

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)

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

**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)

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

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.

Page 1

**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	
	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.

---

**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

## Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

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**



## Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

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.

---

**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.

---

**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.



---

**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

## Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

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.

Page 17

---

**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.

---

**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.





---

**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

---

**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;

---

**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.

---

**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-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.

Even where patients have access to insurance, their insurance co-payment amounts may represent a barrier to obtain Soliris. In the United States, Alexion will financially support 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 may be dependent on funding from Alexion, and we cannot guarantee that such funding will be provided by Alexion or other parties 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 achieve profitability.

In furtherance of our efforts to facilitate access to Soliris, we have created the Soliris OneSource Program, a treatment support service for patients with PNH and their healthcare providers. OneSource case managers will provide education about PNH and Soliris and help facilitate solutions for reimbursement, coverage and access. Although case managers will 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. We are currently engaging the appropriate authorities in major European markets on the operational, reimbursement, price approval and funding processes that are separately required by each European country. 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 (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.

---

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

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. As a result, 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 in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of Soliris or substantially increase the costs and expenses of commercializing and marketing Soliris.

We may be sued by people who use Soliris, whether as a prescribed therapy, during a clinical trial, during an investigator initiated study, or otherwise. Many patients who use Soliris are already very ill. Any informed consents or waivers obtained from people who enroll in our trials or use Soliris may not protect us from liability or litigation. Our product liability insurance may not cover all potential types of liabilities or may not cover covered types of 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 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 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.

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.

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 eculizumab for PNH.

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

***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 few outside suppliers for manufacturing and a single manufacturer for commercial supply. 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 eighteen to twenty-four months 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.

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.

---

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

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 incur future losses.***

We have incurred losses since we started our company in January 1992. As of March 31, 2008, we had an accumulated deficit of approximately \$734 million. If we continue to incur operating losses and fail to achieve or maintain profitability, we may be unable to continue our operations. Since we began our business, we have focused on research and development of product candidates. We launched Soliris for sale in the United States 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 may operate at a net loss for additional periods 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. We may never generate sufficient revenues to achieve or sustain profitability. Even if we do achieve profitability, 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. 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 and preparing for the commercialization of Soliris in several countries in Europe, evaluating and preparing regulatory submissions for Soliris 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 Europe and as we initiate or continue clinical trials for our product candidates.

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

the cost necessary to sell, market and distribute Soliris;

the rate of new patient sales and drug utilization by treated patients;

the time and cost necessary to obtain regulatory approvals for Soliris outside the United States and Europe and for eculizumab for other indications;

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

the ability to obtain 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;

Page 28

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

the time and cost necessary to purchase or to further develop manufacturing processes, arrange for contract manufacturing or build manufacturing facilities and obtain 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 are 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. Each of Adprotech Ltd., Avant Immunotherapeutics, Inc., XOMA, Ltd., Novo Nordisk A/S, Archemix Corporation, Evolotec Ltd., Amgen Inc., Genentech, Inc., Pharming Group N.V., CSL-Behring, Peptech Ltd., Lev Pharma, Inc., Ophtherion, Inc., Jerini AG, Potentia Pharmaceuticals, Inc., Ophthotech Corporation and ChemoCentryx, Inc. have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. We are also aware that Abbott Laboratories, Inc., Baxter International, Inc., Millennium Pharmaceuticals, Inc. and Neurogen Corporation, have had programs to develop complement inhibitor therapies. Each of AstraZeneca, MorphoSys AG and Dyax Corporation has publicly announced intentions to develop

## Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

therapeutic human antibodies from libraries of human antibody genes. Additionally, each of Amgen, Inc. and Medarex, Inc. has publicly announced intentions to develop therapeutic human antibodies from mice that have been bred to include some human antibody genes. These and other pharmaceutical 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

Page 29

---

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

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 March 31, 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 issued a note payable in an aggregate principal amount of \$7 million in connection with the acquisition of certain patents from OMRF.

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

make it difficult for us to make payments on our notes and our loans;

make it difficult for us to obtain financing for acquisitions or 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.





**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

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.

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

---

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

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 \$6.8 million expired.

**Risks Related to Our Industry**

*We are subject to extensive government regulation and, if we do not maintain our regulatory approvals in the United States or in Europe, we will not be able to sell Soliris in such market.*

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,

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

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;

finances 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. We have commenced clinical studies with Soliris in patients with PNH in Japan; there is no assurance that the Japanese regulatory agency will find these studies sufficient for registration of Soliris in Japan.

***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

## **Table of Contents**

### **ALEXION PHARMACEUTICALS, INC.**

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;

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;



---

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

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.

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.



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

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 acquired 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. 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. If it is finally determined that we infringe the SB2, Inc. patents, we may be required to pay royalties to SB2, Inc. on sales of Soliris. Although we do not believe that any valid patent of PDL or SB2, Inc. is necessary for the commercialization of Soliris, we cannot guarantee that we will be successful in defending against such actions. 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 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 the actions filed by PDL 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 and SB2, Inc., 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

---

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

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 and SB2, Inc. actions; 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 December 31, 2007, the sales price of our common stock fluctuated from a low of \$35.77 per share to a high of \$79.80 per share. While we cannot predict our future performance, if our stock price continues to fluctuate in a wide range, an investment in our common stock may result in considerable uncertainty for an investor.

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

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

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

**Table of Contents**

**ALEXION PHARMACEUTICALS, INC.**

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

10.1 Credit Agreement, dated February 13, 2008, by and between Alexion Pharmaceuticals, Inc. and Bank of America, N.A.

10.2 Security Agreement, dated February 13, 2008, by and between Alexion Pharmaceuticals, Inc., Bank of America, N.A., and the other loan parties named therein

10.3 Note, dated February 13, 2008, issued by Alexion Pharmaceuticals, Inc. to Bank of America, N.A.

31.1 Certification by Leonard Bell, Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 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 March 31, 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 March 31, 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 March 31, 2008.

Certain portions of this exhibit have been omitted pursuant to a request for an order granting confidential treatment by the Securities and Exchange Commission. The omitted non-public information has been filed with the Securities and Exchange Commission.

**Table of Contents**

**SIGNATURES**

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

**ALEXION PHARMACEUTICALS, INC.**

Date: May 12, 2008

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

Date: May 12, 2008

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

Page 39