ALEXION PHARMACEUTICALS INC
Form 10-Q
October 30, 2008
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended September 30, 2008

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 is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

Common Stock, $0.0001 par value	77,925,725
Class	Outstanding at October 28, 2008

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CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(in thousands, except per share amounts)	September 30, 2008	December 31, 2007
Assets		
Current Assets:		
Cash and cash equivalents	$ 124,150	$ 95,321
Marketable securities	1,700	10,433
Trade accounts receivable	70,715	46,278
Inventories	49,724	32,907
Prepaid manufacturing costs	5,497	13,775
Prepaid expenses and other current assets	18,634	6,640
Total current assets	270,420	205,354
Property, plant and equipment, net	128,450	104,280
Intangible assets, net	9,992	
Goodwill, net	19,954	19,954
Restricted cash	552	958
Other assets	975	3,811
Total assets	$ 430,343	$ 334,357
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 9,890	$ 9,072
Accrued expenses	41,809	28,324
Deferred revenue	2,398	41
Current portion of long-term debt obligation	7,000	
Current portion of capital lease obligations	290	272
Total current liabilities	61,387	37,709
Capital lease obligations, less current portion	280	499
Mortgage loan	44,000	44,000
Convertible notes	150,000	150,000
Other liabilities	916	593
Total liabilities	256,583	232,801
Commitments and contingencies (Note 15)		
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; 78,022 and 75,746 shares issued at September 30, 2008 and December 31, 2007, respectively	8	4
Additional paid-in capital	881,511	833,534
Treasury stock, at cost, 115 shares	(1,260)	(1,260)
Accumulated other comprehensive loss	4,967	(1,443)
Accumulated deficit	(711,466)	(729,279)

Total stockholders equity	173,760	101,556
Total liabilities and stockholders equity	$ 430,343	$ 334,357

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

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(in thousands, except per share amounts)	Three months ended September 30, 2008	2007	Nine months ended September 30, 2008	2007
Revenues:				
Net product sales	$ 76,500	$ 21,793	$ 181,605	$ 32,524
Contract research revenues		317	95	5,660
Total revenues	76,500	22,110	181,700	38,184
Cost of sales	8,948	2,154	21,554	3,305
Operating expenses:				
Research and development	14,874	16,906	47,306	53,318
Selling, general and administrative	32,064	24,944	94,754	67,571
Total operating expenses	46,938	41,850	142,060	120,889
Operating income (loss)	20,614	(21,894)	18,086	(86,010)
Other income and expense:				
Investment income	690	1,796	2,071	6,724
Interest expense	(634)	(643)	(1,975)	(1,854)
Foreign currency gain (loss)	(566)	578	(200)	924
Income (loss) before income tax benefit	20,104	(20,163)	17,982	(80,216)
Income tax provision (benefit)	415	(78)	169	(258)
Net income (loss)	$ 19,689	$ (20,085)	$ 17,813	$ (79,958)
Net income (loss) per share:				
Basic	$ 0.26	$ (0.27)	$ 0.24	$ (1.11)
Diluted	$ 0.23	$ (0.27)	$ 0.22	$ (1.11)
Weighted average common shares used to compute net income (loss) per common share:				
Basic	76,658	73,328	75,794	72,046
Diluted	89,843	73,328	88,797	72,046

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)	Nine months ended September 30, 2008	2007
Cash flows from operating activities:		
Net income (loss)	$ 17,813	$ (79,958)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	5,529	3,206
Share-based compensation expense	17,881	16,386
Loss on disposal of property, plant and equipment	44	
Changes in operating assets and liabilities:		
Accounts receivable	(26,125)	(31,625)
Inventories	(15,980)	(29,898)
Prepaid expenses and other assets	(2,148)	1,695
Accounts payable and accrued expenses	22,879	7,318
Deferred revenue	2,456	(5,325)
Net cash provided by (used in) operating activities	22,349	(118,201)
Cash flows from investing activities:		
Purchases of marketable securities	(174,215)	(96,556)
Proceeds from maturity or sale of marketable securities	182,948	125,878
Purchases of property, plant and equipment	(27,180)	(56,002)
Purchase of technology rights	(3,000)	
Release of restricted cash	406	19,768
Net cash used in investing activities	(21,041)	(6,912)
Cash flows from financing activities:		
Payments under capital lease obligations	(202)	(97)
Proceeds from mortgage loan		18,000
Debt issuance costs	(312)	
Net proceeds from issuance of common stock	28,018	31,700
Net cash provided by financing activities	27,504	49,603
Effect of exchange rate changes on cash	17	184
Net change in cash and cash equivalents	28,829	(75,326)
Cash and cash equivalents at beginning of period	95,321	166,826
Cash and cash equivalents at end of period	$ 124,150	$ 91,500

See Notes 6 and 12 for investing and financing non-cash disclosures.

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

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(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 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 January 1992, and we began commercial sales of Soliris in the United States and in certain countries in 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, 2007. In our opinion, the accompanying unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to state fairly our financial position as of September 30, 2008, the results of our operations for the three and nine months ended September 30, 2008 and 2007, and our cash flows for the nine months ended September 30, 2008 and 2007. The December 31, 2007 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, 2007 included in our Annual Report on Form 10-K. The results of operations for the three and nine months ended September 30, 2008 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 and 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.

In July 2008, the Company s Board of Directors approved a two-for-one stock split to be effected in the form of a 100 percent stock dividend. The additional shares were distributed on August 22, 2008 to stockholders of record as of the close of trading on August 12, 2008. All share and per share data presented in the accompanying consolidated financial statements and throughout these notes has been retroactively restated to reflect this stock split.

3. Revenue

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

To date, our product sales have consisted solely of Soliris. We recognize revenue from product sales when persuasive evidence of an arrangement exists, 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. Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in the Company s statements of operations, and do not impact net product sales.

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In the United States, our customers are primarily specialty distributors and specialty pharmacies who 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.

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

To date, actual refunds and returns have been negligible. Because of the pricing of Soliris, the limited number of patients, the short period from sale of product to patient infusion and lack of return rights, Soliris customers generally carry limited inventory. Accordingly, we expect that sales related to Soliris will be closely tied to patient demand. To the extent that our actual experience differs from our estimates, we will revise these estimates resulting in an impact in the period in which the adjustment was made.

We record estimated rebates payable under governmental programs, including Medicaid and programs in countries outside the United States, 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 review our estimates and assumptions each period and record any necessary adjustments to our reserves. 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 will revise our estimates of rebates payable, which will have an impact on revenue in the period in which the adjustment was made.

We also 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.

During the three months ended September 30, 2008, certain government payors agreed to reimburse for Soliris shipments which were delivered in prior periods. Accordingly, we recognized $5,300 of net product sales in the third quarter associated with these prior shipments.

4. Royalties

Our cost of sales for the three and nine months ended September 30, 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 current litigation, the results of which are uncertain (see Note 15). On a periodic basis and based on events such as the outcome of litigation, we may reassess these estimates, resulting in adjustments to cost of sales.

5. Inventories

The following table summarizes the components of our inventories:

	September 30, 2008	December 31, 2007
Raw materials	$ 6,553	$ 4,985
Work-in-process	24,625	17,677
Finished goods	18,546	10,245
	$ 49,724	$ 32,907

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6. Intangible Assets

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, we are required to make a payment of $4,500 by December 2008 and 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, or 3.0%, at September 30, 2008. We recorded the $10,000 as an intangible asset which is amortized over its useful life of 6 years, which represents the remaining life of the acquired patents on the date of the agreement.

7. Debt

In February 2008, we entered into a Credit Agreement with Bank of America, N.A. to provide for a revolving credit facility of up to $25,000 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, Rhode Island. The borrowing base is limited to the lesser of $25,000 or 80% of eligible domestic receivables. At September 30, 2008, we have no outstanding balance 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.

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8. Comprehensive Income (Loss)

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

	Three months ended September 30		Nine months ended September 30	
	2008	2007	2008	2007
Net income (loss)	$ 19,689	$ (20,085)	$ 17,813	$ (79,958)
Unrealized gains on hedging activity	6,861		6,861	
Defined benefit pension plan activity			(245)	
Net unrealized gains on available for sale securities		28		52
Foreign currency translation adjustment	(294)	(143)	(1,649)	(818)
Comprehensive income (loss)	$ 26,256	$ (20,200)	$ 22,780	$ (80,724)

9. 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 nine months ended September 30, 2008 and 2007:

	Nine Months Ended September 30	
	2008	2007
Accrual balance, beginning of period	$ 763	$ 7,276
Revision of estimate		(123)
Payments and other settlements	(124)	(6,203)
Accrual balance, end of period	$ 639	$ 950

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.

10. Net Income (Loss) Per Common Share

Basic earnings per share (EPS) is 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 and nine month periods ended September 30, 2008 and 2007:

	Three Months Ended September 30		Nine Months Ended September 30	
	2008	2007	2008	2007
Net income (loss) used for basic calculation	$ 19,689	$ (20,085)	$ 17,813	$ (79,958)
Effect of dilutive securities:				
Interest expense and deferred financing cost amortization, net of tax, related to our 1.375% convertible senior notes	528		1,694	
Net income (loss) used for diluted calculation	20,217	(20,085)	19,507	(79,958)
Shares used in computing net income (loss) per common share basic	76,658	73,328	75,794	72,046
Effect of dilutive securities:				
Shares issuable upon the assumed conversion of our 1.375% convertible senior notes	9,538		9,538	
Stock awards	3,647		3,465	
Dilutive potential common shares	13,185		13,003	
Shares used in computing net income (loss) per common share diluted	89,843	73,328	88,797	72,046
Earnings (loss) per share:				
Basic	$ 0.26	$ (0.27)	$ 0.24	$ (1.11)
Diluted	$ 0.23	$ (0.27)	$ 0.22	$ (1.11)

The following table represents the potentially dilutive shares excluded from the calculation of EPS for the three and nine month period ended September 30, 2008 and 2007 because their effect is anti-dilutive:

	Three Months Ended September 30		Nine Months Ended September 30	
	2008	2007	2008	2007
Potentially dilutive securities:				
Shares issuable upon conversion of our convertible notes		9,538		9,538
Stock awards	1,230	10,396	1,594	10,396
Dilutive potential common shares	1,230	19,934	1,594	19,934

11. Derivative Instruments and Hedging Activities

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

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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.

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 the qualifying 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.

Beginning in the third quarter of 2008, we entered into foreign exchange contracts, with durations of 12 months or less, to hedge exposures resulting from portions of our forecasted revenues that are denominated in currencies other than the U.S. dollar. These hedges were designated as cash flow hedges upon inception. As of September 30, 2008, we have open contracts with notional amounts totaling $105,253 that qualified for hedge accounting and $6,861 in accumulated other comprehensive income representing the anticipated gain to be reclassified to revenue over the next twelve months as the forecasted transactions occur. During the third quarter, we recognized a gain of $610 in revenue relating to hedged transactions which occurred. All of our hedge contracts were deemed effective. Therefore, we did not record any gains or losses resulting from any ineffectiveness of these hedge transactions, as required by SFAS 133.

Beginning in the first quarter of 2008, we entered 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. As of September 30, 2008, the notional settlement amount of forward foreign exchange contracts relating to monetary assets and liabilities was $21,786. We recognized a gain of $1,976 and $1,862 for the three and nine months ended September 30, 2008 associated with these derivative instruments.

12. Stock-Based Compensation

Stock-based compensation expense for the three and nine months ended September 30, 2008 totaled $5,990 and $17,881, respectively, of which $4,790 and $13,530 was included in selling, general and administrative expense and $1,200 and $4,355 was included in research and development expense. Stock-based compensation expense for the three and nine months ended September 30, 2007 totaled $6,066 and $16,386, respectively, of which $3,198 and $8,831 was included in selling, general and administrative expense and $2,868 and $7,555 was included in research and development expense. The following table summarizes the stock-based compensation capitalized to inventory and fixed assets:

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

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13. Fair Value Measurement

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements, (SFAS 157), which is effective for fiscal years beginning after November 15, 2007 and for interim periods within those years. This statement defines fair value, establishes a framework for measuring fair value and expands the related disclosure requirements. This statement applies under other accounting pronouncements that require or permit fair value measurements. The statement indicates, among other things, that a fair value measurement assumes that the transaction to sell an asset or transfer a liability occurs in the principal market for the asset or liability or, in the absence of a principal market, the most advantageous market for the asset or liability. SFAS 157 defines fair value based upon an exit price model. We adopted SFAS 157 as of January 1, 2008.

SFAS 157 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value.

The following table presents information about our assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2008, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value:

		Fair Value Measurement at September 30, 2008 Using		
	Total Carrying Value at September 30, 2008	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash equivalents	$ 118,384	$	$ 118,384	$
Available for sale securities	$ 1,700	$	$ 1,700	$
Derivative contracts	$ 7,734	$	$ 7,734	$

14. Income Taxes

We currently record a full valuation allowance against its US federal and state deferred tax assets and against a substantial portion of its foreign deferred tax assets.

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The tax provision (benefit) for the three and nine months ended September 30, 2008 includes a cash exchange of certain state research and development tax credits of $67 and $247, respectively. These benefits were offset by a current tax provision related to state and foreign taxes of $482 and $416, during the three and nine months ended September 30, 2008, respectively. Additionally, the tax provision for the nine months ended September 30, 2008 includes a benefit of $106 associated with the reversal of a valuation allowance against the deferred tax asset of a foreign subsidiary.

We will continue to monitor its valuation allowances on deferred tax assets to assess whether it is more likely than not that the related tax benefits would be realized and whether the related valuation allowance is necessary.

15. Commitments and Contingencies

Litigation

On March 16, 2007, PDL BioPharma, Inc., or PDL, filed a civil action against Alexion in the U.S. District Court for the District of Delaware. PDL claims willful infringement by Alexion of PDL patents due to sales of Soliris. PDL seeks unspecified damages, but no less than a reasonable royalty, plus attorney s fees. We have denied PDL s claims. In addition, we filed counterclaims seeking declarations of non-infringement and invalidity of PDL patents U.S. no. 5,693,761, no. 5,693,762 and no. 6,180,370 B1.

The results of the PDL action cannot be predicted with certainty due to the stage of the proceedings. However, depending on the outcome of the matter, the operating results of the Company could be materially impacted (See Note 4).

16. Employee Benefit Plans

We maintain a defined benefit plan for employees of its subsidiary located in Switzerland. The plan is part of an independent collective fund which provides pensions combined with life and disability insurance. 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. The fund s benefit obligations are fully reinsured by Allianz Insurance Switzerland. 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.

As of September 30, 2008, we recorded a net pension liability of $323 with a corresponding adjustment to other comprehensive income. Pension costs for the three months ended September 30, 2008 were not material to the Company s statement of operations.

17. Recently Issued Accounting Pronouncements

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). This statement is intended to improve transparency in financial reporting by requiring enhanced disclosures of an entity s derivative instruments and hedging activities and their effects on the entity s financial position, financial performance, and cash flows. SFAS 161 applies to all derivative instruments within the scope of SFAS 133, Accounting for Derivative Instruments and Hedging Activities (SFAS 133) as well as related hedged items, bifurcated derivatives, and nonderivative instruments that are designated and qualify as hedging instruments. Entities with instruments subject to SFAS 161 must provide more robust qualitative disclosures and expanded quantitative disclosures. SFAS 161 is effective prospectively for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application permitted. We are currently evaluating the disclosure implications of this statement, and we expect to include expanded disclosures of our derivative instruments as a result of the adoption of SFAS 161.

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In April 2008, the FASB issued FSP No. FAS 142-3, Determination of the Useful Life of Intangible Assets. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets (SFAS 142). The objective of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141(R), and other U.S. Generally Accepted Accounting Principles (GAAP). This FSP applies to all intangible assets, whether acquired in a business combination or otherwise and shall be effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years and applied prospectively to intangible assets acquired after the effective date. Early adoption is prohibited. We have evaluated the new statement and have determined that it will not have a significant impact on our financial results.

18. Subsequent Events

In October 2008, certain holders of our convertible notes exercised conversion rights with respect to an aggregate principal amount of $52,778 of the notes resulting in the issuance of 3,355,770 shares of common stock. The shares will be issued in November 2008.

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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, timing and effect of sales of Soliris in foreign markets, status and levels of reimbursement, price approval and funding processes outside the United States, interest and sense of urgency 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 clinical trials and studies, clinical trial results, evaluation of our clinical trial results by regulatory agencies in other countries, prospects for regulatory approval in other countries, plans for and status of clinical programs for Soliris in non-PNH indications, 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, timing for seeking regulatory approval of our manufacturing facility in Rhode Island, potential costs resulting from product liability or other third party claims, including pending litigation, the sufficiency of our existing capital resources and projected cash needs, recording of valuation allowances on deferred tax assets, estimates on future cash outflows, results of pending litigation, assessment of impact of recent accounting pronouncements as well as assumptions relating to the foregoing. Words such as anticipates, expects, intends, plans, believes, seeks, estimates, variations of such words and similar expre 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 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 related to chronic hematologic and neurological disorders, transplant rejection, and autoimmune disorders. Soliris is a humanized antibody that 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 U.S. Food and Drug Administration, or FDA, granted approval for Soliris, for the treatment of patients with PNH. 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 has been completed. In several countries outside the United States, we continue meaningful sales to individual patients through approved named-patient programs. In September 2008, the British government notified the Company that they will begin reimbursement of Soliris on a national level beginning in the second quarter of 2009.

We have submitted an application for marketing authorization in Australia for Soliris for the treatment of patients with PNH. The application was accepted for priority review. Soliris has received Orphan Drug Designation in Australia, which provides certain regulatory and filing fee advantages, including market exclusivity for several years once approved.

We have also submitted applications for marketing authorization in Canada and Switzerland for Soliris for the treatment of patients with PNH.

Clinical

We completed enrollment of Japanese patients in our AEGIS study in March 2008. This study is a single registration study to evaluate the safety, efficacy, and pharmacology of Soliris as a treatment for Japanese patients with PNH. The open label study was authorized by Japan s Pharmaceutical and Medical Devices Agency.

We are also focusing our research efforts on the use of eculizumab in other rare and severe complement-mediated conditions, including in chronic hemolytic and thrombotic disorders, transplant rejection and in chronic and debilitating neurological disorders. The FDA has authorized our Investigational New Drug Application, or IND, for studying the safety and effectiveness of eculizumab in treating myasthenia gravis, a rare autoimmune syndrome characterized by the failure of neuromuscular transmission, and we are expecting to begin clinical development in 2008. We are also aware that independent investigators have commenced a study to evaluate eculizumab in organ transplantation. We are currently developing clinical programs to investigate the use of Soliris as a treatment for patients with other complement-mediated disorders, including three severe, life-threatening, and rare hematologic disorders: atypical hemolytic uremic syndrome, a disease in which the lack of naturally occurring complement inhibitors can cause life-threatening kidney damage; catastrophic anti-phospholipid syndrome, a disorder in which uncontrollable blood clotting often leads to multiple organ failure; and cold hemagglutinin disease, an auto-immune hemolytic anemia.

The FDA has also authorized our IND to study the safety and efficacy of an antibody to the immune regulator CD200 in chronic lymphocytic leukemia, or CLL, an incurable chronic cancer that results from expansion of B-lymphocytes, and other myeloid tumors such as multiple myeloma. 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, manufacturing development and manufacturing of future products. We have begun validation production of Soliris in 2008 and expect to file for regulatory approval by mid-2009. We transferred our pilot manufacturing capabilities from New Haven, Connecticut to Smithfield, Rhode Island during 2007, and are using

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this facility for the production and purification of certain of our product candidates for clinical studies. The pilot plant was placed in service in the fourth quarter 2007, and we expect to place the manufacturing plant in service once regulatory approval is obtained

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 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.

We are required to prepay certain amounts to Lonza 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 plant.

Other Events

In July 2008, the Company s Board of Directors approved a two-for-one stock split to be effected in the form of a 100 percent stock dividend. The additional shares were distributed on August 22, 2008 to stockholders of record as of the close of trading on August 12, 2008.

In October 2008, certain holders of our convertible notes exercised conversion rights with respect to an aggregate principal amount of $52,778 of the notes resulting in the issuance of 3,355,770 shares of common stock. The shares will be issued in November 2008.

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, 2007. 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

Prepaid manufacturing

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, 2007. We have reviewed our critical accounting policies as disclosed in our Form 10-K, and, we have not noted any material changes.

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Results of Operations

Revenues

Net product sales

The following table summarizes product revenue for the three and nine months ended September 30, 2008 and 2007:

	Three months ended September 30		Increase /(Decrease)	Nine months ended September 30		Increase/(Decrease)
	2008	2007	$ Change	2008	2007	$ Change
Net product sales	$ 76,500	$ 21,973	$ 54,527	$ 181,605	$ 32,524	$ 149,081

In March 2007, the FDA granted approval for Soliris for the treatment of PNH. In June 2007, the E.C. also approved Soliris for the treatment of PNH. Our product sales have been solely attributable to sales of Soliris and have been generated from three sources: commercial sales in the United States (beginning in the second quarter of 2007), named-patient sales prior to full-scale commercialization in certain countries outside the United States (beginning in the first quarter of 2007) and commercial sales in countries outside the United States (beginning in the fourth quarter of 2007). The increases in revenue for the three and nine months ended September 30, 2008 were due to an increased number of patients treated with Soliris as a result of our product launches in the United States and Europe. During the three months ended September 30, 2008, certain government payors agreed to reimburse for Soliris shipments which were delivered in prior periods. Accordingly, we recognized $5,300 of net product sales in the third quarter associated with these prior shipments.

Contract research revenue

We recorded no contract research revenue for the three months and recorded $95 and $5,660 for the nine months ended September 30, 2008 and 2007, respectively. The decrease in contract research revenues relates primarily to the termination of our collaborative agreement with Proctor & Gamble, effective March 30, 2007.

Cost of sales

Cost of sales was $8,948 and $2,154, for the three months and $21,554 and $3,305 for the nine months ended September 30, 2008 and 2007, respectively. For the three and nine months ended September 30, 2008, cost of sales includes manufacturing costs, as well as royalty expenses associated with sales of Soliris.

Product sold during the three and nine months ended September 30, 2007 was previously expensed prior to submission of our Biologics License Application, or BLA, and therefore is not included in the cost of sales during this period. During the fourth quarter of 2007, we fully exhausted the supply of previously expensed inventory. Beginning in 2008, our cost of sales includes the full manufacturing cost of the inventory. Accordingly, cost of sales for the three and nine months ended September 30, 2007 primarily includes royalty expenses associated with sales of Soliris and certain quality control costs.

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 related to Soliris, including regulatory filings, post-marketing expenses and patient registries. These research and development costs primarily include preclinical and clinical studies, discovery research, quality control and quality

assurance, non-inventoried manufacturing costs, pharmacovigilance, regulatory and other product development expenses.

Research and development expenses were $14,874 and $16,906, for the three months and $47,306 and $53,318 for the nine months ended September 30, 2008 and 2007, respectively.

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For the three months ended September 30, 2008, the decrease in research and development expense of $2,032, as compared to the same period in the prior year, was primarily related to the following:

Decrease of $1,387 in research and development payroll and benefit expense related primarily to a reduction in stock-based compensation due to employee forfeitures and additional capitalization to inventory and property, plant and equipment.

Decrease of $733 in discovery research related primarily to a reduction in external research and consulting fees.

Decrease of $666 in operating and occupancy charges related primarily to the expiration of our lease at our New Haven, CT location.

Increase of $533 in non-labor clinical development due largely to an increase in spending of $1,849 related to our AEGIS clinical study in Japan, studies of eculizumab in non-PNH indications and costs of the PNH registry. These costs were offset by a decrease in spending on the EXTENSION and EXPLORE studies of approximately $1,317.

For the nine months ended September 30, 2008, the decrease in research and development expense of $6,012, as compared to the same period in the prior year, was primarily related to the following:

Decrease of $4,559 in research and development payroll and benefit expense related primarily to a reduction in stock-based compensation due to employee forfeitures and additional capitalization to inventory and property, plant and equipment.

Decrease of $1,388 in non-labor discovery research expense, due largely to a reduction in external research and consulting fees.

Decrease of $1,036 in operating and occupancy charges related primarily to the expiration of our lease at our New Haven, CT location.

Decrease of $642 in product development related primarily to additional capitalization of costs associated with the validation of our manufacturing facility in Smithfield, Rhode Island.

Increase of $1,001 in depreciation and amortization related primarily to the amortization of costs associated with our new pilot plant located at our manufacturing facility in Smithfield, RI, which was placed in service in the fourth quarter 2007.

Increase of $612 in non-labor clinical development due largely to an increase in spending of $5,062 related to our AEGIS clinical study in Japan, studies of eculizumab in non-PNH indications and costs of the PNH registry. These costs were offset by a decrease in spending on the EXTENSION, EXPLORE and EMBRACE studies and BLA costs of approximately $4,534.

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.

Selling, general and administrative expenses were $32,064 and $24,944, for the three months and $94,754 and $67,571 for the nine months ended September 30, 2008 and 2007, respectively.

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For the three months ended September 30, 2008, the increase of $7,120 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to the following:

- Increase in non-labor commercial operations of $4,006 was due primarily to our foreign operations, which we expanded significantly throughout 2007.

- Increase in salary, benefits and other labor expenses of $2,825 including increased share-based compensation cost of $1,592. 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. This increase was also due to increases in payroll and benefits within other certain operational groups to support our growth as a commercial entity.

For the nine months ended September 30, 2008, the increase of $27,183 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 $12,962 including increased share-based compensation cost of $4,699. 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. This increase was also due to increases in payroll and benefits within certain operational groups to support our growth as a commercial entity.

- Increase in non-labor commercial operations of $8,138 was comprised primarily of expansion of our foreign operations, which we expanded significantly in the latter half of 2007.

- Increase in non-labor general and administration of $5,421 primarily related to increases in legal costs associated with ongoing litigation and increases in infrastructure costs to support our growth as a commercial entity.

Other Income and Expense

We recognize investment income primarily from our portfolio of cash equivalents and short-term marketable securities. Investment income was $690 and $1,796, for the three months and $2,071 and $6,724 for the nine months ended September 30, 2008 and 2007, respectively. The decrease was due primarily to lower interest rates and cash, cash equivalents and marketable securities during the three and nine month periods ended September 30, 2008, versus the same periods in the prior year.

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 $182 and $430 for the three and nine months ended September 30, 2008. Interest expense was $634 and $643, for the three months and $1,975 and $1,854 for the nine months ended September 30, 2008 and 2007, respectively.

Foreign currency transaction gains and losses relate to our foreign operations, which increased significantly beginning in 2007. The foreign currency transaction gains totaled $566 and $578, for the three months and $200 and $924 for the nine months ended September 30, 2008 and 2007, respectively. The gains were primarily a result of the fluctuation in exchange rates for the U.S. Dollar compared to the Euro and British Pound on the unhedged portion of our monetary assets and liabilities.

Income Taxes

We currently record a full valuation allowance against its US federal and state deferred tax assets, and against a substantial portion of its foreign deferred tax assets.

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The tax provision (benefit) for the three and nine months ended September 30, 2008 includes a cash exchange of certain state research and development tax credits of $67 and $247, respectively. These benefits were offset by a current tax provision related to state and foreign taxes of $482 and $416, during the three and nine months ended September 30, 2008, respectively. Additionally, the tax provision for the nine months ended September 30, 2008 includes a benefit of $106 associated with the reversal of a valuation allowance against the deferred tax asset of a foreign subsidiary.

We will continue to monitor its valuation allowances on deferred tax assets to assess whether it is more likely than not that the related tax benefits would be realized and whether the related valuation allowance is necessary.

Net Income (Loss)

The Company recorded net income for the three and nine month periods ended September 30, 2008 of $19,689 and $17,813 or $0.23 and $0.22 per diluted share, respectively, versus a net loss of $20,085 and $79,958 or $0.27 and $1.11 per diluted share, respectively, for the corresponding periods in 2007.

Liquidity and Capital Resources

As of September 30, 2008, our consolidated cash, cash equivalents and marketable securities totaled $126,402. The $19,690 increase from December 31, 2007 is largely attributable to the collection of accounts receivable and management s focus on efficient use of our capital resources. Until required for use in the business, we invest our cash reserves in money market funds and high quality commercial, corporate and U.S. Government notes in accordance with our investment policy. We do not have any investments in auction rate securities.

Financial instruments that potentially expose the Company to concentrations of credit risk are limited to accounts receivable and our foreign exchange derivative contracts. At September 30, 2008, two individual customers accounted for 27.3% and 20.2% of the accounts receivable balance. For the three months ended September 30, 2008, one customer accounted for 18.5% of our product sales. For the nine months ended September 30, 2008, one customer accounted for 21.6% of our product sales.

At September 30, 2008, we have foreign currency forward contracts with notional amounts totaling $127,039. These outstanding foreign currency forward contracts had a fair value of $7,734, which is included in other current assets. The counterparty to these forward contracts is a multinational commercial bank, and we believe the risk of nonperformance is not material.

At September 30, 2008, our working capital was $209,033, compared to $167,645 at December 31, 2007. At September 30, 2008, our current ratio was 4.4, compared to 5.4 at December 31, 2007.

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 $22,349 for the nine months ended September 30, 2008. Net cash used in operating activities was $118,201 for the nine months ended September 30, 2007, a change of $139,454. The change is primarily due to the net income achieved in 2008 versus the net loss as compared to the same period in 2007. The components of cash provided by operating activities for the nine months ended September 30, 2008 are as follows:

Our reported net loss, plus non-cash items, including depreciation and amortization unrealized currency gain and stock compensation, of $42,287.

Net cash outflow due to changes in operating assets of $44,253, primarily attributable to increases in inventories and accounts receivable. The growth in our sales of Soliris has required substantial investments in working capital items such as inventories and accounts receivable.

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During 2008, changes in cash from operations will be highly dependent on sales levels, and related cash collections, from sales of Soliris. In addition, we expect that cash outflows related to the changes in operating assets will continue to increase as sales and the resulting accounts receivable balances increase. We expect a smaller cash outflow for inventory purchases for the remainder of 2008 than in the first nine months of 2008.

Investing Activities

Net cash used in investing activities was $21,041 for the nine months ended September 30, 2008. Net cash used in investing activities was $6,912 for the nine months ended September 30, 2007. For the nine months ended September 30, 2008, the net cash used for investing activities consisted of the following:

$8,733 cash inflow from the net sale or maturity of marketable securities, which was used to fund our operations;

$27,180 of additions to property, plant and equipment, of which $21,198 were costs incurred in seeking regulatory approval, including engineering runs, related to our Rhode Island manufacturing facility, with the remaining attributable to spending on information technology and facility capital costs; and

$3,000 related to the purchase of patents from OMRF.

Through September 30, 2008, we have capitalized $113,678 related to the manufacturing facility, which includes all costs associated with construction, renovation and upgrades, engineering runs and capitalized interest. This amount includes the pilot plant which was placed in service in the fourth quarter of 2007. Through September 30, 2008, costs incurred in seeking regulatory approval, including engineering runs, was $40,951, and capitalized interest was $7,824.

Financing Activities

Net cash provided by financing activities was $27,504 and $49,603 for the nine months ended September 30, 2008 and 2007, respectively. The $27,504 consisted primarily of proceeds of $28,018 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, 2007, in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations under the caption Contractual Obligations. Material changes in our contractual obligations since December 31, 2007 include our revolving credit facility and the other long-term obligation related to the purchase of patents from OMRF, which are described below.

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 September 30, 2008, we had no outstanding balance 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.

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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.

OMRF Obligation

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. In addition to the initial payment of $3,000 paid in February 2008, we are required to make a payment of not less than $4,500 during or prior to December 2008 and a final payment of $2,500 during or prior to July 2009. Interest accrues on the unpaid amount at the rate of 50% of the sum of prime rate plus 1%, per annum.

Convertible Notes

We hold $150,000 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.

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. The conversion rate and conversion price have been adjusted for the stock split we effected on August 22, 2008.

As of September 30, 2008, the market value of our $150,000, 1.375% Convertible Notes due February 1, 2012, based on quoted market prices, was estimated at $380,931. The $5,931 increase from December 31, 2007 is largely attributable to the increase in the price of our common stock from the period from December 31, 2007 through September 30, 2008.

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.

As a condition of the loan, we are required to maintain restricted cash accounts. These accounts must maintain certain operating escrow balances. At September 30, 2008, the balance of restricted cash was $552.

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

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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 September 30, 2008, we held essentially all of our cash equivalents and investments in financial instruments, primarily money market funds, with original maturity dates of three months or less. These financial instruments are subject to interest rate risk and will decline in value if interest rates increase. However, we expect to hold time-based investments, such as corporate bonds, through maturity.

Our outstanding long-term liabilities as of September 30, 2008 included our $150,000, 1.375% Convertible Senior Notes due February 1, 2012. As the notes bear interest at a fixed rate, our results of operations would not be impacted by interest rate changes. As of September 30, 2008, the market value of our $150,000 1.375% convertible senior notes due February 1, 2012, based on quoted market prices, was estimated at $380,931.

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 an additional 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 fixed 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. Accordingly, any changes in the interest rate will not impact our financial statements.

Foreign Exchange Market Risk

As a result of our foreign operations, we face exposure to movements in foreign currency exchange rates, primarily the Euro and British Pound. 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.

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(in thousands, except share and per share amounts)

In the first quarter of 2008, we began a program to limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet. In the third quarter of 2008, we commenced 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 fluctuation in foreign currency rates.

As of September 30, 2008, we had foreign currency forward contracts with notional amounts totaling $127,039. As of September 30, 2008, our outstanding foreign currency forward contracts had a fair value of $7,734, which is included in other current assets/liabilities.

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.

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

We have carried out an evaluation, as of the end of the period covered by this report, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level in ensuring that (i) information required to be disclosed by us in the reports that we file under the Securities Exchange Act of 1934, as amended, (the Exchange Act) is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and (ii) information relating to us and required to be included in the reports we file under the Exchange Act is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer or other persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

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 1. Legal Proceedings

As previously reported in Alexion s filings with the SEC, on March 16, 2007, PDL BioPharma, Inc., or PDL, filed a civil action against Alexion in the U.S. District Court for the District of Delaware. PDL claims willful infringement by Alexion of PDL patents due to sales of Soliris. PDL seeks unspecified damages, but no less than a reasonable royalty, plus attorneys fees. Alexion has denied PDL s claims. In addition, we filed counterclaims seeking declarations of non-infringement and invalidity of PDL patents U.S. no. 5,693,761, no. 5,693,762 and no. 6,180,370 B1.

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 Business

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. If we are unable to successfully commercialize and sell Soliris 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 successful commercialization of Soliris in the United States and throughout the rest of the world and whether physicians, patients and healthcare payers view Soliris as therapeutically effective relative to cost. For the nine months ended September 30, 2008, sales related to Soliris constituted almost all of our total revenue, 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 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 the product;
- successful launch of commercial sales of the product in European countries and elsewhere where we have not yet commenced sales and successful continuation of commercial sales in the United States and in those European countries where we are already selling Soliris;
- acceptance of the product in the medical community;
- ability to effectively market and distribute the product in the United States and the rest of the world;

ability to obtain and maintain sufficient coverage or reimbursement by third-party payers;

receipt and maintenance of marketing approvals from 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. We are engaging with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country. We have commenced commercial sales in some countries in Europe. In addition, in other European countries, we continue meaningful sales to individual patients through approved named-patient programs. We cannot guarantee that reimbursement and other processes will be concluded successfully or on a timely basis and, as a result, sales in certain European countries may be delayed or never occur. 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.

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. 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. 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 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 among physicians, patients, healthcare payers, and others. Although we have received regulatory approval for Soliris in the United States and Europe, such approvals do not guarantee future revenue. We cannot predict whether physicians, other healthcare providers, government agencies or private insurers will determine that 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 market acceptance, we may not be able to market and sell it successfully, which would limit our ability to generate revenue and could harm our business.

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

In the United States, we sell Soliris to distributors who in turn sell to patient health-care providers. We do not promote Soliris to these distributors and they do not set or determine demand for Soliris. For the nine month period ended September 30, 2008, our three largest customers accounted for approximately 37.6% of our net product sales, and we expect such customer concentration to continue for the foreseeable future. Our ability to successfully commercialize Soliris will depend, in part, on the extent to which we are able to provide adequate distribution of Soliris to patients. Although a number of specialty distributors and specialty pharmacies, which supply physician office clinics, hospital outpatient clinics, infusion clinics, home health care providers, and governmental organizations, distribute Soliris, they generally carry a very limited inventory and may be reluctant to distribute Soliris in the future if demand for the product does not increase. Further, it is possible that our distributors could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to distribute smaller volume products such as Soliris, or cause higher product distribution costs, lower margins or the need to find alternative methods of distributing our product. Although we believe we can find alternative distributors on a relatively short notice, our revenue during that period of time may suffer and we may incur additional costs to replace a distributor. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us or any failure to pay for the products we have shipped to them could materially and adversely affect our results of operations and financial condition.

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

We are marketing and selling Soliris ourselves in the United States and through our subsidiaries in Europe, but have only limited experience thus far with marketing, sales or distribution of drug products. We have 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 maintain capabilities to sell, market and distribute our product, either through our own capabilities or by entering into agreements with others, 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. In Europe, regulatory and commercial requirements vary on a country by country basis and we cannot guarantee that we will have the capabilities or resources to successfully conclude the necessary processes and commercialize Soliris in every country in Europe. Reimbursement sources are different in each European country and in each country may include a combination of distinct potential payers, including private insurance and governmental payers. Even if we hire the qualified sales and marketing personnel we need in the United States and in Europe, 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 our product. 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 may be disproportional compared to the revenues we may be able to generate on sales of our product. We cannot guarantee that we will be successful in commercializing Soliris.

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. 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 consumer. If these entities refuse to provide coverage and reimbursement with respect to Soliris or determine to provide an insufficient level of coverage

and reimbursement, Soliris may be too costly for general use, and physicians may not prescribe it. Soliris is significantly more expensive than traditional drug treatments. 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 our products may also reduce our profitability and worsen our financial condition. In the United States 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.

Since Soliris is a high-cost treatment, most patients require some form of third party coverage. If adequate coverage and reimbursement by third-party payers is not available, our ability to successfully commercialize Soliris may be adversely impacted. Any limitation on the use of Soliris or any decrease in the price of Soliris will have a material adverse effect on our ability to achieve or maintain profitability on a quarterly or annual basis in the future.

Even where patients have access to insurance, their insurance co-payment amounts may represent a barrier to obtaining Soliris. In the United States, Alexion has financially supported the PNH Foundation 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 who have no insurance coverage for drugs or 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 for related charitable purposes. We are not able to predict the financial impact of the support we may provide for these and other charitable purposes; however, substantial support could have a material adverse effect on our 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.

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. For example, the European Union provides options for its member states to 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 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. In some European countries, we are currently engaging the appropriate authorities on the reimbursement, price approval and funding processes that are separately required in those countries. Our results of operations may suffer if we are unable to successfully and timely conclude such processes and begin to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

If the use of Soliris or our product candidates harms people, or is perceived to harm patients even when such harm is unrelated to Soliris or our product candidates, 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 our products, including Soliris and our product candidates, could

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(1) lessen the frequency with which physicians decide to prescribe our products, (2) encourage physicians to stop prescribing our products to their patients who previously had been prescribed our products, (3) cause serious adverse events and give rise to product liability claims against us, and (4) result in our need to withdraw or recall our products 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 may be discovered, and risks previously viewed as inconsequential 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 or our product candidates, whether as a prescribed therapy, during a clinical trial, during an investigator initiated study, or otherwise. Many patients who use Soliris and our product candidates are already very ill. Any informed consents or waivers obtained from people who enroll in our trials or use Soliris or our product candidates 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 our products, 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 the 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.

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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. 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.

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.

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 or our other drug candidates. We expect that it will be at least until 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 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 in Europe that is manufactured in this facility and we will continue to be subject to ongoing European regulatory inspection thereafter.

We have executed a commercial-scale product supply agreement with Lonza for the long-term manufacture of eculizumab on which we will be relying for manufacturing commercial sale quantities of Soliris. The failure of Lonza to manufacture appropriate supplies of eculizumab, on a timely basis, or at all, may prevent or impede the commercialization of Soliris. Lonza or we will be required to manufacture substantially more material than we have required for clinical and preclinical trials. 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.

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.

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Manufacture of our drug products is highly technical and only a few third-parties have the ability and capacity to manufacture our drug products for our development and commercialization needs. We cannot assure you that these potential third-party collaborators will agree to manufacture our products on our behalf on commercially reasonable terms, if at all. If we do achieve agreement from one or more third parties to manufacture our drug products, we cannot assure you that they will be able or willing to honor the terms of the agreements, 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.

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. We could owe substantial penalty payments to Lonza if we were not to use the manufacturing capacity for which we 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.

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 emerge and affect us. We may make errors in predicting and reacting to relevant business trends, which could harm our business. As of September 30, 2008, we had an accumulated deficit of approximately $711 million. 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 commercializing Soliris in the United States and Europe, and we do not know when we will have products 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 transition from a research and development company to a sales and marketing company, 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 approval of Soliris in other countries, and our ability to successfully manufacture approved drugs. The extent and the timing of our future losses and our profitability are highly uncertain.

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 the development and continue the commercialization of our products and product candidates. We are currently selling or preparing for the commercialization of Soliris in several countries in Europe, 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.

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

- the cost necessary to sell, market and distribute Soliris;
- the rate of new patient sales and drug utilization by treated patients;
- the time and cost necessary to obtain and maintain regulatory approvals for Soliris outside the United States and Europe and for eculizumab for other indications;
- 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;
- 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. 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 are unable to engage and retain third-party collaborators, our research and development efforts may be delayed.

Currently, none of our product candidates is being jointly developed with third party collaborators. We may experience significant delays in the development of our product candidates if we cannot engage additional collaborators when required. We would be required to devote additional funds or other resources to these activities or to terminate them. Either of these events would divert funds or other resources from other parts of our business.

We cannot assure you that:

- we will be able to negotiate acceptable collaborative agreements to develop or commercialize our product candidates;
- any arrangements with third parties will be successful; or
- potential collaborators will not pursue treatments for other diseases or seek other ways of developing treatments for our disease targets.

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

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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. 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 even before we are able to finish our clinical trials. Other pharmaceutical companies also compete with us to attract academic research institutions as drug development partners, including for licensing these institutions proprietary technology. If our competitors successfully enter into such arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may not be able to find equivalent opportunities elsewhere.

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

We are highly dependent upon the efforts of our senior management and scientific personnel, particularly Dr. Leonard Bell, M.D., our Chief Executive Officer and a member of our Board of Directors, David W. Keiser, our President, Chief Operating 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, Mr. Keiser, 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 September 30, 2008, we had outstanding $150 million principal amount of 1.375% convertible senior notes which will mature on February 1, 2012. Our subsidiary Alexion Manufacturing borrowed $44 million 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 $489,000, 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 million, with up to a $5 million 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 $3 million and agreed to pay an additional principal amount of $7 million in connection with the acquisition of certain patents from the Oklahoma Medical Research Foundation, or OMRF.

Our 1.375% convertible senior notes, the mortgage loan, the revolving credit facility and the OMRF debt 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;

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make it difficult for us to obtain financing for acquisitions or other purposes on favorable terms, if at all;

make us more vulnerable to industry downturns and competitive pressures; and

limit our flexibility in planning for, or reacting to changes in, our business.

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

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

We are subject to various federal, state and local environmental laws and regulations that govern our operations, including 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 that could disrupt our business and harm our financial condition.

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions to do so. Acquisitions involve numerous risks, including:

substantial cash expenditures;

potentially dilutive issuance of equity securities;

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

difficulties in assimilating the operations of the acquired companies;

diverting our management s attention away from other business concerns;

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

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

We cannot assure you that any acquisition 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. In addition, our future success would depend in part on our ability to manage the rapid growth associated with

some of these acquisitions. 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. Furthermore, the development or expansion of our business or any acquired business or companies 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, 2007, we had approximately $733 million of U.S. Federal net operating loss carry forwards, or NOLs, available to reduce taxable income in future years. We believe that some of these NOLs are currently subject to an annual limitation under section 382 of the Internal Revenue Code of 1986, as amended.

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Our ability to utilize our NOLs may be further limited if we undergo an ownership change, as defined in section 382, as a result of subsequent changes in the ownership of our outstanding stock, which are generally outside of our control. We would undergo an ownership change if, among other things, 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 thereunder, 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 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 generation of taxable income. The net operating loss carryforwards may expire before we generate sufficient taxable income. In the year-ended December 31, 2007, NOLs of $3.8 million expired.

Risks Related to Our Industry

We are subject to extensive government regulation and, if we do not maintain our regulatory approvals in any country, we will not be able to sell Soliris in such country.

We and our partners cannot sell or market our products without regulatory approval. We obtained marketing approval of Soliris in the United States and in Europe for PNH. 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. In the United States, we or our partners must obtain and maintain approval from the FDA for each indication for each drug that we intend to sell and for each facility where such drug is manufactured. Obtaining FDA approval is typically a lengthy and expensive process, and although we obtained approval for Soliris in PNH, approval is highly uncertain for our other drug candidates. Governments in Europe and other parts of the world also regulate drugs distributed outside the United States and facilities outside the United States where such drugs are manufactured, and obtaining their approvals can also be lengthy, expensive and highly uncertain. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. In certain jurisdictions, we are required to finalize operational, reimbursement, price approval and funding processes prior to marketing our products. Soliris became commercially available in certain countries in Europe in the fourth quarter of 2007. We may not receive regulatory approval for Soliris outside the United States and Europe or for any of our product candidates for at least the next several years, if ever.

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 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. These regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, adverse event reporting requirements, and export of biologics. As a condition of approval for marketing our product, the FDA or governmental authorities in other countries 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 perform clinical studies assessing long term safety outcomes in the Soliris Safety Registry, monitoring immunogenicity, monitoring compliance with vaccination requirements, and determining 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. 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 health agency may have to notify healthcare providers of any such developments. The discovery of any previously unknown problems with a product, manufacturer or facility may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product 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 our products 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 our products 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;
- delays in approving or refusal to approve a product candidate;
- withdrawal of a previously granted approval;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

The discovery of previously unknown problems with a product 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 one or more of our products or services from the market.

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

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 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. In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. 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.

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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 other indications for Soliris, 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 materially harmed.

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;

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- 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 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.

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 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.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or off-label uses. Although physicians are permitted to use products for indications other than those cleared or approved by the FDA based on their medical judgment referred to as off-label uses, we are prohibited from promoting 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 promotion of unapproved uses of Soliris, the FDA may disagree. If the FDA determines that our promotional materials, training or other activity constitutes promotion of Soliris for a use not covered by our FDA clearances, 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.

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, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

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 Intellectual Property

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

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

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

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

Parts of our technology, techniques and proprietary compounds and potential drug candidates, including those which are or may be in-licensed, may be found to infringe patents owned by or granted to others. In March 2007, we reported that two civil actions were filed against us relating to the commercialization of Soliris and the intellectual property rights of third parties. Oklahoma Medical Research Foundation, or OMRF, filed a civil action against us in Oklahoma alleging, among other things, breach of contract of an existing license agreement between OMRF and Alexion and Alexion s willful infringement of OMRF patents. During the first quarter of 2008, Alexion agreed to acquire all rights to the relevant patents for a total payment of $10 million; and OMRF agreed to withdraw its civil action and release Alexion from all liabilities in connection with such license agreement and patents upon payment in full. PDL BioPharma, Inc., or PDL, filed a civil action against us in Delaware, alleging willful infringement of PDL patents. If it is finally determined that we infringe the PDL patents, we may be required to pay royalties to PDL on sales of Soliris. Although we do not believe that any patent of PDL is necessary for the commercialization of Soliris, we cannot guarantee that we will be successful in defending against such action. In January 2008, SB2, Inc. filed a civil action against us relating to the commercialization of Soliris and alleged infringement of SB2, Inc. s intellectual property rights. In May 2008, SB2, Inc. voluntarily dismissed the action without prejudice, meaning the action may be re-filed. We cannot guarantee that SB2, Inc. will not re-file its claim. If we cannot successfully defend against these or any other future actions or conflicts, 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.

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

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others relating to the manufacture, use and sale of recombinant humanized antibodies, recombinant humanized single chain 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 humanized single chain antibodies, recombinant human antibodies, or recombinant human single chain antibodies. In addition to actions filed by PDL, OMRF and SB2, Inc., 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:

- our products 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.

In addition to PDL, 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 any patent holder successfully challenges our judgment that our products do not infringe their patents or that their patents are invalid, we could be required to pay costly damages or to obtain a license to sell or develop our drugs. 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, including the PDL 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 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 July 31, 2008, the closing sales price of our common stock fluctuated from a low of $17.89 per share to a high of $46.88 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.

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

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

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

Pursuant to our stockholder rights plan, each share of common stock has an associated preferred stock purchase right. The rights will not trade separately from the common stock until, and are exercisable only upon, the acquisition or the potential acquisition through tender offer by a person or group of 20% or more of the outstanding common stock. The rights are designed to make it more likely that all of our stockholders receive fair and equal treatment in the event of any proposed takeover of us and to guard against the use of partial tender offers or other coercive tactics to gain control of us.

These provisions could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices. These provisions could also limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and could adversely affect the price of our common stock.

Item 6. EXHIBITS

(a) Exhibits

31.1 Certification by Leonard Bell, Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2008.

31.2 Certification by Vikas Sinha, Senior Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2008.

32.1 Certification by Leonard Bell, Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2008.

32.2 Certification by Vikas Sinha, Senior Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2008.

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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: October 30, 2008

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

Date: October 30, 2008

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