

ALEXION PHARMACEUTICALS INC

Form 10-Q

May 12, 2008

[Table of Contents](#)

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 10-Q

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

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**13-3648318**  
(I.R.S. Employer  
Identification No.)

**352 Knotter Drive, Cheshire, Connecticut 06410**  
(Address of principal executive offices) (Zip Code)

**203-272-2596**  
(Registrant's telephone number, including area code)

**N/A**  
(Former name, former address, and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant 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

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

Common Stock, \$0.0001 par value  
Class

38,418,574  
Outstanding at May 7, 2008

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**INDEX**

	<b>Page</b>
<b>PART I. FINANCIAL INFORMATION</b>	
<b>Item 1. Condensed Consolidated Financial Statements (Unaudited)</b>	
<u>Condensed Consolidated Balance Sheets as of March 31, 2008 and December 31, 2007</u>	1
<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2008 and 2007</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2008 and 2007</u>	3
<u>Notes to Condensed Consolidated Financial Statements</u>	4
<b>Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	11
<b>Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u></b>	19
<b>Item 4. <u>Controls and Procedures</u></b>	20
<b>PART II. <u>OTHER INFORMATION</u></b>	22
<b>Item 1. <u>Legal Proceedings</u></b>	22
<b>Item 1A. <u>Risk Factors</u></b>	22
<b>Item 6. <u>Exhibits</u></b>	38
<b><u>SIGNATURES</u></b>	39

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

(UNAUDITED)

(in thousands, except per share amounts)	March 31, 2008	December 31, 2007
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 104,854	\$ 95,321
Marketable securities	1,693	10,433
Trade accounts receivable	53,702	46,278
Inventories	33,085	32,907
Prepaid manufacturing costs	14,653	13,775
Prepaid expenses and other current assets	10,138	6,640
<b>Total current assets</b>	<b>218,125</b>	<b>205,354</b>
Property, plant and equipment, net	111,219	104,280
Intangible assets, net	10,489	
Goodwill, net	19,954	19,954
Restricted cash	417	958
Other assets	3,790	3,811
<b>Total assets</b>	<b>\$ 363,994</b>	<b>\$ 334,357</b>
<b>Liabilities and Stockholders Equity</b>		
Current Liabilities:		
Accounts payable	\$ 6,080	\$ 9,072
Accrued expenses	28,695	28,324
Deferred revenue	880	41
Revolving credit facility	18,000	
Current portion of note payable	4,500	
Current portion of capital lease obligations	280	272
<b>Total current liabilities</b>	<b>58,435</b>	<b>37,709</b>
Capital lease obligations, less current portion	427	499
Mortgage loan	44,000	44,000
Convertible notes	150,000	150,000
Note payable, less current portion	2,500	
Other liabilities	593	593
<b>Total liabilities</b>	<b>255,955</b>	<b>232,801</b>
Commitments and contingencies (Note 14)		
Stockholders Equity:		
Preferred stock, \$0.0001 par value; 5,000 shares authorized, no shares issued or outstanding		
Common stock, \$0.0001 par value; 145,000 shares authorized; 38,238 and 37,873 shares issued at March 31, 2008 and December 31, 2007, respectively	4	4
Additional paid-in capital	844,534	833,534
Treasury stock, at cost, 57 shares	(1,260)	(1,260)
Accumulated other comprehensive loss	(1,711)	(1,443)
Accumulated deficit	(733,528)	(729,279)

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Total stockholders' equity	108,039	101,556
Total liabilities and stockholders' equity	\$ 363,994	\$ 334,357

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

**Table of Contents****ALEXION PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(UNAUDITED)

(in thousands, except per share amounts)	Three months ended March 31,	
	2008	2007
Revenues:		
Net product sales	\$ 45,546	\$ 974
Contract research revenues	95	5,343
Total revenues	45,641	6,317
Cost of sales	5,464	85
Operating expenses:		
Research and development	15,609	21,219
Selling, general and administrative	29,781	19,838
Total operating expenses	45,390	41,057
Operating loss	(5,213)	(34,825)
Other income and expense:		
Investment income	767	2,769
Interest expense	(596)	(700)
Foreign currency gain (loss)	703	(27)
Loss before income tax benefit	(4,339)	(32,783)
Income tax benefit	90	90
Net loss	\$ (4,249)	\$ (32,693)
Net loss per share basic and diluted	\$ (0.11)	\$ (0.92)
Shares used in computing basic and diluted net loss per common share	37,514	35,361

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

**Table of Contents****ALEXION PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(UNAUDITED)

(in thousands)	Three months ended March 31,	
	2008	2007
<b>Cash flows from operating activities:</b>		
Net loss	\$ (4,249)	\$ (32,693)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,289	873
Share-based compensation expense	5,884	4,980
Loss on disposal of property, plant and equipment	42	
Changes in operating assets and liabilities:		
Accounts receivable	(7,029)	(1,173)
Inventories	78	(799)
Prepaid expenses and other assets	(3,912)	(1,094)
Accounts payable and accrued expenses	(4,219)	(4,111)
Deferred revenue	863	(5,343)
<b>Net cash used in operating activities</b>	<b>(11,253)</b>	<b>(39,360)</b>
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(70,797)	(43,157)
Proceeds from maturity or sale of marketable securities	79,537	46,214
Purchases of property, plant and equipment	(7,950)	(16,219)
Purchase of technology rights	(3,489)	
Release of (increase in) restricted cash	542	11,346
<b>Net cash (used in) provided by investing activities</b>	<b>(2,157)</b>	<b>(1,816)</b>
<b>Cash flows from financing activities:</b>		
Payments under capital lease obligations	(64)	(18)
Proceeds from revolving credit facility	18,000	
Net proceeds from issuance of common stock	4,486	11,412
<b>Net cash provided by financing activities</b>	<b>22,422</b>	<b>11,394</b>
Effect of exchange rate changes on cash	521	(52)
<b>Net change in cash and cash equivalents</b>	<b>9,533</b>	<b>(29,834)</b>
Cash and cash equivalents at beginning of period	95,321	166,826
<b>Cash and cash equivalents at end of period</b>	<b>\$ 104,854</b>	<b>\$ 136,992</b>

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

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**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(in thousands, except share and per share amounts)**

**1. Business**

Alexion Pharmaceuticals, Inc. ( Alexion or the Company ) is a biopharmaceutical company engaged in the discovery, development and delivery of biologic therapeutic products aimed at treating patients with severe and life-threatening disease states, including hematologic and neurologic diseases, cancer and autoimmune disorders. We have one marketed product, Soliris® (eculizumab), which is the first therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH. Since our incorporation in January 1992 until we began commercial sales of Soliris in the U.S. in April 2007, we devoted most of our resources to drug discovery, research, and product and clinical development.

In March 2007, the U.S. Food and Drug Administration, or FDA, granted approval for our lead product Soliris for the treatment of PNH, a rare, life-threatening blood disorder. In June 2007, the European Commission, or E.C., also approved Soliris for the treatment of PNH.

Through March 31, 2008, 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).

We have incurred operating losses since our inception. As of March 31, 2008, we had an accumulated deficit of \$733,528. We may incur operating losses and negative cash flow for additional future periods due to costs associated with the worldwide commercialization of Soliris, pre-commercialization activities and anticipated commercialization activities in other countries, development of our manufacturing plant in Rhode Island, including engineering and validation runs, product research and development, preclinical studies and clinical testing, regulatory activities, commercial-scale manufacturing at our third party contractor and at our own manufacturing plant when that site is approved to manufacture Soliris, and other infrastructure support costs.

Until we can generate sufficient levels of cash from our operations, we expect to finance future cash needs primarily through the use of available cash, cash equivalents and short-term investments, availability under our credit agreement and, to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements.

**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 March 31, 2008, the results of our operations for the three months ended March 31, 2008 and 2007, and our cash flows for the three months ended March 31, 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 months ended March 31, 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.

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(in thousands, except share and per share amounts)**

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

**3. Revenue**

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

To date, our product sales have consisted solely of Soliris for the treatment of PNH. We recognize revenue from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured and we have no further performance obligations. Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in the Company's statements of operations, and do not impact net product sales.

In the United States, our customers are primarily specialty distributors and specialty pharmacies 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. Soliris is generally shipped directly from our third party warehouse to the patients' health-care provider, who is not typically our direct customer. Revenue is recorded upon receipt of the product by the patients' health-care provider, which is typically a hospital or physician's office.

Through March 31, 2008, we have recorded revenue on sales for individual patients through named-patient programs outside the United States. The relevant authorities 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. In Europe, we have entered into transitional agreements with a distributor to distribute Soliris on a named-patient basis in specified European countries.

Outside the United States, we continue to engage with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required by each country. Our customers are expected to be primarily hospitals, hospital buying groups, pharmacies, other health care providers and distributors. Sales outside the United States are recorded upon receipt of product by the hospital, hospital buying group, pharmacy or other health-care provider.

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. We monitor inventory within our distribution channel to determine whether reserves are required related to inventory in our sales channels. 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.

**Table of Contents****ALEXION PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****(in thousands, except share and per share amounts)**

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.

**4. Royalties**

Our cost of sales for the three months ended March 31, 2008 consists of actual and estimated royalties to third parties related to the sale and commercial manufacture of Soliris, as well as other manufacturing costs. We estimate royalties potentially owed to third parties based on contractual arrangements with certain parties, as well as our assessment of possible royalty amounts owed to other third parties. These estimates may be influenced by the outcome of current litigation, the results of which are uncertain (see Note 14). 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:

	<b>March 31, 2008</b>	<b>December 31, 2007</b>
Raw materials	\$ 6,372	\$ 4,985
Work-in-process	16,741	17,677
Finished goods	9,972	10,245
	<b>\$ 33,085</b>	<b>\$ 32,907</b>

**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 have agreed to pay \$10,000, plus interest, to OMRF for the rights to the patents, in various amounts to be remitted in 2008 and the first half of 2009. In accordance with our agreement, we paid \$3,000 to OMRF in February 2008.

**7. Long-Term Debt**

In conjunction with the purchase of patents from OMRF (see also Note 6), we issued an uncollateralized note payable in 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 by December 2008 and a final payment of the balance by July 2009. Interest shall accrue on any unpaid amount at the rate of 50% of the prime rate (as published in the Money Rates section of the Wall Street Journal (New York edition) plus 1%, per annum, or 3.63%, at March 31, 2008.

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, Rhode Island. The borrowing base is limited to 80% of eligible domestic receivables, as defined. At March 31, 2008, we have \$18,000 outstanding 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

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and (B) the Federal Funds Rate then in effect plus 0.50%, plus 0% to 0.25% depending on Alexion's liquidity, as defined. 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 interest rate applied to the outstanding balance at March 31, 2008 was 5.25%.

Page 6

**Table of Contents****ALEXION PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****(in thousands, except share and per share amounts)**

The revolving credit facility requires that Alexion 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 Alexion's ability and the ability of Alexion's 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.

**8. Comprehensive Loss**

The following table summarizes components of our comprehensive loss:

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2008</b>	<b>2007</b>
Net loss	\$ (4,249)	\$ (32,693)
Defined benefit pension plan activity	(245)	
Net unrealized gains on available for sale securities		24
Foreign currency translation adjustment	(1,467)	(52)
<b>Comprehensive loss</b>	<b>\$ (5,961)</b>	<b>\$ (32,721)</b>

**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 three months ended March 31, 2008 and 2007:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2008</b>	<b>2007</b>
Accrual balance, beginning of period	\$ 763	\$ 7,044
Revision of estimate		93
Payments and other settlements	(43)	(5,554)
<b>Accrual balance, end of period</b>	<b>\$ 720</b>	<b>\$ 1,584</b>

The Company remains obligated for lease payments through 2012. In September 2007, the Company 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.



**Table of Contents****ALEXION PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****(in thousands, except share and per share amounts)****10. Net Loss Per Common Share**

Basic earnings (loss) per share (EPS) is computed by dividing net loss by the weighted average number of shares of common stock outstanding. For purposes of calculating diluted EPS, net 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 or other contracts to issue common stock were exercised or converted into common stock.

There is no difference between basic and diluted net loss per common share, as the effect of potential common share equivalents is anti-dilutive for the periods presented.

Potential dilutive securities include:

	March 31,	
	2008	2007
Options to purchase common stock	4,394,517	5,382,823
Unvested restricted stock	580,092	482,139
Common stock issuable under convertible debt	4,768,710	4,768,710
	9,743,319	10,633,672

**11. Derivative Instruments and Hedging Activities**

We are exposed to fluctuations in foreign currency exchange rates, primarily related to the Euro and British Pound, related to our foreign operations. Beginning in March 2008, we entered into derivative instruments with a duration of approximately 30 days, to limit the balance sheet exposure of monetary assets and liabilities of our foreign subsidiaries. The derivative instruments do not qualify for hedge accounting under SFAS No. 133. Therefore, gains and losses on these derivative instruments, which offset changes in the fair value of these assets and liabilities, are recorded in foreign currency gain or loss within other income and expense.

At March 31, 2008, the notional settlement amount of these contracts was 7,500 Euros. We recognized a loss of \$108 for the three months ended March 31, 2008 related to our derivative instruments.

**12. Stock-Based Compensation**

Stock-based compensation expense for the three months ended March 31, 2008 totaled \$5,884, of which \$4,260 was included in selling, general and administrative expense and \$1,624 was included in research and development expense. Stock-based compensation expense for the three months ended March 31, 2007 totaled \$4,980, of which \$2,595 was included in selling, general and administrative expense and \$2,385 was included in research and development expense. For the three months ended March 31, 2008, stock-based compensation of \$257 and \$368 was capitalized into inventory and fixed assets, respectively.

**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



**Table of Contents****ALEXION PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(in thousands, except share and per share amounts)

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. In accordance with FSP No. FAS 157-2, Effective Date of FASB Statement No. 157, we have elected to defer implementation of SFAS 157 as it relates to our non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a nonrecurring basis until January 1, 2009.

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 March 31, 2008, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

	Total Carrying Value at March 31, 2008	Fair Value Measurement at March 31, 2008 Using		
		Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash equivalents	\$ 75,296	\$	\$ 75,296	\$
Available for sale securities	\$ 1,693	\$	\$ 1,693	\$

**14. Commitments and Contingencies***Litigation*

As previously reported in Alexion's filings with the SEC, PDL BioPharma, Inc., or PDL, and SB2, Inc., or SB2, each filed a civil action against Alexion in federal district court.

On March 16, 2007, 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. 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.

On January 31, 2008, SB2, filed a civil action against Alexion in the U.S. District Court for the Northern District of California. SB2 claims willful infringement by Alexion of SB2 patents due to sales of Soliris. SB2 seeks unspecified monetary damages, equitable relief and attorney's fees. Alexion believes it has good and valid defenses to SB2's claims and intends to vigorously defend the case.

The results of such civil actions cannot be predicted with certainty due to their early stages. However, depending on the outcome of these legal matters, the operating results of the Company could be materially impacted through adjustments to cost of sales.

**15. Employee Benefit Plans**

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The Company maintains a defined benefit plan for employees of 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 the Company's 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 March 31, 2008, we recorded a net pension liability of \$283 with a corresponding adjustment to other comprehensive income. Pension costs for the period ended March 31, 2008 were not material to the Company's statement of operations.

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(in thousands, except share and per share amounts)**

**16. 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.

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**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**(in thousands, except share and per share amounts)**

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**  
**Note Regarding Forward-Looking Statements**

This quarterly report on Form 10-Q contains forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management's beliefs and certain assumptions made by our management, and may include, but are not limited to, statements regarding the potential benefits and commercial potential of Soliris, timing and effect of sales of Soliris in foreign markets, status of reimbursement, price approval and funding processes outside the United States, progress in developing commercial infrastructure, 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, 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, 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, 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, estimates, variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this report under the section entitled Risk Factors. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in other reports or documents we file from time to time with the Securities and Exchange Commission.

**Business**

*Overview*

We are a biopharmaceutical company engaged in the discovery, development and delivery of biologic therapeutic products aimed at treating patients with severe and life-threatening disease states, including hematologic and neurologic diseases, cancer and autoimmune disorders. We have one marketed product, Soliris, which is the first therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH, a rare, life-threatening blood disorder.

Soliris® (eculizumab) 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 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).

From our inception in January 1992 until we began commercial sales of Soliris in the U.S. in April 2007, we devoted most of our resources to drug discovery, research, and product and clinical development. In March 2007, the U.S. Food and Drug Administration, or FDA, granted approval for our lead product Soliris. We began commercial sale of Soliris in the United States during April 2007.

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**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**(in thousands, except share and per share amounts)**

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. Outside the United States, we are engaging with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country. In several countries outside the United States, we continue meaningful sales to individual patients through approved named-patient programs.

Since September 2005, we have formed a number of wholly owned subsidiaries to support commercial and regulatory operations throughout the world, including Alexion Europe SAS, our European headquarters in Paris, France, Alexion International S.a.r.l., our European shared service center in Lausanne, Switzerland, and additional sales and marketing subsidiaries in Belgium, France, Germany, Italy, Spain, Switzerland and the United Kingdom.

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 after approval. In Japan, we completed enrollment of 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 previously authorized by Japan's Pharmaceutical and Medical Devices Agency (PMDA).

We are also focusing our research efforts on the use of eculizumab in other indications, including use in rare and severe complement-mediated conditions, including in chronic hemolytic and thrombotic disorders and in chronic and debilitating neurological disorders. Separate studies on the effectiveness of eculizumab in treating myasthenia gravis and multifocal motor neuropathy are expected to begin in 2008. We are also aware that independent investigators have commenced a study to evaluate eculizumab in organ transplantation.

In addition, we anticipate beginning a clinical study of the safety and efficacy of an antibody to the immune regulator CD200 in chronic lymphocytic leukemia in 2008.

*Recent Developments*

In February 2008, we agreed to purchase certain patents related to complement-inhibition technology from Oklahoma Medical Research Foundation, or OMRF. We will pay \$10,000, plus interest, to OMRF for the rights to the patents, in various amounts to be remitted in 2008 and the first half of 2009. No further amounts, including royalties, will be owed to OMRF in respect of sales of Soliris or other use of the patents. Accordingly, the previously announced claims filed by OMRF and counterclaims filed by Alexion in the U.S. District Court for the Northern District of Oklahoma have been resolved.

In February 2008, we entered into a credit agreement with Bank of America, N.A. The agreement provides 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, Rhode Island. The borrowing base is limited to 80% of eligible domestic accounts receivables, as defined. We may elect that the loans under the agreement bear interest at a rate per annum equal to (i) LIBOR plus 1.75% to 2.25% depending on Alexion's liquidity (as calculated in accordance with the agreement), or (ii) a Base Rate equal to the higher of the (A) Prime Rate then in effect and (B) the Federal Funds Rate then in effect plus 0.50%, plus 0% to 0.25% depending on Alexion's liquidity (as calculated in accordance with the agreement). 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.

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**(in thousands, except share and per share amounts)**

*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 transferred our pilot manufacturing capabilities from New Haven, Connecticut to Smithfield, Rhode Island during 2007, and are using this facility for the production and purification of certain of our product candidates for clinical studies.

Our most significant agreement with a third party manufacturer is the Large-Scale Product Supply Agreement with Lonza Sales AG, or Lonza, dated December 18, 2002, which has been amended from time to time. This agreement, the Lonza Agreement, relates to the manufacture of eculizumab. We 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 as well as the progress of our clinical development programs.

**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 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.

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**(in thousands, except share and per share amounts)**

**Results of Operations**

**Comparison of the Three Months ended March 31, 2008 to the Three Months ended March 31, 2007**

**Revenues**

*Net product sales*

In March 2007, the U.S. Food and Drug Administration, or FDA, granted approval for Soliris for the treatment of PNH. In June 2007, the European Commission, or 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).

We generated net product sales of Soliris of \$45,546 and \$974 for the three months ended March 31, 2008 and 2007, respectively. The \$974 in net product sales reported in the three month period ended March 31, 2007 was associated with named-patient sales outside the United States prior to regulatory approval.

*Contract research revenue*

We recorded contract research revenues of \$95 and \$5,343 for the three months ended March 31, 2008 and 2007, respectively. Contract research revenue recorded in 2008 reflects grant revenue from our U.S. government funded asthma program. The \$5,343 in contract research revenues recorded in 2007 relates to the termination of our collaborative agreement with Proctor & Gamble, effective March 30, 2007.

**Cost of sales**

Cost of sales was \$5,464 and \$85 for the three months ended March 31, 2008 and 2007, respectively. For the three months ended March 31, 2008, cost of sales includes both manufacturing costs, as well as actual and estimated royalty expenses associated with sales of Soliris.

Product sold during the three months ended March 31, 2007 was previously expensed prior to submission of our 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 months ended March 31, 2007 includes only actual and estimated royalty expenses associated with sales of Soliris.

Changes in the estimates of royalties owed to certain third parties 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 assurance, pharmacovigilance costs, and other product development expenses, such as regulatory costs.

The following table provides information regarding the changes in research and development expenses. The clinical development, product development and discovery research groupings exclude the costs of payroll and benefits, operating and occupancy and depreciation and amortization, which are listed separately for the periods presented:



**Table of Contents****ALEXION PHARMACEUTICALS, INC.**

(in thousands, except share and per share amounts)

	Three months ended March 31,		Increase/ (Decrease) \$ Change
	2008	2007	
Clinical development	\$ 4,140	\$ 7,206	\$ (3,066)
Product development	2,524	2,653	(129)
Discovery research	276	1,003	(727)
Payroll and benefits	6,813	8,746	(1,933)
Operating and occupancy	1,030	1,085	(55)
Depreciation and amortization	826	526	300
<b>Research and development expense</b>	<b>\$ 15,609</b>	<b>\$ 21,219</b>	<b>(5,610)</b>

Research and development expenses decreased \$5,610 for the three months ended March 31, 2008, as compared to the same period in 2007, respectively.

For the three months ended March 31, 2008, the decrease in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

Decrease of \$3,066 in clinical development expense due largely to a decrease in spending on the EXTENSION, EXPLORE and EMBRACE studies of approximately \$2,502, decreased spending on pexelizumab based on the 2007 cancellation of the P&G agreement of \$1,626, offset by an increase in spending on our AEGIS clinical study in Japan of \$1,246.

Decrease of \$727 in non-labor discovery research expense, due largely to reduction in external research and consulting fees of \$511.

Decrease of \$1,933 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.

**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 \$29,781 and \$19,838, for the three months ended March 31, 2008 and 2007, respectively. The increase of \$9,943 was primarily due to the following:

Increase in salary, benefits and other labor expenses of \$4,757 for the three months ended March 31, 2008 including increased share-based compensation cost of \$1,664. 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 our executive, finance, information technology, human resources and legal groups to support our growth as a commercial entity.



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**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**(in thousands, except share and per share amounts)**

Increase in non-labor commercial operations of \$1,220 for the three months ended March 31, 2008. For the three months ended March 31, 2008, this increase 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 \$3,935 for the three months ended March 31, 2008 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 \$767 for the three months ended March 31, 2008, as compared to \$2,769 for the same period in 2007. The decrease was due primarily to a smaller cash position and lower interest rates during the three month period ended March 31, 2008, versus the same period in the prior year.

We incur interest expense on our convertible note, mortgage debt, revolving credit facility and capital lease obligations. Our interest expense is net of interest capitalized related to the construction of our Rhode Island manufacturing facility, which was \$1,196 for the three months ended March 31, 2008. Interest expense was \$596 for the three months ended March 31, 2008, as compared to \$700 for the same period in 2007. The decrease reflects the additional capitalization of interest in connection with the acquisition and construction of the Smithfield, Rhode Island manufacturing facility.

Foreign currency transaction gains relate to our foreign operations, which increased significantly beginning in 2007. The foreign currency transaction gains totaled \$703 for the three months ended March 31, 2008 and were primarily a result of the weaker U.S. Dollar compared to the Euro. Our foreign currency program to limit balance sheet exposure, which was initiated in March 2008, had a minor impact on the foreign currency gain for the three months ended March 31, 2008.

*Income Taxes*

We currently record a full valuation allowance against our state and federal deferred tax assets and, accordingly, we do not record a tax benefit related to our significant net operating losses and other deferred tax assets. We record current tax expense related to certain state income taxes. In addition, we record the benefit of certain research and development tax credits which are subject to a cash exchange with the State of Connecticut. We recorded a state tax benefit of \$90 and \$90 for the three months ended March 31, 2008 and 2007, respectively.

We will continue to monitor our deferred tax assets to determine whether necessary adjustments may be required relating to our valuation allowance.

**Net Loss**

The Company incurred a net loss for the three month period ended March 31, 2008 of \$4,249 or \$0.11 per common share, versus a net loss of \$32,693 or \$0.92 per common share, for the same period in 2007.

**Liquidity and Capital Resources**

As of March 31, 2008, our consolidated cash, cash equivalents and marketable securities totaled \$106,547, essentially unchanged from the balance at December 31, 2007. 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. For the quarter ended March 31, 2008, three individual customers accounted for 33.2%, 16.9% and 12.5% of the accounts receivable balance. For the quarter ended March 31, 2008, three individual customers accounted for 22.8%, 9.5% and 8.6% of our product sales.



**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**(in thousands, except share and per share amounts)**

At March 31, 2008, our working capital was \$159,689, compared to \$167,645 at December 31, 2007.

We have incurred operating losses since our inception. As of March 31, 2008, we had an accumulated deficit of \$733,528. We may incur operating losses and negative cash flows for additional periods due to costs associated with the commercialization of Soliris in the United States, pre-commercialization activities and anticipated commercialization activities outside of the United States, development of our manufacturing plant in Rhode Island, product research and development, pre-clinical studies and clinical testing, regulatory activities, commercial-scale manufacturing at our third party contractor and at our own manufacturing plant when that site is qualified to manufacture Soliris, and other infrastructure support costs.

Until we can generate sufficient levels of cash from our operations, we expect to continue to finance future cash needs primarily through cash, cash equivalents and short-term investments, and to the extent necessary, through proceeds from equity or debt financings, loans, including availability under our revolving credit agreement, and collaborative agreements. The requirement to obtain additional cash from debt or equity financing will be highly dependent on our sales, and related cash collections of Soliris.

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 used in operating activities was \$11,253 and \$39,360 for the three months ended March 31, 2008 and 2007, respectively, a decrease of \$28,107, or 71.4%. The decrease in cash used compared to the same period in the previous year is primarily due to lower net loss compared to the same period in 2007. The components of cash used in operating activities for the three months ended March 31, 2008 are as follows:

Our reported Net loss of \$4,249, adjusted for non-cash items, including depreciation and amortization of \$1,289 and stock compensation of \$5,884.

Net cash outflow due to changes in operating assets of \$10,863, primarily attributable to increases in accounts receivable and prepaid expenses. Due to the payment terms granted to our U.S. and foreign customers, a significant portion of our product sales to date have not yet been collected. These increases were offset by an increase in our accrued expenses for compensation and actual and estimated royalties.

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 related to sales and resulting accounts receivable increases.

**Investing Activities**

Net cash used in investing activities was \$2,157 for the three months ended March 31, 2008 versus \$1,816 provided by investing activities for the three months ended March 31, 2007. For the three months ended March 31, 2008, the net cash used for investing activities consisted of the following:

\$8,740 cash inflow from the net sale of marketable securities, which was used to fund our operations

\$7,950 of additions to property, plant and equipment, of which \$6,955 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

\$3,489 related to the purchase of patents from OMRF

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Through March 31, 2008, we have capitalized \$98,554 related to the facility, which includes all costs associated with construction, renovation and upgrades, engineering runs and capitalized interest. This includes the pilot plant which was placed in service in the fourth quarter of 2007. Through March 31, 2008, costs incurred in seeking regulatory approval, including engineering runs, was \$28,126, and capitalized interest was \$5,524.

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**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**(in thousands, except share and per share amounts)**

**Financing Activities**

Net cash provided by financing activities was \$22,422 and \$11,394 for the three months ended March 31, 2008 and 2007, respectively. The \$22,422 consisted of proceeds from our revolving credit facility of \$18,000 and approximately \$4,500 from the issuance of common stock related to the exercise of stock.

**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 includes our revolving credit facility and the note payable 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 80% of eligible domestic receivables, as defined. The outstanding amount due under the revolving credit facility as of March 31, 2008 was repaid in April 2008.

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

*Note Payable*

In conjunction with the purchase of patents from OMRF, we issued a note payable in 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 the balance during or prior to July 2009. Interest shall accrue on any unpaid amount at the rate of 50% of the prime rate (as published in the Money Rates section of the Wall Street Journal (New York edition) plus 1%, per annum.

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**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**(in thousands, except share and per share amounts)**

*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 have covenants related to our financial performance.

The 1.375% Notes are convertible into our common stock at an initial conversion rate of 31.7914 shares of common stock (equivalent to a conversion price of approximately \$31.46 per share) per \$1 principal amount of the 1.375% Notes, subject to adjustment, at any time prior to the close of business on the final maturity date of the notes. We do not have the right to redeem any of the 1.375% Notes prior to maturity.

As of March 31, 2008, the market value of our \$150,000, 1.375% Convertible Notes due February 1, 2012, based on quoted market prices, was estimated at \$298,013. The \$76,987 decrease from December 31, 2007 is largely attributable to the decrease in the price of our common stock during the period.

*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 March 31, 2008, the balance of restricted cash was \$417.

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

*Lonza Agreement*

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

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

**Item 3. Quantitative and Qualitative Disclosure about Market Risks**  
**Interest Rate Market Risk**

As of March 31, 2008, we held essentially all of our cash and investments, including restricted cash, 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. We estimate that a change of 100 basis points in interest rates would result in an increase or decrease of approximately \$23 in the fair value of our cash and investments.



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**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**(in thousands, except share and per share amounts)**

Our outstanding long-term liabilities as of March 31, 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 March 31, 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 \$298,013.

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 new fixed annual rate of 9.12%. Accordingly, any changes in the interest rate will not impact our Statement of Operations.

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

In conjunction with the purchase of patents from OMRF, we issued a note payable in an aggregate principal amount of \$7,000, representing the balance of the \$10,000 purchase price for the OMRF patent rights. Interest shall accrue on any unpaid amount at the rate of 50% of the prime rate (as published in the Money Rates section of the Wall Street Journal (New York edition) plus 1%, per annum

**Foreign Exchange Market Risk**

As a result of our foreign operations, we may face exposure to adverse movements in foreign currency exchange rates, primarily to the Euro. The current exposures arise primarily from monetary instruments, accounts receivable and intercompany receivables and payables denominated in foreign currencies. In March 2008, we began a program to limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet.

Accordingly, we expect that a hypothetical 10% adverse change in exchange rates would not result in a material loss in fair value of our foreign currency exposure monetary assets and liabilities on our balance sheet.

In addition to our balance sheet risk, we anticipate future revenues and costs denominated in currencies other than the U.S. Dollar. Accordingly, future revenues and costs may be impacted by changes in foreign exchange rates. In the future, we may elect to limit this future exposure through the use of cash flow hedges.

**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.



**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**(in thousands, except share and per share amounts)**

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.

Page 21

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**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

As previously reported in Alexion's filings with the SEC, Oklahoma Medical Research Foundation, or OMRF, PDL BioPharma, Inc., or PDL, and SB2, Inc., or SB2, each filed a civil action against Alexion in federal district court.

On March 15, 2007, OMRF filed a civil action against Alexion in the U.S. District Court for the Northern District of Oklahoma, alleging, among other things, (i) breach of contract by Alexion, (ii) willful infringement by Alexion of an OMRF patent, and (iii) fraud and constructive fraud under Oklahoma law. During the first quarter of 2008, Alexion agreed to acquire all rights to the relevant patents for a total payment of \$10 million. Accordingly, the previously announced claims filed by OMRF and counterclaims filed by Alexion in the U.S. District Court for the Northern District of Oklahoma have been resolved.

On March 16, 2007, 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. 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.

On January 31, 2008, SB2 filed a civil action against Alexion in the U.S. District Court for the Northern District of California. SB2 claims willful infringement by Alexion of SB2 patents due to sales of Soliris. SB2 seeks unspecified monetary damages, equitable relief and attorney's fees. Alexion believes it has good and valid defenses to SB2's claims and intends to vigorously defend the case.

**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 and cost effective. For the three months ended March 31, 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 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 Europe and successful continuation of commercial sales in the United States;

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;

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**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

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

receipt 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.

***Because the target patient population for Soliris 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.***

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, it does 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 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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**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

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

In the United States, we sell Soliris to distributors who in turn sell to patient health-care providers. We do not promote Soliris to these distributors and they do not set or determine demand for Soliris. For the three month period ended March 31, 2008, our three top customers accounted for approximately 22.8%, 9.5% and 8.6% 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 who supply physician office clinics, hospital outpatient clinics, infusion clinics or 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 is 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 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.***

Our future revenues and profitability will be adversely affected if we cannot depend on governmental, private third-party payers and other third-party payers, including Medicare and Medicaid in the United States and country specific governmental organizations in Europe, 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,

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

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-par