our financial performance.

In April 2009, we issued an aggregate of 3,299,865 shares of our common stock in exchange for $51,042 principal amount of our 1.375% Convertible Senior Notes due 2012 owned by certain noteholders. The issuance of the shares was made solely in exchange of the notes pursuant to an exemption from the registration requirements of the Securities Act of 1933, as amended, under Section 3(a)(9) of such Act. We did not receive any cash proceeds as a result of the exchange, and the notes were retired and cancelled. The noteholders received shares from the exchange in excess of the amount that they would have received pursuant to their conversion rights under the notes. In the second quarter of 2009, the fair value of the additional shares over the stated conversion rate will be recorded as an expense of approximately $2,000. As of April 30, 2009, $46,180 of the convertible notes remains outstanding.

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

As of March 31, 2009, the market value of our $97,222, 1.375% Convertible Notes due February 1, 2012, based on quoted market prices, was estimated at $236,082. The $24,976 increase from December 31, 2008 is primarily attributable to the increase in the price of our common stock from the period from December 31, 2008 through March 31, 2009.

Mortgage Loan

We have a mortgage loan of $44,000 to finance the purchase and construction of our manufacturing facility in Smithfield, Rhode Island. The mortgage loan bears interest at a fixed annual rate of 9.12%. The loan principal is required to be repaid in equal monthly installments of $489, starting March 2010 and until August 2017, at which time all outstanding balances are due. The loan is collateralized by the assets of our Smithfield, RI manufacturing facility. The loan may not be prepaid in whole or in part prior to July 2009. After that date, the loan can be prepaid in whole, but not in part, and must include a prepayment premium as described in the loan agreement.

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As a condition of the loan, we are required to maintain restricted cash accounts. These accounts must maintain certain operating escrow balances. At March 31, 2009, the balance of restricted cash was $686.

The mortgage loan does not contain covenants related to our financial performance.

Lonza Agreement

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

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 Disclosure about Market Risks
Interest Rate Market Risk

As of March 31, 2009, we held essentially all of our cash equivalents and investments in money market funds with original maturity dates of three months or less.

Our outstanding long-term liabilities as of March 31, 2009 included our $97,222, 1.375% Convertible Senior Notes due February 1, 2012. As the notes bear interest at a fixed rate, our results of operations would not be impacted by interest rate changes. As of March 31, 2009, the market value of our $97,222 1.375% convertible senior notes due February 1, 2012, based on quoted market prices, was estimated at $236,082. As of April 30, 2009, the balance was reduced to $46,180 due to conversions of $51,042 of the Notes during April 2009.

In July 2006, we borrowed $26,000 to finance the purchase and construction of our Smithfield, Rhode Island manufacturing facility. In July 2007, we amended the mortgage loan agreement with iStar Financial Inc. to increase the loan amount by $18,000, resulting in an aggregate principal balance of $44,000. From the effective date of the amendment, the mortgage loan bears interest at a fixed annual rate of 9.12%. Accordingly, any changes in the interest rate will not impact our financial statements.

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

In conjunction with the purchase of patents from OMRF, we agreed to pay an aggregate principal amount of $7,000, representing the balance of the $10,000 purchase price for the OMRF patent rights. Interest shall accrue on any unpaid amount at the rate of 50% of the sum of the prime rate (as published in the Money Rates section of the Wall Street Journal (New York edition) plus 1%, per annum. We do not expect changes in interest rates related to this payable to have a material effect on our financial statements.

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Foreign Exchange Market Risk

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

As of March 31, 2009, we had foreign currency forward contracts with notional amounts totaling $161,637. As of March 31, 2009, our outstanding foreign currency forward contracts had a net fair value of $4,065.

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

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

Item 4. Controls and Procedures

As of March 31 2009, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2009.

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

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PART II. OTHER INFORMATION

Item 1A. Risk factors

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

Risks Related to Our Lead Product Soliris

We depend heavily on the success of our lead product, Soliris, which was approved in the United States and in Europe in March 2007 and June 2007, respectively, and in Canada in January 2009 for the treatment of PNH. If we are unable to increase sales of Soliris in the United States and Europe and commercialize Soliris in additional countries or if we are significantly delayed or limited in doing so, our business will be materially harmed.

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

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

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

We obtained marketing approval for Soliris in Europe in June 2007 however such approval did not automatically authorize us to commence commercial sales in every country in the European Union. We continue discussions with appropriate authorities in different countries in Europe so that we may, upon conclusion of such discussions, commence commercial sales in those countries. We have submitted applications for marketing authorization in countries outside the European Union and have received approval in Canada in January 2009 and Australia in February 2009. We cannot guarantee that reimbursement and other discussions and processes will be concluded successfully or on a timely basis and, as a result, sales in certain countries may be delayed or never occur, or may be subsequently reduced. If we are not successful in commercializing Soliris in the United States and the rest of the world, or are significantly delayed or limited in doing so, we may experience a surplus inventory, our business will be materially harmed and we may need to curtail or cease operations.

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

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

If we are unable to obtain and maintain reimbursement for Soliris from government health administration authorities, private health insurers and other organizations, Soliris may be too costly for regular use and our ability to generate revenues would be harmed.

We may not be able to sell Soliris on a profitable basis or our profitability may be reduced if we are required to sell our product at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. Soliris is significantly more expensive than traditional drug treatments and almost all patients require some form of third party coverage to afford its cost. Our future revenues and profitability will be adversely affected if we cannot depend on governmental, private third-party payers and other third-party payers, such as Medicare and Medicaid in the United States or country specific governmental organizations, to defray the cost of Soliris to the patient. If these entities refuse to provide coverage and reimbursement with respect to Soliris or determine to provide a lower level of coverage and reimbursement than anticipated, Soliris may be too costly for general use, and physicians may not prescribe it.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us, or such coverage, pricing, and reimbursement may differ in separate regions in the same country. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country and we cannot guarantee that we will have the capabilities or resources to successfully conclude the necessary processes and commercialize Soliris in every or even most countries in which we seek to sell Soliris. Reimbursement sources are different in each country and in each country may include a combination of distinct potential payers, including private insurance and governmental payers. For example, countries in the European Union may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may from time to time approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to successfully and timely conclude reimbursement, price approval or funding processes and begin to market Soliris in foreign countries or if coverage and reimbursement for Soliris in foreign countries is limited. If we discover we are not able to obtain coverage, pricing or reimbursement on terms acceptable to us or at all, or if such terms should change, in any foreign countries, we may not be able to or we may determine not to sell Soliris in such countries and our plans for geographic expansion of sales and our business may be adversely affected as a result.

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

In addition to potential restrictions on coverage, the amount of reimbursement for Soliris may also reduce our profitability and worsen our financial condition. In the United States, European countries, and elsewhere, there have been, and we expect there will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs. See additional discussion below under the headings Healthcare reform measures could adversely affect our business and The current credit and financial market conditions may aggravate certain risks affecting our business.

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Even where patients have access to insurance, their insurance co-payment amounts or annual or lifetime caps on reimbursements may represent a barrier to obtaining Soliris. In the United States, Alexion has financially supported the PNH Fund of the National Organization for Rare Disorders, or NORD, which, among other things, assists patients in acquiring drugs such as Soliris. Organizations such as NORD assist patients whose insurance coverage leaves them with prohibitive co-payment amounts or other expensive financial obligations. NORD s ability to provide financial assistance to PNH patients is dependent on funding from external sources, and we cannot guarantee that such funding will be provided at adequate levels, if at all. We have also provided Soliris without charge to patients who have no insurance coverage for drugs for related charitable purposes. We are not able to predict the financial impact of the support we may provide for these and other charitable purposes; however, substantial support, or delays in patient treatment related to such support, could have a material adverse effect on our ability to maintain profitability on a quarterly or annual basis in the future.

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

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

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

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

We cannot guarantee that we will be able to maintain our regulatory approvals for Soliris. If we do not maintain our regulatory approvals for Soliris, the value of our company and our results of operations will be materially harmed. We and our future partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by the FDA, other federal and state agencies, and governmental authorities in other countries or group of countries. These regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, risk mitigation, adverse event reporting requirements, and export of biologics. As a condition of approval for marketing our product, the FDA or other governmental authorities outside the United States may require us to conduct additional clinical trials. For example, in connection with the approval of Soliris in the United States, we have agreed to establish a PNH Registry, monitor immunogenicity, monitor compliance with vaccination requirements, and determine the effects of anticoagulant withdrawal among PNH patients receiving eculizumab. The FDA can propose to withdraw approval if new clinical data or information shows that a product is not safe for use in an approved indication or determines that such studies are inadequate. We are required to report any serious and unexpected adverse experiences and certain quality problems with Soliris to the FDA, the EMEA and certain other health agencies. We, the FDA, the EMEA or another

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health agency may have to notify healthcare providers of any such developments. The discovery of any previously unknown problems with Soliris, manufacturer or facility may result in restrictions on Soliris, manufacturer or manufacturing 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. Any third party we would use to manufacture Soliris for sale must also be licensed by applicable regulatory authorities.

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

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

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

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

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

We have tested Soliris in only a small number of patients. As more patients begin to use Soliris, new risks and side effects, or the rate of such risks or side effects, may be discovered, and risks previously viewed as less significant could be determined to be significant. Previously unknown risks and adverse effects of Soliris may also be discovered in connection with unapproved, or off-label, uses of Soliris. We do not promote, or in any way support or encourage the promotion of Soliris for off-label uses in violation of relevant law, but physicians are permitted to use products for off-label purposes and we are aware of such off-label uses of Soliris. In addition, we expect to study Soliris in diseases other than PNH in controlled clinical settings, and expect independent investigators to do 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

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consents or waivers obtained from people who enroll in our trials or use Soliris may not protect us from liability or litigation. Our product liability insurance may not cover all potential types of liabilities or may not cover certain liabilities completely. Moreover, we may not be able to maintain our insurance on acceptable terms. In addition, negative publicity relating to the use of Soliris or a product candidate, or to a product liability claim, may make it more difficult, or impossible, for us to market and sell Soliris. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

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

Some patients treated with Soliris for PNH or other diseases, including patients who have participated in our clinical trials, have died or suffered potentially life-threatening diseases either during or after ending their Soliris treatments. In particular, use of C5 Inhibitors, such as Soliris, is associated with an increased risk for certain types of infection, including Neisseria bacteria. Serious cases of Neisseria infection can result in severe illness, including but not limited to brain damage, loss of limbs or parts of limbs, kidney failure, or death. PNH patients in our TRIUMPH and SHEPHERD trials all received vaccination against Neisseria bacteria prior to first administration of Soliris and all patients who are prescribed Soliris in the United States and Europe are required by prescribing guidelines to be vaccinated prior to receiving their first dose; however, vaccination does not eliminate all risk of becoming infected with Neisseria bacteria. Some patients treated with Soliris, who had been vaccinated, including patients who have participated in our trials of Soliris for the treatment of PNH and other diseases, have become infected with Neisseria bacteria, including patients who have suffered serious illness or death. Each such incident is required to be reported to appropriate regulatory agencies in accordance with relevant regulations.

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

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

Governments in countries outside the United States and Europe also regulate drugs distributed in such countries and facilities in such countries where such drugs are manufactured, and obtaining their approvals can also be lengthy, expensive and highly uncertain. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. In certain jurisdictions, we are required to finalize operational,

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reimbursement, price approval and funding processes prior to marketing our products. Soliris became commercially available in certain countries in Europe in the fourth quarter of 2007. We received regulatory approval for Soliris for treatment of patients with PNH in Canada in January 2009 and Australia in February 2009. We may not receive regulatory approval for Soliris outside the United States, Canada, Australia and Europe for at least the next several years, if ever.

Regulatory agencies may require additional information or data with respect to our submissions for Soliris for PNH. We may have to conduct additional lengthy clinical testing and other costly and time-consuming procedures to satisfy foreign regulatory agencies. Even with approval of Soliris by the FDA, Health Canada, Therapeutic Goods Administration in Australia, and the E.C., other regulatory agencies may not agree with our interpretations of our clinical trial data for Soliris and may decide that our results are not adequate to support approval for marketing of Soliris. In those circumstances, we would not be able to obtain regulatory approval in such country on a timely basis, if ever. Even if approval is granted in such country, the approval may require limitations on the indicated uses for which the drug may be marketed. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. We must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. For example, we were required to conduct clinical studies with Soliris in patients with PNH in Japan; however, there is no assurance that the Japanese regulatory agency will find these studies sufficient for registration of Soliris in Japan.

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

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

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

In the United States, we sell Soliris to distributors who in turn sell to patient health-care providers. We do not promote Soliris to these distributors and they do not set or determine demand for Soliris. For the three months ended March 31, 2009, our single largest customer, Amerisource Bergen, accounted for 20.5% of our Soliris net product sales, and our three largest customers accounted for approximately 35.3% of our net product sales. As of March 31, 2009, two individual customers accounted for 20.8% and 11.3% 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.

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

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

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

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

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program.

Although physicians are permitted to, based on their medical judgment, prescribe products for indications other than those cleared or approved by the FDA, manufacturers are prohibited from promoting their products for such off-label uses. We market Soliris for PNH and provide promotional materials and training programs to physicians regarding the use of Soliris for PNH. Although we believe our marketing, promotional materials and training programs for physicians do not constitute off-label promotion of Soliris, the FDA may disagree. If the FDA determines that our promotional materials, training or other activities constitute off-label promotion of Soliris, it could request that we modify our training or promotional materials or other activities or subject us to regulatory

enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is later determined we are not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our position and have to divert significant management resources from other matters.

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

In recent years, several states and localities, including California, the District of Columbia, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

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

Including Eculizumab for Indications Other than PNH

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

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

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

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

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

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

For human trials, patients must be recruited and each product candidate must be tested at various doses and formulations for each clinical indication. In addition, to ensure safety and effectiveness, the effect of drugs often must be studied over a long period of time, especially for the chronic diseases that we are studying. Unfavorable results or insufficient patient enrollment in our clinical trials could delay or cause us to abandon a product development program. We may decide to abandon development of a product candidate at any time, or we may have to spend considerable resources repeating clinical trials or conducting additional trials, either of which would increase costs and delay any revenue from those product candidates, if any.

Additional factors that can cause delay, impairment or termination of our clinical trials or our product development efforts include:

- slow patient enrollment, including for example due to the rarity of the disease being studied;
- long treatment time required to demonstrate effectiveness;
- lack of sufficient supplies of the product candidate;
- disruption of operations at the clinical trial sites;
- adverse medical events or side effects in treated patients;
- the failure of patients taking the placebo to continue to participate in our clinical trials;
- insufficient clinical trial data to support effectiveness of the product candidates;
- lack of effectiveness or safety of the product candidate being tested;

lack of sufficient funds;

inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner; or

failure to obtain the necessary regulatory approvals for the product candidate or the approvals for the facilities in which such product candidate is manufactured.

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

The preclinical development, clinical trials, manufacturing, marketing and labeling of pharmaceuticals are all subject to extensive regulation by numerous governmental authorities and agencies in the United States and other countries. We must obtain regulatory approval for each of our product candidates before marketing or selling any of them. It is not possible to predict how long the approval processes of the FDA or any other applicable federal or foreign regulatory authority or agency for any of our product candidates will take or whether any such approvals ultimately will be granted. The FDA and foreign regulatory agencies have substantial discretion in the drug approval process, and positive results in preclinical testing or early phases of clinical studies offer no assurance of success in

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later phases of the approval process. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. Generally, preclinical and clinical testing of product candidates can take many years and require the expenditure of substantial resources, and the data obtained from these tests and trials can be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. If we encounter significant delays in the regulatory process that result in excessive costs, this may prevent us from continuing to develop our product candidates. Any delay in obtaining, or failure to obtain, approvals could adversely affect the marketing of our products and our ability to generate product revenue. The risks associated with the approval process include:

- failure of our product candidates to meet a regulatory agency s requirements for safety, efficacy and quality;
- limitation on the indicated uses for which a product may be marketed;
- unforeseen safety issues or side effects; and
- governmental or regulatory delays and changes in regulatory requirements and guidelines.

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

Physicians may elect not to recommend our drugs even if they receive marketing approval for a variety of reasons, including the timing of the market introduction of competitive drugs; lower demonstrated clinical safety and efficacy compared to other drugs; lack of cost-effectiveness; lack of availability of reimbursement from third-party payers; convenience and ease of administration; prevalence and severity of adverse side effects; other potential advantages of alternative treatment methods; and ineffective marketing and distribution support. Sales of pharmaceutical products depend in significant part on the coverage and reimbursement policies of government programs, including Medicare and Medicaid in the United States and programs in other countries, and other third-party payers. These health insurance programs may restrict coverage of some products by using payor formularies under which only selected drugs are covered, variable co-payments that make drugs that are not preferred by the payor more expensive for patients, and by using utilization management controls, such as requirements for prior authorization or failure on another type of treatment. Payors may especially impose these obstacles to coverage for higher-priced drugs, and consequently Soliris may be subject to payor-driven restrictions. In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, countries in the European 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 on commercially reasonable terms, or failure or delay by us or our third-party manufacturers, in manufacturing our drug products in the volumes and quality required, would have a material adverse effect on our business.

Clinical quantities of eculizumab are manufactured by us in our Rhode Island facility and by Lonza. Clinical quantities of CD200 are manufactured solely by us in Rhode Island. Manufacture of our drug products is highly technical and only a small number of companies have the ability and capacity to manufacture our drug products for our development and commercialization needs. We cannot be certain that any third party will be able or willing to honor the terms of its agreement, including any obligations to manufacture the drug products in accordance with regulatory requirements and to our quality specifications and volume requirements. Due to the highly technical requirements of manufacturing our drug products, our third-party collaborators and we may be unable to manufacture our drug products despite their and our efforts.

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

We currently have no experience or capacity for manufacturing drug products in volumes that would be necessary to support commercial sales and we can provide no assurance that we will be able to do so successfully. We depend on a single manufacturer for commercial supply of Soliris and a few outside vendors for other manufacturing services, such as packaging, vialing and labeling. We acquired a commercial-scale manufacturing plant in Smithfield, Rhode Island in July 2006. However, that plant is not currently approved by the FDA or other regulatory agencies to manufacture Soliris. We expect that it will be at least 2010 before product from the plant is approved for commercial sale in the United States. We have no experience in developing commercial-scale manufacturing similar to anticipated production in Smithfield, Rhode Island. We can provide no assurance that we will be able to develop the Smithfield, Rhode Island site into a plant capable of manufacturing our drug products under conditions required by the FDA or foreign regulatory agencies on a timely basis, if at all. Our plant in Smithfield, Rhode Island will be subject to FDA inspection and approval before we can begin sales of Soliris or other drug products manufactured in this facility, and we will continue to be subject to ongoing FDA inspections thereafter. Our Smithfield, Rhode Island plant will also be subject to European regulatory inspection and approval before we can sell Soliris or any other drug product in Europe that is manufactured in this facility and we will continue to be subject to ongoing European regulatory inspection thereafter.

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

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

Risks Related to Intellectual Property

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

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

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

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

Parts of our technology, techniques and proprietary compounds and potential drug candidates, including those which are or may be in-licensed, may be found to infringe patents owned by or granted to others. We previously reported that three civil actions were filed against us relating to the commercialization of Soliris and the intellectual property rights of third parties. Each of these cases was resolved in 2008, however, additional third parties may claim that the manufacture, use or sale of Soliris or other drugs under development infringes patents owned or granted to such third parties. We are aware of broad patents owned by others relating to the manufacture, use and sale of recombinant humanized antibodies, recombinant human antibodies, and recombinant human single chain antibodies. Soliris and many of our product candidates are either genetically engineered antibodies, including recombinant humanized antibodies, recombinant human antibodies, or recombinant human single chain antibodies. In addition to the actions described above, we have received notices from the owners of some of these patents claiming that their patents may be infringed by the development, manufacture or sale of Soliris or some of our drug candidates. We are also aware of other patents owned by third parties that might be claimed by such third parties to be infringed by the development and commercialization of Soliris and some of our drug candidates. In respect to some of these patents, we have obtained licenses, or expect to obtain licenses. However, with regard to such other patents, we have determined in our judgment that:

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

Any holder of these patents or other patents covering similar technology could sue us for damages and seek to prevent us from manufacturing, selling or developing our drugs. Legal disputes can be costly and time consuming to defend. If we cannot successfully defend against any future actions or conflicts, if they arise, we may incur substantial legal costs and may be liable for damages, be required to obtain costly licenses or need to stop manufacturing, using or selling Soliris, which would adversely affect our business. A required license may be costly or may not be available on acceptable terms, if at all. A costly license, or inability to obtain a necessary license, could have a material adverse effect on our business.

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

Risks Related to Our Operations

We have had a history of losses and may not be able to maintain profitability on a quarterly or annual basis in the future.

Until the quarter ended June 30, 2008, we had never been profitable since we started our company in January 1992. We may not be able to generate sufficient revenues to achieve profitability in any subsequent quarters or on an annual basis. Even if we do achieve profitability in any subsequent quarters, we may not be able to sustain or increase profitability on a quarterly or annual basis. You should not consider our revenue growth in recent periods as indicative of our future performance. Our revenue in future periods could decline. Because we have only limited experience thus far with marketing, sales and distribution of Soliris, we have limited insight into the trends that may

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emerge and affect us. We may make errors in predicting and reacting to relevant business trends, which could harm our business. As of December 31, 2008, we had an accumulated deficit of approximately $696,000. Since we began our business, we have focused on research and development of product candidates. We launched Soliris for sale in the United States during April 2007 and began commercial sales in Europe during the fourth quarter of 2007. We cannot guarantee that we will be successful in marketing and selling Soliris in the United States and Europe, on a continued basis, and we do not know when we will have Soliris available for sale in other countries and regions, if ever. All of our other product candidates are still in the early stages of research and development. We will have substantial expenses as we continue our research and development efforts, continue to conduct clinical trials, and continue to develop manufacturing, sales, marketing and distribution capabilities in the United States and abroad. Our future profitability depends on our ability to successfully market Soliris in the United States and Europe, on receiving regulatory, pricing, coverage, and reimbursement approvals of Soliris in other countries and regions, our ability to successfully market Soliris in other countries and regions, and our ability to successfully manufacture and commercialize our drug candidates. The extent and the timing of our future losses and our profitability are highly uncertain.

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

Both the FDA and the European Medicines Evaluation Agency, or EMEA, have granted orphan drug designation for Soliris in the treatment of PNH, which entitles us to exclusivity for seven years in the United States and for ten years in Europe. However, if a competitive product that is the same as Soliris, as defined under the applicable regulations, is shown to be clinically superior to Soliris in the treatment of PNH, or if a competitive product is different from Soliris, as defined under the applicable regulations, the orphan drug exclusivity we have obtained may not block the approval of such competitive product. Several biotechnology and pharmaceutical companies throughout the world have programs to develop complement inhibitor therapies or have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. Other companies have publicly announced intentions to develop therapeutic human antibodies from libraries of human antibody genes or therapeutic human antibodies from mice that have been bred to include some human antibody genes. A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us. These and other companies, many of which have significantly greater resources than us, may develop, manufacture, and market better or cheaper drugs than Soliris or our product candidates. They may establish themselves in the marketplace before Alexion for Soliris for other indications or for any of our other product candidates. Other pharmaceutical companies also compete with us to attract academic research institutions as drug development partners, including for licensing these institutions proprietary technology. If our competitors successfully enter into such arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may not be able to find equivalent opportunities elsewhere.

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, cash equivalents and marketable securities 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 Europe, Canada, Latin America and Asia-Pacific, evaluating and preparing regulatory submissions for Soliris in other 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;

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

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

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

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

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

We are significantly leveraged.

On April 30, 2009, we had outstanding $46,180 principal amount of 1.375% convertible senior notes which will mature on February 1, 2012. Our subsidiary Alexion Manufacturing borrowed $44,000 to finance the purchase and construction of our Smithfield, Rhode Island manufacturing facility which may not be prepaid in whole or in part prior to July 11, 2009. The loan is guaranteed by us and bears a fixed annual rate of 9.12%. The loan principal is required to be repaid in equal monthly installments of $489, starting March 2010 and until August 2017, at which time all outstanding balances are due. During the first quarter of 2008, we entered into a revolving credit facility with Bank of America and may borrow up to $25,000, with up to a $5,000 sublimit for letters of credit that can be used

for working capital requirements and other general corporate purposes. The loan is collateralized by substantially all of our assets, including the pledge of the equity interests of certain direct subsidiaries, but excluding intellectual property, assets of foreign subsidiaries and assets related to our manufacturing facility in Smithfield, Rhode Island. We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.75% to 2.25% depending on our liquidity (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect and (B) the Federal Funds Rate then in effect plus 0.50%, plus 0% to 0.25% depending on our liquidity (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 February 28, 2011, the maturity date. In addition, we paid $7,500 and are required to pay an additional principal amount of $2,500 in connection with the acquisition of certain patents from the Oklahoma Medical Research Foundation, or OMRF. In connection with the settlement of our patent litigation with PDL, we agreed to make a $25,000 payment to PDL, $12,500 of which has been paid in January 2009 and $12,500 of which is due in June 2009.

Our 1.375% convertible senior notes, the mortgage loan, the revolving credit facility and the OMRF and PDL obligation, remain outstanding or available, and the degree to which we are leveraged could, among other things:

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

Our ability to meet our debt service obligations, including our compliance with the applicable financial and other covenants required by these arrangements, will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

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

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

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

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

- substantial cash expenditures;

potentially dilutive issuance of equity securities;

incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;

difficulties in assimilating the operations of the acquired companies;

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diverting our management s attention away from other business concerns;

risks of entering markets in which we have limited or no direct experience; and

the potential loss of our key employees or key employees of the acquired companies.

We compete with pharmaceutical companies that have significantly greater resources than us for many of the same acquisition and in-licensing opportunities. Such pharmaceutical companies that are less leveraged and have better access to capital resources may preclude us from completing any acquisition or in-licensing. Even if we are able to complete an acquisition or in-licensing, we cannot assure you that any acquisition or in-licensing of new products will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or an acquired or in-licensed product. In addition, our future success would depend in part on our ability to manage the rapid growth associated with any such acquisitions or in-licensing. We cannot assure you that we will be able to make the combination of our business with that of acquired businesses or companies work or be successful. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all. Furthermore, the development or expansion of our business, any acquired business or any acquired or in-licensed products may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our capital stock, which could dilute current stockholders ownership interest in our company, or securities convertible into our capital stock, which could dilute current stockholders ownership interest in our company upon conversion.

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

As of December 31, 2008, we have approximately $745,000 of U.S. Federal net operating loss carryforwards (NOLs) available to reduce taxable income in future years. A portion of these NOLs are currently subject to an annual limitation under section 382 of the Internal Revenue Code of 1986, as amended.

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

In addition, the ability to use net operating loss carryforwards will be dependent on our ability to generate taxable income. The net operating loss carryforwards may expire before we generate sufficient taxable income. NOLs totaling $3,800 expired in the year ended December 31, 2007. No NOLs expired during the year-ended December 31, 2008.

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

As a company with international operations, we are subject to income taxes, as well as non-income based taxes, in both the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities. Although we believe our estimates are reasonable, the ultimate outcome with respect to the

taxes we owe may differ from the amounts recorded in our financial statements. If the Internal Revenue Service, or other taxing authority, disagrees with the positions taken by our company, we could have additional tax liability and this could have a material impact on our results of operations and financial position. In addition, the United States government and other governments are considering and may adopt tax reform measures that significantly increase our worldwide tax liabilities and materially harm our business, financial condition and results of operations.

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

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

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

We conduct a substantial portion of our business in currencies other than the U.S. dollar, primarily Euros. While we attempt to hedge certain currency risks, currency fluctuations between the U.S. dollar and the currencies in which we do business have caused foreign currency transaction gains and losses in the past and will likely do so in the future. Likewise, past currency fluctuations have at times resulted in foreign currency transaction gains, and there can be no assurance that these gains can be reproduced.

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

Sales of Soliris are dependent, in large part, on reimbursement from government health administration organizations and private and governmental third-party payers, and also co-payments from individual patients in certain situations. As a result of the current credit and financial market conditions, and the overall financial climate, these governmental organizations and payors, and/or individuals, may reduce or delay initiation of treatment, may be unable to satisfy their reimbursement obligations, may delay payment or may seek to reduce reimbursement for Soliris in the future, which could have a material adverse effect on our business and results of operations.

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

Healthcare reform measures could adversely affect our business.

The United States government and governments in foreign countries have shown significant interest in pursuing healthcare reform in order to reduce costs of healthcare. Any government-adopted reform measures could adversely impact the pricing of Soliris or the amount of reimbursement available for Solilris from governmental agencies or other third-party payors. The pricing and reimbursement environment for Soliris may become more challenging due to, among other reasons, policies of a new presidential administration or new healthcare legislation

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passed by Congress, or other changes in policy in the United States or in foreign countries. While we cannot predict what, if any, legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could delay or prevent our entry into new markets, affect our reimbursement or sales in the markets where we are already selling Soliris and materially harm our business, financial condition and results of operations.

Risks Related to Our Common Stock

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

The trading price of our common stock has been volatile and may continue to be volatile in the future. Factors such as announcements of fluctuations in our or our competitors operating results or clinical or scientific results, fluctuations in the trading prices or business prospects of our competitors and collaborators, changes in our prospects, particularly with respect to sales of Soliris, and market conditions for biopharmaceutical stocks in general could have a significant impact on the future trading prices of our common stock and our convertible senior notes. In particular, the trading price of the common stock of many biopharmaceutical companies, including ours, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of the companies whose stocks were affected. This is due to several factors, including general market conditions, sales of Soliris, the announcement of the results of our clinical trials or product development and the results of our efforts to obtain regulatory approval for our products. In particular, between January 1, 2007 and December 31, 2008, the closing sales price of our common stock fluctuated from a low of $17.89 per share to a high of $47.51 per share, as reported after giving effect to the forward two-for-one stock split effected on August 22, 2008. While we cannot predict our future performance, if our stock price continues to fluctuate in a wide range, an investment in our common stock may result in considerable uncertainty for an investor.

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

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

Our corporate charter and by-law provisions and stockholder rights plan may discourage certain types of transactions involving an actual or potential change of control that might be beneficial to Alexion or its stockholders. Our bylaws provide that special meetings of our stockholders may be called only by the Chairman of the Board, the President, the Secretary, or a majority of the Board of Directors, or upon the written request of stockholders who together own of record 50% of the outstanding stock of all classes entitled to vote at such meeting. Our bylaws also specify that the authorized number of directors may be changed only by resolution of the board of directors. Our certificate does not include a provision for cumulative voting for directors, which may have enabled a minority stockholder holding a sufficient percentage of a class of shares to elect one or more directors. Under our certificate of incorporation, our board of directors has the authority, without further action by stockholders, to designate up to 5,000,000 shares of preferred stock in one or more series. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any class or series of preferred stock that may be issued in the future.

Pursuant to our stockholder rights plan, each share of common stock has an associated preferred stock purchase right. The rights will not trade separately from the common stock until, and are exercisable only upon, the acquisition or the potential acquisition through tender offer by a person or group of 20% or more of the outstanding common stock. The rights are designed to make it more likely that all of our stockholders receive fair and equal

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ALEXION PHARMACEUTICALS, INC.

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 6. EXHIBITS

(a) Exhibits

10.1	Summary of 2009 Director Compensation.
10.2	Waiver and First Amendment to Credit Agreement, dated May 7, 2009, between the Company and Bank of America, N.A.
31.1	Certification by Leonard Bell, Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
31.2	Certification by Vikas Sinha, Senior Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
32.1	Certification by Leonard Bell, Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
32.2	Certification by Vikas Sinha, Senior Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.

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SIGNATURES

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

ALEXION PHARMACEUTICALS, INC.

Date: May 8, 2009

By: /s/ Leonard Bell
Leonard Bell, M.D.
Chief Executive Officer, Secretary and Treasurer

(principal executive officer)

Date: May 8, 2009

By: /s/ Vikas Sinha
Vikas Sinha
Senior Vice President and Chief Financial Officer

(principal financial officer)